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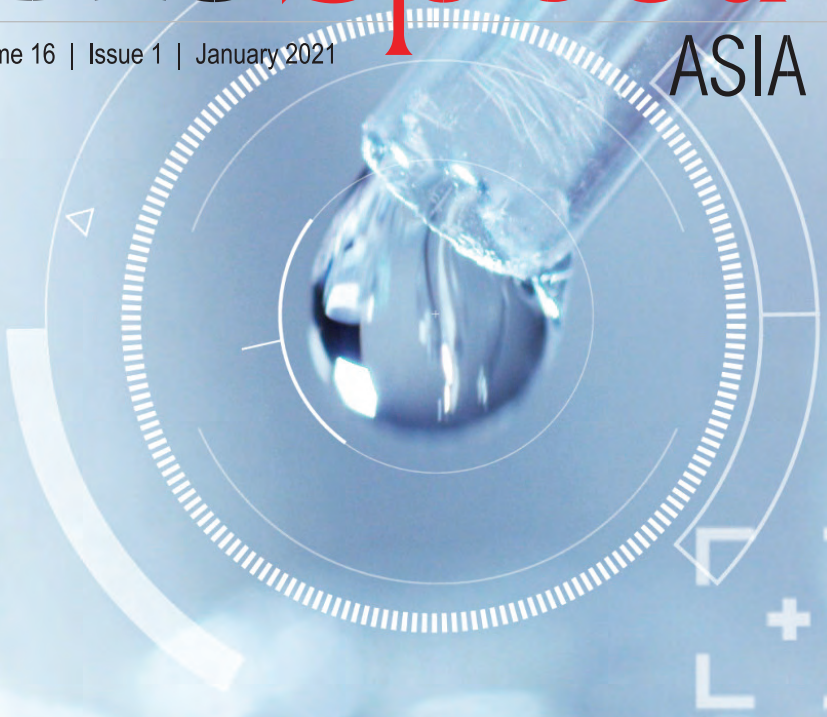

2021 beckons major investments in R&D

"We are confident that Sputnik V will be providing long-term immunization defence against potential new coronavirus infections"
-Kirill Dmitriev, CEO, Russian Direct Investment Fund (RDIF), Russia – 36

Evaluating COVID-19 vaccines on mutant viral strains – 32

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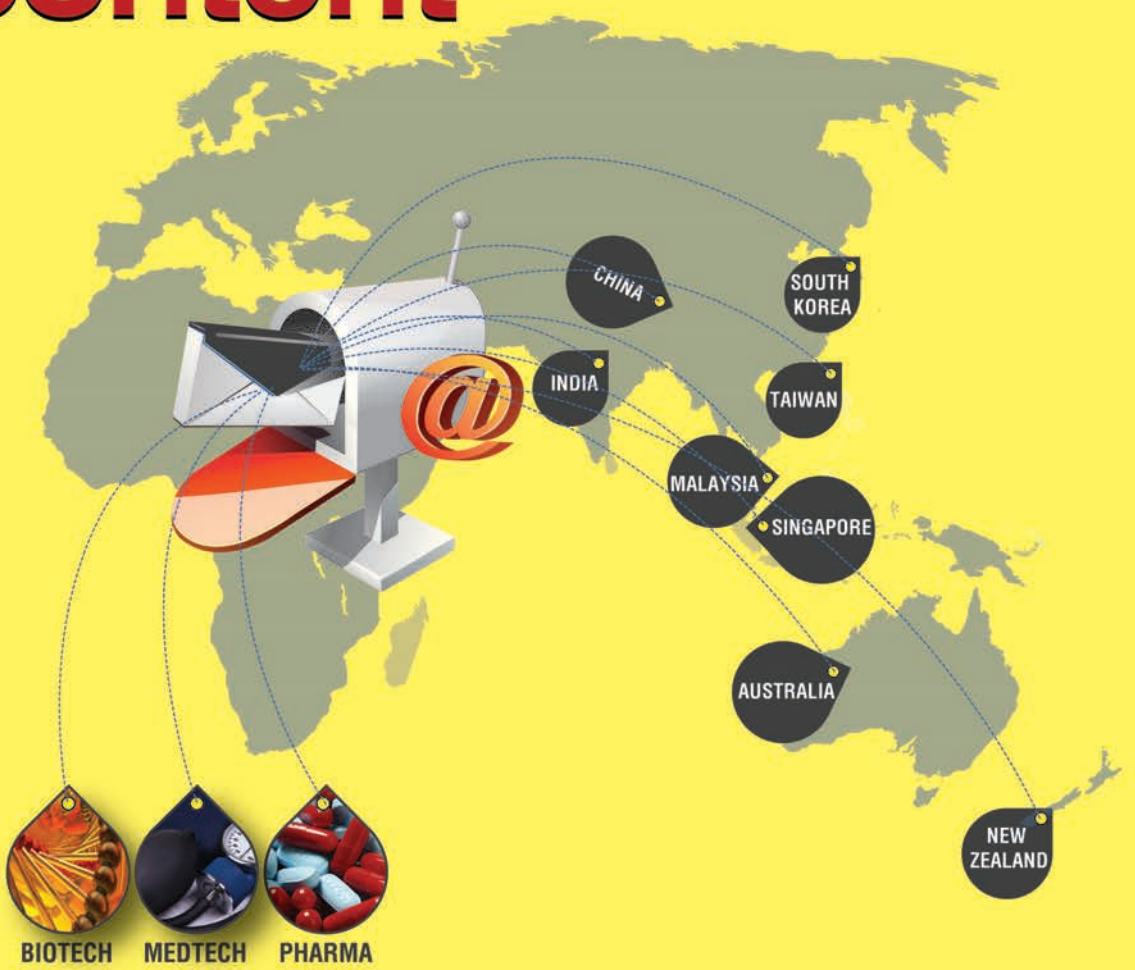

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RUSH FOR VACCINATION

Dr Milind Kokje
Chief Editor
milind.kokje@mmactiv.com

COVID-19 had begun to establish its stranglehold on the world at the start of 2020. A year later, as the world bids adieu to 2020, the rush for COVID-19 vaccination is dominating the scene amidst apprehensions over the emergence of a new variant of the virus detected in the UK that is spreading to other countries. As Asian countries are in a rush to begin vaccination in the new year, the implementation programmes for the same continue to be at different stages in those countries.

Singapore had granted emergency use authorisation (EUA) and received the first shipment of Pfizer's vaccine in December, becoming the first Asian country to get it. Australia has secured 134.8 million doses of four vaccine candidates and access to the international COVAX facility aiming to vaccinate its entire population. Indonesia has taken the apparent lead in Southeast Asia with the delivery of vaccines from China's Sinovac Biotech Ltd. It has already received 1.2 million doses of the Sinovac vaccine with another 1.8 million shots to arrive in the current month.

Korea has signed contracts to acquire 65 million doses from four companies and vaccination is expected to start soon. It is expediting its vaccination plan since it has already detected first cases infected by the new UK variant of Coronavirus. At several other places in Asia, phase III trials are being conducted, while processes for EUA are also underway. Still, they appeared to be lagging behind US and Europe in the 'vaccination race', despite the region's quick response in the spread of the disease.

Among Asian countries, due to its sheer size and population, India may have to face several challenges to vaccinate its huge population. It is preparing well for a mega vaccination drive to deliver 60 crore doses to 30 crore Indians in priority groups, in the first phase. Three vaccine producing firms have already approached the Central Drugs Standard Control Organisation (CDSCO) for EUA.

But, the CDSCO's expert committee had deferred the approval of two Indian companies as they had failed to provide sufficient data. The committee had asked the vaccine producer applicants, Pune-based Serum Institute and Hyderabad's Bharat Biotech, to provide more data on safety and immunogenicity. Pfizer's application was not discussed as the company had sought more time to make a presentation to the committee.

This has obviously delayed the vaccination in India. By the time readers get to see this editorial, it is possible that the Indian regulator might have been granted EUA and the vaccination programme has begun in India.

Urgent need to begin vaccination is acknowledged considering the number of deaths and infections caused by the Coronavirus. Still, the CDSCO was probably more careful because unlike the UK's provision for EUA in its regulation or the US's guidelines on it, Indian regulation does not have a defined procedure for EUA.

It is, but, natural that the vaccine producers and governments will be in a great hurry to begin the vaccination drive for various reasons. The companies have invested huge amounts in vaccine research and are looking for early returns on their investments. In a stiff competition when 25 vaccines are at various stages of development and about five of them are in the final race now, the first few companies to put their vaccines on the shelves will be able to capture the maximum market. Hence, the rush to get things moving. Governments, the world over, are facing various issues due to the pandemic, particularly related to the economy, and hence are looking for a solution at the earliest. But both of them need to understand that if speed is given priority overlooking safety even marginally, it will lead to a trust deficit for both of them. Hence, the regulator's role is very important in maintaining the right balance between speed and safety in this time of rush for the vaccine. BS

Acknowledgements

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- Amanda O'Hare, UK

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- Josephine Ziel, Germany

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COVER STORY 18

2021 beckons MAJOR investments IN R&D

The life sciences industry in Asia Pacific (APAC) region entered the year 2020 with companies entering into new agreements for expansion and focusing on applied research to develop new drugs that are affordable. During 2020, the industry, which acted timely, as covered in the January 2020 issue of BioSpectrum Asia, witnessed unprecedented collaborations with the governments due to the unexpected spread of coronavirus since December 2019. COVID-19 is expected to remain a defining issue for the life sciences industry across the globe in 2021, compelling companies to invest heavily in research and development.

COVID-19

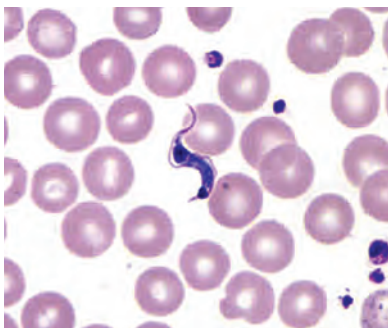
Q&A

Q&A

REGULARS

Japan focuses on developing drugs for malaria and Chagas disease

The Global Health Innovative Technology (GHIT) Fund, an international public-private partnership between the Government of Japan, 16 pharmaceutical and diagnostics companies, the Bill & Melinda Gates Foundation, the Wellcome Trust and United Nations Development Programme, has announced a total of approximately 230 million yen to invest in four partnerships to develop new lifesaving drugs for malaria and Chagas disease. This includes three new projects and one that will receive continued funding. As on December 8, 2020, there are 53 ongoing projects, including 29 discovery, 16 preclinical and eight clinical trials in the GHIT portfolio. The total amount of investments since 2013 is 22.5 billion yen. These awarded projects were selected from a number of proposals for Target Research Platform, Screening Platform, Hit-to-Lead Platform, and Product Development Platform, which was open for applications from November 2019 to March 2020. The GHIT board conducted in June 2020 approved these new investments.



Korea contributes $3M to CEPI to advance vaccine development

The government of the Republic of Korea (ROK) has decided to contribute $3 million in 2020 for the first time to the Norway based Coalition for Epidemic Preparedness Innovations (CEPI), which leads global efforts for the development of vaccines for infectious diseases, including COVID-19. The ROK government plans to contribute $3 million annually to CEPI from 2020 to 2022 through the Global Disease Eradication Fund, an air-ticket solidarity levy. CEPI is a global health partnership launched in 2017 with the aim to develop vaccines to stop future epidemics. With regard to COVID-19, it is supporting the development of a total of nine vaccine candidates, including those by Moderna and AstraZeneca. In particular, CEPI is providing $6.9 million in research fund for clinical trials of Inovio's COVID-19 vaccine candidate in the ROK, and has partnered with Korean pharmaceutical companies to reserve manufacturing capacities for CEPI-funded COVID-19 vaccines. The ROK government has underscored the importance of the international community's solidarity and cooperation in overcoming the COVID-19 health crisis on the occasion of the sessions of the World Health Assembly and the United Nations General Assembly, and its contribution to CEPI came as part of such efforts.

Australia invests $4M for new COVID-19 research

The Australian government is supporting six new COVID-19 research projects across four institutions, allowing researchers continue to examine the virus and its response to the pandemic. More than $4 million will be distributed from the Medical Research Future Fund (MRFF) through two grant rounds to institutions including Monash University, Deakin University and Macquarie University. These grants aim to develop high priority digital health infrastructure, improving the speed and features of health system responses during acute crises, such as the COVID-19 pandemic. Each of these projects have the ability to assist and inform government responses to the pandemic. Three projects will receive funding through the 2020 Rapid Response Digital Health Infrastructure Grant Opportunity, worth approximately $3.5 million. This includes $1.9 million to support Monash University's work to create a national data management platform and Learning Health System, alongside real-time monitoring of Australia's COVID-19 response.

India approves first indigenous COVID-19 mRNA vaccine for Ph I/II trial

India's first indigenous mRNA vaccine candidate has received approval from Indian drug regulators to initiate Phase I/II human clinical trial. The novel mRNA vaccine candidate, HGCO19 has been developed by Gennova Biopharmaceuticals and supported with seed grant under the Ind-CEPI mission of Department of Biotechnology (DBT), Government of India. mRNA-based vaccines are scientifically the ideal choice to address a pandemic because of their rapid developmental timeline. The mRNA vaccine is considered safe as it is non-infectious, non-integrating in nature, and degraded by standard cellular mechanisms. Gennova, in collaboration with HDT Biotech Corporation, US, has worked to develop an mRNA vaccine candidate HGCO19 that has already demonstrated safety, immunogenicity, neutralisation antibody activity in animals. The neutralising antibody response of the vaccine in mice and non-human primates was comparable with the sera from the convalescent patients of COVID-19.

Singapore gives nod to Pfizer-BioNTech COVID-19 vaccine

The Health Sciences Authority (HSA) has granted an authorization under the Pandemic Special Access Route (PSAR) for the Pfizer-BioNTech COVID-19 vaccine to be used in Singapore for the prevention of COVID-19. The vaccination regime submitted by Pfizer-BioNTech requires two doses of vaccine to be administered 21 days apart, in individuals aged 16 years and above. HSA's review of the available clinical data found that the benefits of the Pfizer-BioNTech COVID-19 vaccine outweigh the known risks. The vaccine was only granted interim authorization after the data submitted by Pfizer-BioNTech was assessed by HSA to demonstrate that the vaccine meets the required safety, efficacy, and quality standards. The vaccine demonstrated a high vaccine efficacy of 95 per cent. Based on the data accrued to-date, the safety profile of the Pfizer-BioNTech COVID-19 vaccine was generally consistent with other registered vaccines.

Taiwan initiates new measures for management of medical masks

Taiwan has initiated two new measures to reinforce the management of medical masks. Since July 7, 2020, the country began to implement border random inspection of medical masks. From September 24, 2020, domestically manufactured medical masks are required to be marked with government-issued debossed stamps. These measures aim to control the quality of imported medical masks and differentiate domestic medical masks from those imported. As the COVID-19 pandemic continues to affect the entire world, the demand for medical

masks, as well as the production capacity, continues to increase. To enhance border inspection of imported medical masks, Taiwan Food and Drug Administration has amended regulations for the inspection and examination of imported medicaments, so that medical masks are included in border inspection. In addition to license of medical devices, imported medical masks are also obliged to meet examination standards, which are divided into different categories, including general medical masks, surgical masks, surgical D2 masks with corresponding inspection items, such as bacteria filtration efficiency, differential pressure, sub-micron filtration efficiency, and respiratory air impedance.

Sinovac receives product license for 23-valent pneumonia vaccine

Sinovac Biotech, based in China, has announced that the China National Medical Products Administration (NMPA) has approved and issued a product license for the company's 23-valent Pneumococcal Polysaccharide Vaccine (PPV) to prevent the infection by streptococcus pneumonia in adults and children aged 2 years old and above. The approval of the pneumococcal vaccine allows the company to provide another high-quality product to address unmet medical needs for the Chinese population. This is the company's first bacterial vaccine product approved so far, broadening the potential of its product portfolio. Sinovac started research and development of the 23-valent pneumococcal polysaccharide vaccine in 2009, completed pre-clinical studies in 2011 and was approved to conduct human clinical trials in May 2014. A phase III non-inferiority study conducted in 2015 demonstrated a good safety and immunogenicity profile and non-inferiority of immunogenicity of all 23 serotypes were observed, which was published in the Human Vaccines and Immunotherapeutics medical journal.

EuBiologics partners with IVI for COVID-19 vaccine development

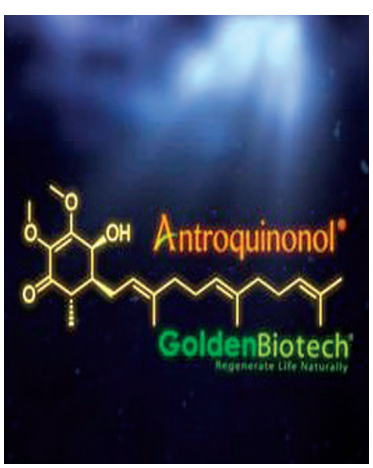
The International Vaccine Institute (IVI) and South Korean company EuBiologics have exchanged a Memorandum of Understanding (MoU) to cooperate in the clinical development of the COVID-19 vaccine the company is currently developing. EuBiologics is currently in the final phase of pre-clinical trial in an effort to develop a COVID-19 vaccine and is planning to apply for a Phase I/II IND clinical trial. Under this MoU, IVI will assess the vaccine's efficacy by analyzing the immunogenicity of EuBiologics' COVID-19 vaccine as part of clinical development progress. The COVID-19 vaccine being developed by EuBiologics uses two platform technologies: its own immunity enhancement technology (EuIMT) and the antigen display technology (Spontaneous nanoliposome antigen particleization: SNAP) of the US-based POP Biotech, which EuBiologics has an investment in. EuBiologics' own COVID-19 vaccine uses protein subunit (synthetic antigen) technique, which is the same method as that used by Sanofi and NovaVax, and SK bioscience in Korea. The protein subunit method is relatively competitive in safety, cold chain, and price when compared with other COVID-19 vaccines in development, and there are already a number of subunit vaccines that are commercially available for various infectious diseases.

Susmed adopts blockchain to enhance clinical trials efficiencies

Susmed Inc., based in Japan, has announced that it has received a response from both the Ministers of Health, Labour, and Welfare, and of Economy, Trade, and Industry that the monitoring process, which is considered as necessary in clinical trials of pharmaceutical or medical equipment, can be replaced with the use of Susmed's blockchain technology, and it does completely comply with the government directive. The company will provide this blockchain technology system with pharmaceutical manufacturers, university hospitals, and other research institutions that are looking to increase efficiencies of clinical trials. Susmed has developed a clinical trial system that uses blockchain technology to thwart data falsification. Not only does this improve security levels in comparison to conventional methods, but this system is also much cost-efficient and enables to manage data in ways that ensure its accuracy. The trial of the system received authorization in April 2019 for a regulatory sandbox as part of a medical application of blockchain technology, and Susmed together with the National Cancer Research Center of Japan carried out monitoring with the system in an actual clinical trial setting.

Golden Biotech announces breakthrough in AML treatment

Golden Biotechnology Corp., based in Taiwan, has announced that its new drug Antroquinonol (HOCENA) outperforms the other listing drugs for the treatment of relapsed AML (acute myeloid leukemia) patients in its Phase II clinical study conducted in Russia. The outcome measures demonstrated higher remission rates and survival rates guaranteeing fewer patients will require blood transfusions. This has made high safety possible during breakthroughs for AML treatment with remarkable monotherapy without combined chemotherapy. The new drug Antroquinonol has been granted orphan drug designation (ODD) by the US FDA for the treatment of AML in 2015. Golden Biotech has achieved excellent breakthrough in the unmet medical needs in AML therapy, which many global pharmaceutical companies are targeting.



Healthium Medtech launches India's first meniscal repair device

Healthium Medtech has announced the launch of Surestitch, the first Made in India meniscal repair device. Manufactured by Healthium as part of its arthroscopy range Sironix, Surestitch has an original product design with design patents applied in India and the US. The meniscus is a C-shaped piece of tough, rubbery cartilage that acts as a shock absorber between the shinbone and thighbone. Surestitch follows a simple 3 step process to repair the meniscus tear called PTF (Pierce The Needle, Turn the Safety Knob and Fire the Implant). The device comes with a 17-gauge stiffer needle that ensures effortless piercing and a built in adjustable depth control sheet to prevent over insertion. Its safety knob prevents misfiring and the audible and visual confirmation ensures sequential implant selection. The device has an audible click feature that ensures implant deployment feedback and its ergonomic design enables single handed use.

Bayer sets up CoE for cardiovascular studies in Singapore

German multinational pharmaceutical company Bayer and National Heart Centre Singapore (NHCS) have entered into a 5-year collaboration agreement to set up a centre of excellence (CoE) for explorative cardiovascular studies with the aim of boosting patient-centricity in research and development (R&D) and improving treatment outcomes in cardiovascular disease (CVD) management. Combining NHCS' vast experience in managing Asian CVD patients and clinical research and Bayer's expertise in pharmaceutical R&D, the centre will generate and integrate high-quality patient data into early clinical research which will allow a better understanding of the underlying biology of CVDs. The results could potentially lead to future targeted therapies to address unmet medical needs in defined patient populations. Bayer will contribute S$5.4 million towards the set-up of the centre. The centre will address three key areas of research namely continuous generation of new data and analysis of existing data of CVD patients and healthy individuals, for early research studies; deep understanding of the underlying disease biology in humans to identify, based on mechanism, specific patient groups that can benefit from targeted therapies; and exploring the pharmacological potential of a candidate cardiovascular drug via explorative in-human studies to validate biology and demonstrate efficacy.

Takeda sells select non-core assets to Chinese firm for $322 M

Japanese firm Takeda Pharmaceutical Company has announced that it has entered into an agreement to divest a portfolio of non-core prescription pharmaceutical products sold in China to Hasten Biopharmaceutic, a company funded by Feidong County of Hefei City, China and established by Ray Capital Management Limited. Takeda will receive $322 million, subject to customary legal and regulatory closing conditions. The portfolio to be divested to Hasten includes cardiovascular and metabolism products sold in mainland China. The portfolio generated FY2019 net sales of approximately $109.5 million, driven by strong sales of cardiovascular products such as Ebrantil. While the products included in the sale continue to play important roles in meeting patient needs in the country, they are outside of Takeda's chosen business areas – Gastroenterology (GI), Rare Diseases, Plasma-Derived Therapies, Oncology and Neuroscience – that are core to its global long-term growth strategy. Takeda intends to use the proceeds from its divestitures to continue to reduce its debt and accelerate deleveraging toward its target of 2x net debt/adjusted EBITDA within FY2021 – FY2023.

Piramal Pharma invests $32M to expand US facility for API production

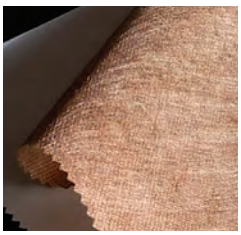
India headquartered Piramal Pharma Solutions (PPS) has announced plans to expand its facility in Michigan with additional capacity and new capabilities for the development and manufacturing of Active Pharmaceutical Ingredients (APIs). The company is investing $32 million in the facility to keep up with expected demand based on current forecasts, including potential new opportunities. This expansion of more than 25,000 square feet, which includes 8,500 square feet of production space, will provide significant benefits to customers and patients. Capacity will increase in large-scale manufacturing with the addition of new reactors capable of handling up to 4000L. PPS is also adding two new kilo labs for process development and GMP manufacture for clinical trials at scales up to 100L. The expansion is planned to be ready for customers beginning Summer 2022. It is expected that the expansion will add approximately 20 new hires to the site, bringing the total headcount to more than 180 employees and further benefitting the local economy.

WuXi Biologics acquires drug substance facility from Bayer

WuXi Biologics and Bayer have announced an acquisition deal, under which WuXi Biologics will take over and operate the Drug Substance (DS) facility at Bayer's Wuppertal site in Germany. The companies also plan to enter into a long-term sublease agreement and a transition service contract. The volume of the transaction, including the sublease agreement, amounts to approximately 150 million euros. The 30,000-square-meter DS facility (MFG19), including 3x1000L perfusion and 6x2000L fed-batch capacity with independent downstream suites, will further enhance the Chinese firm WuXi Biologics' global network to supply COVID-19 vaccines and other biologics. Together with the Drug Product facility in Leverkusen (DP7), this new DS facility will be used for commercial manufacturing, allowing WuXi Biologics to meet clients' increasing demand for outsourced manufacturing services. As cornerstone of WuXi Biologics' European network, the two facilities are expected to be ready for drug substance and drug product manufacturing by 2021.

Australian startup develops antiviral textile technology

Materials science and technology startup based in Australia, Xefco in collaboration with Swiss textile innovator, HeiQ, has developed XViroblock, the world's first thin-film antimicrobial copper surface treatment for textiles that is proven to exhibit significant viricidal activity against SARS-CoV-2. Studies conducted by the Peter Doherty Institute for Infection and Immunity showed textiles coated with XViroblock inactivated SARS-CoV-2, with significant inactivation occurring within five minutes of direct contact. By developing textile treatments that provide rapid viricidal and antibacterial functionality, Xefco hopes to reduce transmission of disease by reducing the persistence of pathogens on treated surfaces. XViroblock treated textiles have also been tested by an independent ISO 17025 accredited laboratory according to the ISO 18184 standard. Treated fabrics tested against influenza A virus subtype H1N1 and human coronavirus 229E showed a reduction of infectious virus present on the textiles of 99.95 and 99.9 per cent respectively.



Narayana Health, MSMF launch incubator for medtech entrepreneurs

Narayana Health in association with Mazumdar Shaw Medical Foundation have announced the launch of a physical incubator called Mazumdar Shaw Medical Foundation (MSMF) MedTech Innovation Centre - BIRAC BIONEST in India. A centre with a dedicated space of around 8000 sq ft Mazumdar Shaw Medical Foundation (MSMF) MedTech Innovation Centre - BIRAC BIONEST will help medtech entrepreneurs who are looking to address affordability, access and innovation challenges in the healthcare eco-system. The MedTech Innovation Centre will also augment further the initiatives undertaken by Mazumdar Shaw Medical Foundation and Narayana Health towards identifying, mentoring and handholding entrepreneurs and innovators in their journey to success. The space will facilitate close interaction and prototyping facility too for startups. The physical infrastructure will help to further strengthen the mission as the infrastructure can support 39 startups at any given point of time with the total seating capacity of 82. The centre is looking at nurturing 10 startups in 2021.

DocDoc plans world's first completely digital health ecosystem

Singapore based startup DocDoc has partnered with SpesNet Global Group, a leading healthcare technology provider, to integrate its digital third-party administrator (TPA) technology and provide a first-of-its-kind complete digital health ecosystem to insurers, supporting their policyholders through the continuum of care. Under this agreement, DocDoc will receive exclusive access to SpesNet's platform to include Singapore, Malaysia, Thailand, Hong Kong, India, and the People's Republic of China. DocDoc will integrate SpesNet's digital TPA technology with DocDoc's telemedicine platform and AI-powered doctor discovery platform, HOPE (Heuristic for Outcome, Price and Experience), which matches policyholders to relevant healthcare providers, to power a holistic offering. Through this integration, the patient intelligence company will be able to offer cashless services, as well as seamless claims processing to payers, including insurance companies, brokers, employers, and bancassurance partners across Asia and beyond.

Yokogawa invests in promoting biotech & life sciences startups

Yokogawa Electric Corporation has announced that it will invest in the Daiwa Taiwan-Japan BioVenture Investment Limited Partnership II, which has been established by DCI Partners. The scope of the Fund's investment activities covers Japan and Taiwan, and includes as yet unlisted drug discovery and regenerative medicine biotech startup companies, and candidate drugs developed by universities, research institutes, and private corporations. With this investment, Yokogawa Electric aims to accelerate the expansion of businesses related to pharmaceuticals and foodstuffs, and contribute to the realization of a healthy and thriving society. In addition to investing in biotech venture companies that have already launched, the Fund has adopted a venture creation model whereby it takes the lead in activities such as technology seed discovery, human resource acquisition, research and development, and support for company establishment. This means that the scope of investment can be expanded, and the number of investment opportunities increased.

Singlera Genomics secures $150M in Series B financing

Singlera Genomics, with R&D centres and business operations in both US and China, has raised $150 million in Series B financing. This round of financing was led by the CICC Kai Tak Innovative Biomedicine Fund, and co-led by Detong Capital and Furong Investment. The new group of investors also include Huamei International, Linden Asset Group, Wuxi Capital, FutureX Skyline Capital, Shanghai Free Trade Zone Fund, and initial investors from the Series A round such as Greenpine Capital, Prosperico Ventures, and Proxima Ventures joined with follow-on investment. Singlera will utilize this round of financing mainly to expand the company's early cancer screening product research and development pipeline and focus on promoting product registration and commercialization, as well as expanding prospective studies into pan-cancer early screening. In July 2020, Singlera and Fudan University published groundbreaking scientific research results, which used Singlera's circulating tumor DNA (ctDNA) methylation multi-cancer screening technology PanSeer to validate early cancer detection in a large population cohort. After this round of financing, Singlera Genomics will continue to carry out large-scale pan-cancer early screening prospective studies.

Neuroglee raises $2.3M to advance product pipeline

Neuroglee Therapeutics, a Singapore based healthtech startup that builds evidence-based, prescription digital therapeutics for neurodegenerative diseases, has raised $2.3 million in pre-seed funding. The funding will be used to advance the product pipeline for their lead product NG-001, intended for treatment and management of patients with early stages of Alzheimer's Disease. The round was led by Eisai Co. Ltd, a leading global pharmaceutical company headquartered in Tokyo, Japan. Kuldeep Singh Rajput, Founder & CEO of Biofourmis, also participated in the round. Neuroglee discovers, designs and commercialises digital therapies to fill the unmet need for complementary therapies to manage neurodegenerative diseases that can run in parallel with pharmacotherapy (treatment through medication). Combining best-in-class closed-loop cognitive intervention strategies and novel biomarkers, Neuroglee's prescription software can be used independently and/or in conjunction with pharmacotherapy for better patient management, creating a more holistic approach to treatment for neurodegenerative diseases.

COVAX plans global rollout of COVID-19 vaccine starting Q1 2021

COVAX, the global initiative to ensure rapid and equitable access to COVID-19 vaccines for all countries, regardless of income level, has announced that it has arrangements in place to access nearly two billion doses of COVID-19 vaccine candidates, on behalf of 190 participating economies. COVAX is the vaccines pillar of the ACT-Accelerator, convened by Coalition for Epidemic Preparedness Innovations (CEPI), Global Alliance for Vaccines and Immunisation (GAVI) and WHO. For the vast majority of these deals, COVAX has guaranteed access to a portion of the first wave of production, followed by volume scales as further supply becomes available. The arrangements will enable all participating economies to have access to doses in the first half of 2021, with first deliveries anticipated to begin in the first quarter of 2021, contingent upon regulatory approvals and countries' readiness for delivery. Given these are arrangements for 2 billion doses of vaccine candidates, which are still under development, COVAX will continue developing its portfolio: this will be critical to achieve its goal of securing access to 2 billion doses of safe and effective, approved vaccines that are suitable for all participants' contexts, and available by the end of 2021.

Sputnik V, AZD1222 to form vaccine cocktail

After the Sputnik V vaccine's clinical trial preliminary results showed its efficacy at above 90 per cent, the Russian Direct Investment Fund (RDIF, Russia's sovereign wealth fund) and Gamaleya Institute have offered British pharmaceutical firm AstraZeneca to use one of the two components (human adenoviral vectors of the Sputnik V vaccine in AstraZeneca's clinical trials. AstraZeneca has accepted RDIF's proposal and will begin clinical trials of its vaccine in combination with Sputnik V's human adenoviral vector type Ad26 soon. This research will allow AstraZeneca's scientists to study the possibility of boosting their vaccine's efficacy through the application of this combined approach. The regimen with two different adenoviral vectors for a prime and a boost immunization is a unique and ground-breaking discovery of the Gamaleya Center scientists. It helps to completely avoid immunity to the first vector, which forms after the first inoculation and thus to raise efficacy and create long-term immunity. Among the leading COVID-19 vaccines only Sputnik V is using the two-vector technology.

FDA issues EUA to Moderna & Pfizer COVID-19 vaccine

The US Food and Drug Administration (FDA) has issued emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine to be distributed in the US. The FDA has determined that both COVID-19 vaccines have met the statutory criteria for issuance of an EUA. The totality of the available data provides clear evidence that the two COVID-19 vaccines may be effective in preventing COVID-19. The data also shows that the known and potential benefits outweigh the known and potential risks supporting the company's request for the vaccine's use in people 18 years of age and older. The vaccines contain messenger RNA (mRNA), which is the genetic material. The vaccines contain a small piece of the SARS-CoV-2 virus's mRNA that instructs cells in the body to make the virus's distinctive "spike" protein. After a person receives this vaccine, their body produces copies of the spike protein, which does not cause disease, but triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2.

Argentina registers Russian Sputnik V vaccine

The Russian Direct Investment Fund (RDIF, Russia's sovereign wealth fund) has announced the registration of the Russian Sputnik V vaccine against coronavirus by the National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT). Argentina was the first country in Latin America to officially register Sputnik V. The vaccine was registered under the emergency use authorization procedure and was approved by the regulator, ANMAT, based on the results of Phase III clinical trials in Russia, without additional trials in Argentina. On December 10, RDIF and the Government of Argentina signed a contract for the supply of 10 million doses of Sputnik V vaccine to the country. ANMAT representatives inspected a number of vaccine production sites that will supply Sputnik V to Argentina. Supplies of the vaccine to Argentina will be facilitated by international partners of RDIF in India, China, South Korea and other countries.

Biocon Biologics makes quality insulins affordable in Tanzania

Biocon Biologics, a fully integrated pure play biosimilars company and a subsidiary of Biocon in continuation of its Mission 10 cents affordable insulins programme for low- and middle-income countries (LMICs), has signed a Memorandum of Understanding (MoU) with the Christian Social Services Commission (CSSC), a faith-based organisation active in Africa. CSSC works closely with the government as well as international and national partners to facilitate health and education services. Tanzania will be the first country in Africa that will benefit from this collaboration between Biocon Biologics and CSSC. Biocon Biologics is helping unlock universal access to quality insulins in LMICs by making recombinant human insulin (rh-insulin) available for less than $0.10 per day as a part of its 'Mission 10 cents' programme. Besides improving access to insulin treatment by making affordable yet high quality insulin available, Biocon Biologics is working with local partners to help strengthen overall healthcare capacity with the aim of supporting all people with diabetes in LMICs, where diabetes prevalence has been rising more rapidly than in high-income countries. Tanzania is among the top 5 countries for the number of people with diabetes in Africa. An estimated 19.4 million adults aged 20-79 years were living with diabetes in the IDF Africa Region in 2019, representing a regional prevalence of approximately 4 per cent.

African Union scales up preparedness for health emergencies

The European Centre for Disease Prevention and Control (ECDC) and the Africa Centres for Disease Control and Prevention (Africa CDC) have launched a new partnership initiative to strengthen the capacity of Africa CDC to prepare for and respond to public health threats in Africa. The four-year project, 'EU for health security in Africa: ECDC for Africa CDC', funded by the EU, will also facilitate harmonised surveillance and disease intelligence, and support the implementation of the public health workforce strategy of Africa CDC. Funded under the European Development Fund, the project includes a contribution agreement with ECDC of €9 million and a complementary grant to Africa CDC of €1 million to cover staffing costs. This project illustrates the engagement of the European Union to help scale up preparedness for global health emergencies and to strengthen support to health systems in Africa. Through this partnership, Africa CDC and ECDC will be able to exchange experiences and lessons learnt from working with African and European Member States on the continental harmonised surveillance of infectious diseases, data sharing, and early detection of threats, as well as on preparedness, risk assessment, rapid response, and emergency operations, and on how to adapt these to their needs.

WHO launches baseline report for healthy ageing

At least 14 per cent of all people aged 60 years and over are currently unable to meet all their basic daily needs according to the baseline report for the Decade of Healthy Ageing, released by the World Health Organization (WHO). The baseline report brings together data available for measuring healthy ageing, defined by WHO as the process of developing and maintaining the functional ability that enables well-being in older age. Optimizing functional ability is the goal of the Decade of Healthy Ageing, which begins in 2021 and addresses five interrelated abilities that all older people should enjoy: the ability to meet basic needs; to continue to learn and make decisions; to be mobile; to build and maintain relationships; and to contribute to society. The baseline report presents the experience of countries, which have been successful in starting healthy ageing initiatives in each of these areas, such as Ireland, Mexico and Viet Nam. It also stresses that older adults must be engaged throughout. The report is intended for people working in government, academia, civil society and the private sector who make decisions that impact people's ability to live well in older age.

WHO, Sanofi renew collaboration to eliminate NTDs

The World Health Organization (WHO) and Sanofi have signed a new agreement for donations of medicines to sustain specific efforts to eliminate neglected tropical diseases (NTDs). Under the new five-year $25 million agreement (2021–2025), Sanofi will support WHO's global programme for elimination of human African trypanosomiasis (sleeping sickness), leishmaniasis, control and prevention of Chagas disease and integrated control of the skin NTDs. Under this new agreement, funding will also be earmarked for in-country capacity-strengthening and training of health workers, improved epidemiological surveillance, and renewed efforts for case-finding and treatment for several diseases, including leishmaniasis, Chagas disease and the skin NTDs.

WHO pre-qualifies Biological E's typhoid conjugate vaccine

Indian firm Biological E Limited (BE) has announced that its Typhoid Conjugate Vaccine (TCV) has been pre-qualified by the World Health Organisation (WHO). With this pre-qualification, BE became one of two pre-qualified suppliers of TCV to the UN agencies. BE's TCV is a single-dose injectable vaccine, which can be administered to children from 6 months of age to adults up to the age of 45 and it is formulated with Vi polysaccharide conjugated to a carrier protein (CRM197). The Vi polysaccharide antigen used in BE's TCV is derived from C freundii, which is a non-pathogenic source (BSL 1 organism), compared to virulent Salmonella Typhi used by other manufacturers, and the carrier protein used for conjugation is a non-toxic CRM197 protein locally developed by BE through in-house R&D effort. Clinical studies conducted in India have shown that the safety and immunogenicity profiles of this vaccine are comparable with those of the other WHO pre-qualified TCV. The vaccine was developed in collaboration with the GSK Vaccines Institute for Global Health (GVGH), based in Siena, Italy, which first developed the vaccine strain and transferred the technology to BE in 2013.

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2021 beckons MAJOR investments IN R&D

The life sciences industry in Asia Pacific (APAC) region entered the year 2020 with companies entering into new agreements for expansion and focusing on applied research to develop new drugs that are affordable. During 2020, the industry, which acted timely, as covered in the January 2020 issue of BioSpectrum Asia, witnessed unprecedented collaborations with the governments due to the unexpected spread of coronavirus since December 2019. COVID-19 is expected to remain a defining issue for the life sciences industry across the globe in 2021, compelling companies to invest heavily in research and development.

2020 began with the industry expecting a buoyant uptick in medtech, biopharma and start up space, focusing on applied research, new technologies, affordability and manageability. However, the pandemic proved to be an unexpected dampner on an international scale.

While most industries have been struggling with the impact of COVID-19 and the slow moving economy, the life sciences industry has quickly adapted itself to control the situation.

Since the virus was first identified in Wuhan, China, in December 2019, the life sciences industry has played a major role in disease management. From prevention - by manufacturing hand sanitisers and personal protective gear, diagnosis - by developing numerous testing kits, to treatment - by designing low cost, yet effective ventilators and the discovery of an efficient vaccine, the industry rose to the occasion.

As a result, in 2020 there were a maximum number of innovations reaching from lab to

"A positive trend is expected in 2021, as the life sciences sector emerges through the impact of COVID-19, and, concurrently, develops innovative solutions for several diseases and disorders."

- KV Subramaniam,
President, Reliance Life Sciences, India

market in the shortest possible time frame. It is likely that COVID-19 will continue to be a defining issue for the life sciences industry across the globe in 2021 that will see companies working on robust investment plans in research and development.

Home to nearly 60 per cent of the world's population, the Asia Pacific (APAC) region with its diverse demography and economies, needs urgent intervention from the respective governments and industry to invest further. Innovative medical research, availability of rapid and flexible supply and access to medicines are the need of the hour to ensure continuity of care to people who might need it in case of a future pandemic.

"The pandemic has forced us to find alternative ways to deliver healthcare, accelerate research and development. COVID-19 has also forced healthcare companies to become faster and more agile. While we witnessed the speed at which the pandemic spread across the world, we also saw the breakneck pace at which scientific progress can move when all of us are working together to tackle significant healthcare challenges. It has never been clearer to us that we need to be more than just a supplier and manufacturer of medicines and devices", says Ryan Harper, General Manager, Roche Pharma Singapore.

For instance, Korean government plans to spend a total of 2.2 trillion won on developing new medicines until 2030. In particular, the Ministry of Science and ICT plans to spend 31.7 billion won on COVID-19 treatment and vaccine development in 2021 and 10.2 billion won to acquire technology to respond to new infectious diseases. Additionally, 36 pharmaceutical companies and five venture capital firms, including Samsung Biologics Co. and Celltrion Inc., have announced a combined 10 trillion won

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- Ryan Harper,
General Manager, Roche Pharma Singapore

"Australia's record investment in 2021 in health includes $20 billion medical research future fund (MRFF) that has reached maturity to deliver life-changing research, with $424.3 million in new grants programmes and opportunities, and $2.3 billion investment in COVID-19 treatments and vaccines amongst others."

- Gregory Andrew Hunt,
Minister of Health and Aged Care,
Government of Australia

"While the healthcare delivery systems have greatly benefitted from welcoming technology, we see a similar effect in the pharmaceutical industry as well. Pharmaceutical companies have begun to embrace technological solutions to expedite drug manufacturing activities. This is especially fundamental at a time where the pandemic has required a vaccine as quickly as possible."

- Poh Hwee Tee,
Managing Director, Singapore and
Asian Emerging Markets, Novartis, Singapore

"While AI has proved its worth in assisting clinicians with diagnosis, its use will be invaluable as healthcare organizations increase their digitalization. AI will continue to play an important role in turning data into fast and meaningful insights, guiding treatment decisions and providing data intelligence."

Caroline Clarke,
Market Leader, Philips ASEAN Pacific, Australia

"With the availability of vaccines, the world will slowly emerge from a pandemic in 2021 but it will take a few years to completely recover. The post pandemic world will, however, not likely be the same. The acceleration of digital and online business will surely continue and connect us all globally."

Dr Visit Thraveeprungsriporn,
Managing Director, Nitto Denko Asia Technical Centre, Singapore

"Healthcare has already begun shifting to telemedicine, so clinical trials that use digital connectivity between the patient and physician will help trailblaze the future of telemedicine. At the same time, virtual trials enable the process to proceed without external interruption while also allowing for better data aggregation and analysis."

Edwin Ng,
Senior Vice President, General Manager Sales, APeJ, Medidata Solutions, Singapore

by 2023 to nurture the country's life sciences industry.

In an effort to make sure that Australia has stockpiles of critical vaccines in the future, the government has announced that the largest flu vaccine manufacturing plant in the southern hemisphere will be built in Melbourne. With the government making a significant contribution, Seqirus, a wholly owned subsidiary of CSL, is investing $800 million to construct a new world-class biotech manufacturing facility in Australia to supply influenza vaccines to Australia and the rest of the world.

Additionally, the Australian government has delivered a record investment of $115.5 billion in 2020–21 and $467 billion over the forward estimates to deliver the essential health services Australians need under the Long Term National Health Plan.

"Australia's record investment in health includes $20 billion medical research future fund (MRFF) that has reached maturity to deliver life-changing research, with $424.3 million in new grants programmes and opportunities, and $2.3 billion investment in COVID-19 treatments and vaccines amongst others", says Gregory Andrew Hunt, Minister of Health and Aged Care, Government of Australia.

A record $597.9 million will be disbursed from the MRFF to support medical research in 2020–21, and the additional investment from the government means that $627.5 million will be available for medical research in 2021-22.

In terms of budget, Japan has announced a record-high 106.61 trillion-yen draft for fiscal 2021 as the country grapples with the coronavirus pandemic. A bulk of the budget will be invested in the development of an infectious crisis management system, enhancement of domestic production capacity of medical equipment, COVID-19 vaccination and inoculation, among others.

Likewise, Singapore has recently announced an investment of S$25 billion in research, innovation and enterprise for the next five years as part of the Research, Innovation and Enterprise 2025 Plan (RIE2025). Nearly 30 per cent of the new budget, or S$7.3 billion, will be set aside for universities and A*STAR research institutes.

RIE2025 will accelerate the development, translation and adoption of key technology areas like artificial intelligence (AI), cybersecurity, trust technologies, communications and connectivity and quantum computing.

"COVID-19 has spurred a digital transformation in healthcare, with solutions such as telemedicine, wearables and mHealth applications, aiding the patient, caregivers, healthcare professionals and other stakeholders to have easy access to health data, increasing convenience much more than before. While the healthcare delivery systems have greatly benefitted from welcoming technology, we see a similar effect in the pharmaceutical industry as well. Pharmaceutical companies have begun to embrace technological solutions to expedite drug manufacturing activities. This is especially fundamental at a time where the pandemic has required a vaccine as quickly as possible", mentions Poh Hwee Tee, Managing Director, Singapore and Asian Emerging Markets, Novartis, Singapore.

The Indian government is not far behind in accelerating research and development across the country. The recently announced stimulus package of Rs 9 billion for Mission COVID Suraksha, India's COVID-19 vaccine development mission, is projected to accelerate pre-clinical and clinical development, licensure of COVID-19 vaccine candidates that are currently in clinical stages or ready to enter the clinical stage The Mission will aid in establishing clinical trial sites and strengthening existing immunoassay laboratories to support vaccine development throughout 2021.

The pandemic has, in fact, made India realise the importance of biomedical resources for the healthcare system and research community. It has pushed India to optimise the latent capabilities it possesses across the public and private sector to promote indigenous development and manufacturing particularly in the space of diagnostics and medical devices. The current situation has come across as a catalyst to reinforce the Make in India initiative.

"The life sciences industry has been in the spotlight in 2020, due to its focus on developing COVID-19 diagnostic tests, therapies and vaccines, as well as point of care medical devices. This unprecedented situation has accelerated not only digitisation in healthcare, but also R&D investments; thereby driving innovation and transforming the way companies operate, conduct research, manufacture and market products. Overall, a positive trend is expected in 2021, as the life sciences sector emerges through the impact of COVID-19, and, concurrently, develops innovative solutions for several diseases and disorders", points out K V Subramaniam, President, Reliance Life Sciences, India.

The pandemic has also forced the Indian pharma industry to move beyond its traditional methods of operating, particularly its dependence on China for active pharmaceutical ingredients (APIs). Revival of India's API industry is another positive outlook for 2021. This revival could become a reality, especially with the government set to establish three bulk drug parks, each with an investment of Rs 100 billion Moreover, the dependence of Indian drug manufacturing companies for API, especially from China, will significantly reduce.

China is, for the moment, sitting strong as the global leader in the production and export of APIs, which is around 20 percent of the world's API production. The pandemic has caused China, like other countries, to rethink its priorities within the healthcare system. Thus, it is likely that healthcare will feature even more heavily in the 14th Five Year Plan, covering 2021-25, than it did in the 13th Five Year Plan.

Meanwhile, China plans to launch a national strategy for circular bioeconomy in the second quarter of 2021. The Chinese government aims to prioritize biotechnology in national scientific and technological development and will vigorously support the development of the biotechnology industry.

2021 and beyond is calling for larger investments in research and development across the life sciences sector. It is also seeking greater collaboration where regulators and government bodies become more flexible and work closely with the industry for meeting the needs of the future today.

In addition, there will be a growing focus on the adaptability of the new age technologies such as artificial intelligence, machine learning, big data, robotics, 3D printing, blockchain, cloud computing etc., that are likely to be the front runners for 2021. This will turn out to be a booming phase for all the technology based startups in the life sciences sector.

As we step into 2021, BioSpectrum Asia showcases the elaborate plans of the industry players within the APAC region ranging from new product launches, announcing huge R&D investments to accelerating adoption of technology. BS

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With inputs from Hithaishi C Bhaskar

CHINA

Gearing up to manufacture vaccines for the entire world

With six COVID-19 vaccine candidates in the final stages of clinical trials, China is gearing up to manufacture vaccines at a large scale for not only itself, but for the entire world in 2021. At the same time, while almost all sectors in China have entered into some form of recession during the COVID-19 pandemic, the healthcare sector has shown the highest resiliency and economic defensiveness during this time.

"Fighting COVID-19 through vaccine development"

Sinovac is at the forefront of the fight against COVID-19 through vaccine development. Our COVID-19 vaccine, or CoronaVac, is currently being tested in phase III clinical trials in Brazil, Indonesia, Turkey and Chile. We have also forged a strategic partnership with Sino Biopharmaceutical with respect to our R&D subsidiary's development of CoronaVac, which will accelerate our efforts to help combat the global pandemic.

WEIDONG YIN,
Chairman, President & Chief Executive Officer,
Sinovac Biotech

"Positioning to distribute our COVID-19 vaccine worldwide"

With positive results from our phase 1 clinical trial demonstrating strong neutralizing immune responses and favourable safety profiles, we look forward to moving our COVID-19 vaccines into the final stages of clinical development. Combined with our ability to potentially produce more than one billion doses of antigen annually and the stability of our vaccines under standard refrigeration conditions, our adjuvanted COVID-19 S-Trimer vaccines are positioned to be well-suited for worldwide distribution. We and our collaborators are steadfast in our commitment to the development of safe, effective and accessible COVID-19 vaccines for the global population.

JOSHUA LIANG,
Chief Executive Officer, Clover Biopharmaceuticals

"Achieving vaccine accessibility & affordability in China"

Fosun Pharma continues to focus on innovation and internationalization, striving to develop strategic products and optimize its pharmaceutical R&D system that integrates generic and innovative drugs, and further enhance the development of 4+3 R&D platforms (Four platforms: biopharmaceutical drugs, small molecular innovative drugs, high-value generic drugs, and new technological therapy; Three systems: in-house research and development, license introduction, and incubation). Since the outbreak of the COVID-19 epidemic, we have been working closely with BioNTech. We are pleased to reach the supply agreement with BioNTech, which is an important step in Fosun Pharma and BioNTech's efforts to achieve vaccine accessibility and affordability in China.

YIFANG WU,
Chairman & Chief Executive Officer, Fosun Pharma

"Expanding pipeline for rare diseases"

We have completed a $43 million Series E financing in December 2020, led by 3W Fund Management. The raise, which was expanded due to high demand, is a follow-on of the $98 million Series D financing, completed in February 2020. The proceeds will be used to expand our rare disease pipeline through internal development and external partnerships, accelerate the clinical development of pre-clinical stage assets, prepare the commercial launch of CAN101, our first rare disease candidate Hunterase for the treatment of Hunter syndrome, and supplement working capital.

DR JAMES XUE,
Founder & CEO, CANbridge Pharmaceuticals

"Preparing for a future IPO"

We have successfully completed a $100 million Series C financing in December 2020. A key goal in the current round is to expand our investor base to include long-term public market-focused institutions and strategic partners in order to prepare for a future IPO. Fidelity, which led the Series C, is an excellent example of the expansion to the strong foundation we are building to continue the company's rapid organic growth and support our acquisition strategy. We are perfectly positioned to work with biopharma clients in accelerating clinical timelines while reducing development costs, helping them to gain entry to the world's fastest growing market for innovative drugs. Our ability to work in true partnership with Western and Chinese innovators globally, using a holistic and collaborative model, has been widely endorsed as the right formula for future success.

DR LINGSHI TAN,
Founder & Chief Executive Officer, dMed

"Collaborating with other pharma companies"

We have recently opened a new drug discovery center based in Shanghai. Located in Zhangjiang and capitalising on the advantages of the Zhangjiang pharmaceutical sector, this center will continue to discover and develop potential first-in-class or best-in-class novel anti-cancer medicines, strengthen and complement our pipeline and take full advantage of the potential of combination treatment. Discovery is beyond borders, and innovation is never-ending. In Zhangjiang, we will jointly explore the establishment of an innovative discovery center and collaborate with other pharmaceutical companies and the talent in the area. We believe that Antengene's professional and experienced scientists will discover more and newer innovative therapies faster. Through our joint efforts, we will benefit patients as soon as possible.

DR JAY MEI,
Founder & Chief Executive Officer,
Antengene Corporation

"Investing $1 billion in capacity expansion"

Amidst the pandemic, the Group received an increased number of inquiries for both regular discovery, development and manufacturing service in addition to the global COVID-19 neutralization antibody programmes. We secured more than 10 COVID-19 projects within only three months, thus providing revenue upsides for the second half of 2020 and throughout 2021. COVID-19 made 2020 challenging with unprecedented impact. The global communities are in urgent need of treatments to address the greatest health challenges posed by the pandemic. This is the reason we are investing approximately $1 billion and continue to expand our capacities in US, Ireland and Germany to enable our global customers and partners for their drug discovery and development efforts and ultimately to benefit patients worldwide.

DR GE LI,
Chairman, WuXi Biologics

SINGAPORE

AI, 5G & CS key drivers in growing digital economy

Artificial intelligence (AI), 5G and cyber security (CS) are likely to be key drivers in growing Singapore's digital economy in 2021 and beyond to transform healthcare and other sectors. And being the first Asian country to receive the Pfizer-BioNTech coronavirus vaccine, it plans to inoculate its 5.7 million people by the third quarter of 2021.

"Investing in upskilling & reskilling employees"

Merck is transforming into a curious, agile, and innovative organisation of the future by adopting an agile and data-led business approach. We are investing in upskilling and reskilling our employees to ensure they are abreast of the latest innovations and can leverage the benefits of new digital tools and platforms. These plans are guided by our mission to solve the toughest problems in life sciences by empowering scientific breakthroughs that accelerate science and improve access to medical care.

RAJEEV NAIR,
Senior Vice President & Head of Research Solutions, APAC, Life Science business, Merck

"Digital solution & data science top our agenda"

In 2021 and beyond, we expect heightened demand for direct-to-patient services as we push towards customer and patient-centricity. Through our newly rebranded ZP Therapeutics division, we hope to expand our product portfolio and be the partner of choice in bringing innovative healthcare solutions and breakthrough products to our communities. Digital solutions, along with real-world evidence and data science will continue to be top of our agenda. We will continue pursuing our mission to make healthcare more accessible for partners, customers and patients.

JOHN GRAHAM,
Chief Executive Officer, Zuellig Pharma

"Advancing around 50 projects through clinical development"

Our recent announcement in setting a Center of Excellence for Explorative Cardiovascular Studies with National Heart Centre Singapore (NHCS) is part of our long-standing commitment in growing our cardiovascular research in Asia to deliver better treatments to patients. The Center will generate and integrate high quality patient data into early clinical research, which will allow better understanding of the underlying biology of cardiovascular diseases (CVD), which could potentially lead to future targeted therapies to address current unmet needs in CVD treatments. In 2021 and beyond, Bayer will continue to launch new products and new indications in prostate and TRK fusion cancers, heart failure, and diabetic kidney disease across many Asia Pacific countries. Globally, we are advancing around 50 projects through clinical development. We will continue to expand on these digital tools in 2021.

DR CATHERINE DONOVAN,
Head of Medical Affairs, Bayer Pharmaceuticals Division Asia Pacific

"Expanding our growing infrastructure"

There are exciting developments planned for 2021 for the company including the continued expansion of its growing infrastructure of more than 100 network stations and drop points around the world. Innovation is key within the sector so we will continue to develop and adapt our award-winning product portfolio to meet the ever evolving requirements of pharma customers in Asia and worldwide.

BENSEN TEO,
Senior Director of Sales, Asia, Pelican BioThermal

"Launching new personalized healthcare index for APAC"

In 2021, we are doubling down on our efforts to create unprecedented opportunities for collaboration focused on building more resilient and future proofed healthcare systems across Asia Pacific and globally. To support this ambition, one of the first things we will be doing in the new year is launching a new Personalised Healthcare (PHC) Index for Asia Pacific, developed in partnership with external experts from across the region involved in our FutureProofing Healthcare initiative. Another key initiative we are very excited about is 2030 Mission Leapfrog, a multi-partner ecosystem inquiry and experiment process we have developed to accelerate healthcare transformation and create new paradigms with societal impact in Asia. It focuses on where there are key opportunities to leapfrog current systems or approaches to care. We look forward to working with partners across the healthcare continuum in 2021 and beyond, to build and implement the policies that will bring healthcare innovation to patients and society at large.

RACHEL FRIZBERG,
Area Head APAC, Roche Pharmaceuticals

"Expecting more cobot utilization"

Across Southeast Asia, we are witnessing increased human interactions with robotics in everyday environments and more interest in having cobots in the work environment. Definitely, the COVID-19 pandemic had a strong impact on the deployment of cobots in 2020 and during the post-pandemic era, changes in trends of cobot utilisation in manufacturing, food & beverage, healthcare, and even new industries are expected. We will do our best to keep the industry up and running because the next big issue that many businesses will face, will be the economic ramifications of the pandemic.

JAMES MCKEW,
Regional Director Asia-Pacific, Universal Robots

"Beginning clinical trials of our lead product"

As the COVID-19 vaccinations' efficacy and success emerges in the coming months, telemedicine and digital therapeutics will be part of the new normal to monitor and take care of the seniors and those with neurodegenerative conditions. Neuroglee's digital therapeutics platform aims to set the benchmark for a new era of personalised, high quality, integrative care for people with dementia and those at risk. Our lead product NG-001 is an investigational prescription digital therapy to manage patients with Mild Cognitive Impairment (MCI) and early stage dementia due to Alzheimer's disease. Our initial focus would be to begin clinical trials for NG-001 in early 2021, and aim to deliver on our promise to reimagining a better quality of life for all those affected by the neurodegenerative conditions.

ANIKET SINGH RAJPUT,
Chief Executive Officer & Founder, Neuroglee

MALAYSIA

"Look forward to achieving much more for 2021"

When the COVID-19 pandemic disrupted how we worked and operated, there was a change within the healthcare landscape, which was inevitable, and this accelerated uncertainties in many ways. There was also an escalating focus on digital strategy within the healthcare ecosystem, which we quickly went into gear and actively organised virtual engagements to keep everyone updated and informed on the latest health advancements. Although 2020 was indeed, a year filled with immense challenges, we have witnessed many key milestones to be proud of, and we look forward to achieving much more for 2021.

LANCE DUAN,
General Manager, Roche (Malaysia) Sdn. Bhd.

JAPAN

Speeding up the recovery by targeting investment in digital innovation

Japan is speeding up the recovery from the country's coronavirus-driven slump by targeting investment in digital innovation. In addition, the Japanese government is getting ready to start the COVID-19 vaccination procedures from February 2021 giving first priority to the healthcare workers.

"Investing in novel technologies"

Technology does not stand still. The Group's goal is to become a pharma discovery partner of choice by providing a highly attractive solution to increasing innovation and productivity. On July 16, 2020 the Group announced that the international offering had been successful in raising a total of JPY 20.9 billion. The majority of funds will be used to pursue strategic growth initiatives including a potentially transformative acquisition to secure long-term revenue growth; investments in novel technologies that complement and future-proof its drug discovery platform; and expansion of its drug candidate discovery and early development capabilities into new target classes.

SHINICHI TAMURA,
Chairman, President & Chief Executive Officer,
Sosei Heptares

"Producing sufficient vaccine by 2021 end"

We are pursuing the discovery and development of a recombinant protein vaccine for COVID-19, in collaboration with the National Institute of Infectious Diseases and Kyoto University. We have initiated a Phase 1/2 clinical trial in Japan in December 2020. In addition, with the goal of producing sufficient vaccine for more than 30 million people by the end of 2021, we are optimizing our manufacturing methods for large-scale production as well as equipping and expanding production facilities.

DR ISAO TESHIROGI,
President & Chief Executive Officer,
Shionogi & Company

"Investing to enhance biopharma production"

We have invested approximately 100 billion yen for major improvements to manufacturing facilities at our Denmark site to further enhance production capacity for biopharmaceuticals. We will be commencing commercial manufacturing of Eli Lilly and Company's COVID-19 therapeutic antibody from April 2021 at the Denmark site. At our UK site, we are investing in plant and equipment to build a new facility, aiming to commence production process development in spring 2021, and manufacturing of drug substances under contract in the fall of 2021.

SHIGETAKA KOMORI,
Chairman & Chief Executive Officer,
Fujifilm Holdings Corporation

"Developing business creation initiative"

As each country settle into the new normal, businesses have to be creative and be resilient in order to survive. In Taiwan, we are collaborating with a research institute to develop a business creation initiative that utilizes medical, health, elderly care data. Going forward, the initiative will drive the creation of new businesses in different sectors, such as insurance and pharmaceutical industries, which will be able to access and leverage healthcare data. Fujitsu has more than 5000 customers in Asia. Combining our technology and their practical industry knowledge, we believe that Fujitsu, together with our customers, can reimagine with Asia to create the new normal.

ARIMICHI KUNISAWA,
Senior Vice President, Corporate Executive Officer,
Head of Asia Region, Fujitsu

AUSTRALIA

Govt is in full swing to support organisations

The government is in full swing in 2021 and beyond to support academic institutions and small to medium sized commercial organisations in conducting valuable research allowing Australians to benefit from life-changing medical discoveries. In addition, the government has signed contracts with companies to partner for safe distribution of COVID-19 vaccines to all Australians from March and completion of the whole of the population in 2021.

"Opening new facility for biopharma market"

We have several expansion plans to meet the increasing demand in the microbiome and recombinant biopharma markets. We are opening an additional small scale (30L) GMP manufacturing suite. This new small-scale suite will allow us to respond to those customers that need a smaller active dose for their initial clinical development, while also giving them access to Luina's proprietary FMP facility flexibility. For the large-scale GMP Facility, we will develop a 10,000 sq mt late phase clinical and commercial production facility for commissioning in late 2021. The new facility will have up to five production lines in parallel, ensuring that multiple-strain live biotherapeutics projects have compressed production times. Luina's largest reactor (2,000L) will allow it to deliver live biotherapeutics volumes compatible with the commercial needs of those companies that have single-strain projects. The facility will also boast new technologies to decrease the downstream processing time of live biotherapeutics and bacterial recombinant biotherapy projects dramatically.

LES TILLACK,
Chief Executive Officer, Luina Bio

"Commencing final product development loop"

In 2021 we plan to complete our current clinical studies, raise a Series A round and commence the final product development loop (design-build-test) for our first medical device. Based on our solid performance during a volatile 2020, we're very confident we can achieve these goals.

ALEX NEWTON,
Co-founder & Chief Executive Officer, Navi Medical

"Launching new clinical trial design software"

Our new clinical trial design software is scheduled for market launch in 2021. Our business has started to scale with new channel partners coming on board and a welcome expansion in our team as we build capacity. New people and roles in the group are exciting and energising for the whole team, everyone is looking forward to this. We plan to continue work on building more sustainable flexibility into our workspace and routines, to give our team and clients more options and opportunity to work productively in their own space and time.

MICHELLE GALLAHER,
Chief Executive Officer, Opyl

"Moving to next phase of clinical development"

While the world responds and adjusts to the COVID-19 pandemic, at Alterity we've remained highly focused on preparing our lead compound ATH434 for further clinical development. Neurodegenerative diseases like our lead disease indication Multiple System Atrophy or MSA continue to devastate the patients inflicted and we remain committed to this patient population in advancing our treatment as quickly as possible whilst balancing the importance of building a strong foundation of data and evidence. Since announcing our phase 1 clinical trial in May 2019, we have continued to analyse and build on the data and we are in a strong position to move into the next phase of clinical development.

GEOFFREY KEMPLER,
Chairman & Chief Executive Officer, Alterity

SOUTH KOREA

Govt has big investment plans to respond to new infectious diseases

South Korea's aggressive responses to COVID-19 have greatly slowed the epidemic without regional lockdowns. Going ahead, the government has big investment plans in 2021 as part of efforts to develop treatment and vaccines for COVID-19 and to acquire technology to respond to new infectious diseases.

"Raising annual production capacity"

Riding on the robust growth in sales, we are planning on raising the annual production capacity to KRW 5 trillion from the current KRW 2 trillion by the first quarter of 2021. The company's five production facilities are located in Hanam City, in the vicinity of capital Seoul. Additionally, Seegene has recently purchased 10,752 square meters of land in Hanam City, able to handle even greater global demand in the future. With the COVID-19 pandemic, the sales of not only the COVID-19 test kits but the demand for those of other illnesses such as HPV, gastrointestinal infections and sexually transmitted infections also increased significantly. With our diverse diagnostic reagent products numbering more than 150, there has been an increasing trend throughout the world to install Seegene's PCR instruments, which in turn would generate more long-term sales. The company installed more PCR instruments in November alone than it did in the entire year of 2019.

DR JONG-YOON CHUN,
Chief Executive Officer, Seegene

"Releasing Foistar Tab for COVID-19 treatment"

We are conducting clinical trials of Foistar Tab which is currently being developed as a treatment for COVID-19. Foistar Tab is a drug in which its safety has been proven through administration to patients with pancreatitis for about 10 years, and it will also serve as a COVID-19 treatment similar to Tamiflu. Not only will Foistar Tab be developed as a drug that has to be immediately administered to patients tested positive for COVID-19, but also as a drug that is to be administered to people who were in close contact, or people displaying symptoms or currently in self-quarantine. We are speeding up development so that COVID-19 patients can progress from mild symptoms to recovery through administration of Foistar Tab, and make COVID-19 a disease that can be controlled such as the common flu, which can even be prevented. We are also planning to actively collaborate with other countries as well as governmental institutions, such as the Ministry of Food and Drug Safety, Ministry of Welfare, and the Ministry of Science and ICT, in order to contribute to treating worldwide COVID-19 patients.

SENGHO JEON,
Chief Executive Officer, Daewoong Pharmaceutical

"Seeking WHO pre-qualification for our typhoid vaccine"

Our typhoid vaccine candidate being developed jointly with the International Vaccine Institute has shown excellent levels of immunogenicity and safety in phase 3 clinical trials. We now plan to apply for an export certificate from the Ministry of Food and Drug Safety in January. We also plan to enter the WHO Pre-qualification certification process after acquiring the certificate from the Ministry of Food and Drug Safety to export the product as a pharmaceutical, based on its high safety and immunogenicity secured through clinical trials.

AHN JAE-YONG,
Chief Executive Officer, SK Bioscience

INDIA

All set to embrace a glocal approach by bracing the local talent

The pandemic has forced the Indian life sciences industry to move beyond its traditional methods of operating, thereby setting new trends for 2021 in the form of strengthening API manufacturing, building diagnostic & medtech capabilities, increasing collaboration, enhancing drug development and adopting digital transformation. India is all set to embrace a glocal approach by bracing the local talent and delivering global standards.

"Housing data scientists to support drug discovery"

As a company, we have accelerated our use of digital solutions and platforms during the pandemic. We now use digital media more extensively than before for customer engagement and multiple other processes. We plan to build on the progress made in 2020 on several fronts. We already have a good presence in India through our three global R&D support groups in Bengaluru, and have just announced the opening of a global capability centre in Bengaluru. This centre will house data scientists and analysts, who will support our drug discovery efforts.

SRIDHAR VENKATESH,
Managing Director, GSK Pharmaceuticals India

"Launching transformative therapy options"

At Roche, we were going through an organization transformation when the pandemic hit. It was a massive disruption to our 2020 plans. However, the team responded with agility and purpose to emerge better and stronger. In 2021, we will focus on implementing our transformation agenda, sharpening the execution engine with a strong focus on our strategic initiatives. There are multiple new launches lined up which will make transformative therapy options available for people in India. We will also forge strong partnerships aimed at ecosystem shaping access initiatives.

V. SIMPSON EMMANUEL,
General Manager, Roche Products India

"Using real world data to accelerate innovation"

2021 will be the year of opportunities. Our world, pivoting in response to the pandemic, has demonstrated great resilience and has shifted quickly to work in new and different ways to accelerate new therapies. Moving forward with a patients-first approach, it will become imperative to design studies keeping in mind patients' convenience and safety. Decentralized trials and improving capabilities in cell and gene therapy research will be instrumental in creating state-of-the-art infrastructure to conduct clinical trials. Parexel is at the forefront of using real world data (RWD) and real world evidence (RWE) to accelerate innovation and improve efficiency in the new global regulatory environment.

SANJAY VYAS,
Senior Vice President, India Country Head &
Managing Director, Parexel

"Expecting to sustain momentum"

We are very pleased with the strong recovery of our business in 2020, demonstrated by sequential growth across all our geographies, in particular US and India. This marks the start of monetization of our complex generic pipeline with the launch of Etanercept biosimilar in Europe and generic Albuterol in the US. We expect to sustain the momentum on margin improvement led by optimization efforts underway and robust growth in our key businesses.

NILESH GUPTA,
Managing Director, Lupin

"Making Sputnik V available with import and indigenous production model"

Our research teams are working on several potential remedies for COVID-19 in addition to the already launched products. We have seen a year-on-year growth of 21 per cent and sequential growth of 46 per cent which is primarily on account of revenues from the acquired business of Wockhardt and contribution from new products including the Avigan (Favipiravir) and Remdesivir launched for treatment of COVID-19. We have further strengthened our development pipeline for COVID-19 treatment drugs including the vaccine candidate Sputnik V. We are working towards making the vaccine available with a combination of import and indigenous production model.

GV PRASAD,
Co-chairman & Managing Director, Dr Reddy's Laboratories

"Launching new generic formulations in the US"

Looking ahead, we expect the generic formulations business to continue to drive growth, based on new launches in the US for products which are currently under regulatory review. We also plan to commercialise remdesivir in India as part of our commitment towards providing treatment for COVID-19. We have submitted drug master files for three APIs in the US and seven APIs in other markets. We also received licenses from MHRA, UK, to import and distribute products there. This is in line with our plans to commercialise our formulations directly in the UK. The construction of a greenfield facility in Visakhapatnam for immunosuppressant APIs has been slightly impacted due to delays by our vendors on account of COVID-19. We expect this facility to be commissioned by CY 2022.

SIDDHARTH MITTAL,
Chief Executive Officer & Managing Director, Biocon

"Rolling out digital solutions"

AstraZeneca will continue to prioritise investments in its focus areas in-line with its global growth platforms. To detail out further: innovating with partners and piloting new ideas at scale and rolling out digital solutions to benefit large numbers of patients. We will also focus on improving the Healthcare Professionals (HCPs) experience, orchestrating across both digital and F2F; continue to work on the ecosystem around the HCPs with virtual care clinics, e-pharmacy support and importantly the patient education initiatives (Tele-Educators); develop end-to end supplies of our oncology products and strengthening the patient support services with supplies to paramedics on home-day care for essential oncology products; continue to leverage technology and accelerate innovative science by educating and empowering HCPs and connecting with national and international experts through virtual continued medical education meetings/conferences/workshops.

GAGANDEEP SINGH,
Managing Director, AstraZeneca Pharma India

"Expanding plant to locally manufacture testing kits"

In October 2020, we announced an investment of Rs 1,300 crore in India, the largest we have ever made in the country. We are setting up an innovation hub in a new campus in Bengaluru that will combine our existing R&D operations with an ultra-modern medical imaging factory. It will be one of the four innovation hubs of Siemens Healthineers, with other hubs located in the United States, Germany, and China. To expand our digital capabilities, we plan to add up to 1,800 digital talents in the next ten years, in addition to our normal growth. We have already made good progress on this front adding over 100 digital experts over the last few months. We are also expanding our manufacturing plant in Baroda to locally manufacture testing kits, which we currently import from our factories in Europe and the US.

GERD HOEFNER,
Managing Director, Siemens Healthcare

"Implementing automation initiatives"

We will create new alliances in niche areas. We are currently assessing options and are in talks with some companies. We will continue with implementation of automation initiatives with the aim of bringing them to market in the coming year. We will bring internal efficiencies to the way current processes are being handled, with the eventual benefit received by our clients, project optimize is what we call it. While growing the SIRO family, we would strive to continue building a culturally strong and happy organization.

AKSHAY DAFTARY,
Director of Business Development, SIRO Clinpharm

"Churning out best molecular diagnostic solutions"

The clinical diagnostics sector has made a major leapfrog jump to molecular diagnostics during COVID-19 pandemic. We have invested in molecular biology R&D over the last 14 years. Post the pandemic, HiMedia started to focus on churning out the best molecular solutions from HiGenoMB for delivering on the opportunities in the diagnostic sector rather than on focusing on the areas like academics and research, which closed down during the pandemic. We have received a very prestigious grant of Rs 25 crore from the National Biopharma Mission to develop Chemically Defined Serum Free Media (CDSFM) to grow CHO/NS0 cells for production of monoclonal antibodies, which are the magic bullets for the treatment of cancers and many chronic diseases. Additionally our media for T-cell expansion for CAR-T cell therapy is also ready and this is very much needed for anti- cancer treatment using cutting edge cell based therapies. We plan to expand our horizons by reaching every country with sensitive, innovative and user- friendly molecular diagnostic solutions.

DR GANGADHAR M. WARKE,
Founder and CMD, HiMedia Laboratories

"Building expertise in advanced technologies"

We will continue to build on our expertise in advanced technologies such as sophisticated immuno-oncology assays, integrated drug discovery and CAR-T design for research of next generation therapies as well as build on our capacities to serve the growing requirements of our clients.

DR MAHESH BHALGAT,
Chief Operating Officer, Syngene International

"Rolling out 2 dose schedule for COVAXIN"

The Phase III human clinical trials of COVAXIN began in November, involving 26,000 volunteers across India. This is India's first and only Phase III efficacy study for a COVID-19 vaccine, and the largest phase III efficacy trial ever conducted for any vaccine in India. COVAXIN trials are based on a 2-dose schedule, given 28 days apart. The vaccine efficacy will be determined 2 weeks after the second dose. We should look at the Covid19 vaccine distribution as a global public policy. There should be a logistical strategy wherein there is also less impact on our environment.

DR KRISHNA ELLA,
Chairman & Managing Director, Bharat Biotech

"Saving countless lives with COVISHIELD vaccine"

As promised, before the end of 2020, we have applied for emergency use authorisation for the first made-in-India vaccine, COVISHIELD. This will save countless lives. COVISHIELD is by far the most advanced vaccine in human testing in India. We have already manufactured 40 million doses of the vaccine, under the at-risk manufacturing and stockpiling license from Drugs Controller General of India (DCGI).

ADAR POONAWALLA,
Chief Executive Officer, Serum Institute of India

Evaluating COVID-19 vaccines on mutant viral strains

While the viral variants and vaccine trials are contesting with each other, Norway based Coalition for Epidemic Preparedness Innovations (CEPI) has launched first-of-its-kind collaboration to tackle emergence of new COVID-19 viral strains and evaluate their impact on vaccine candidates in development. Tracking viral mutations and diversity is essential to ensure efficacy of COVID-19 vaccine candidates on mutant virulent strains.

In response to the worldwide health predicament, global vaccine development programme has accelerated several advanced molecular platforms with about 240 vaccines in early stage of development, 44 in clinical trials and 9 already in the final stage of human clinical trials. While the world is eagerly looking forward to a safe and affordable vaccines there arises a concerns around few mutant variants of SARS-CoV-2, pushing vaccine development to paradox and challenging R&D efforts.

To rapidly monitor the emergence of new COVID-19 viral strains and evaluate their impact on vaccine candidates in development, Norway based Coalition for Epidemic Preparedness Innovations (CEPI) has launched a consortium of Global Initiative on Sharing All Influenza Data (GISAID), a global science initiative, Public Health England (PHE) and the National Institute for Biological Standards and Control (NIBSC) to further strengthen real-time global tracking and testing of SARS-CoV-2 sequences, following recent attention to a mutant strain of the virus casing COVID-19.

GISAID has taken initiative utilising genetic, phenotypical and virological data of SARS-CoV-2 to enable real-time progress in understanding geographical spread, circulation, and evolution of COVID-19. Earlier on January 10, 2020, it was GISAID, which publicly shared the complete SARS-CoV-2 viral genome to make it available for the global R&D purposes. The initiative made available over 200,000 SARS-CoV-2 viral sequences on its publicly accessible platform, creating CEPI genomic diversity report.

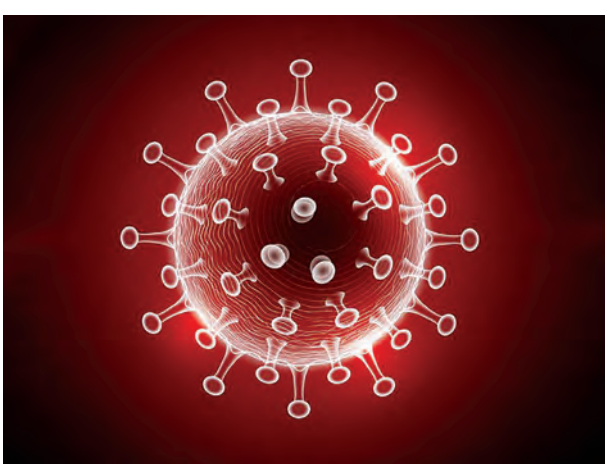
GISAID is currently reporting updates on spike mutations of recent submissions and any sequence can be tested for spike mutations. This signifies tracking and analysis of mutations and its rates. GISAID has involved public-private-partnerships with governments around the world including Brazil, Germany, Singapore and United States.

"This joint collaboration between CEPI, GISAID, PHE and NIBSC, fills a key gap in the global outbreak response through acting as a mechanism to both monitor and test emerging viral strains and evaluate whether these circulating strains may impact COVID-19 vaccine development. Through this effort we can provide information to support continuing global efforts to develop effective COVID-19 vaccines and bring an end to this pandemic as quickly as possible", says Dr Richard Hatchett, Chief Executive Officer, CEPI, Norway.

A total of $1.3 million in funding is allotted by CEPI to GISAID to enhance their global operations.

CURRENT CONCERNS WITH VARIANT STRAIN

- Transmissible ability, rate and severity of the new virus variant
- Impact and responses to SARS-CoV-2 diagnostics
- Potential on the occurrence of variant viruses to increase frequency of reinfections
- Impact on the efficacy and functionality of the vaccines currently under final stage of trial or approved under Emergency Use Authorisation (EUA)



Up to an additional $1.3 million funding will also be provided to PHE and the NIBSC to carry out the neutralisation tests to provide information on the effectiveness of vaccine candidates in development against mutant SARS-CoV-2 strains.

"The NIBSC is on standby to support CEPI with this vital work in response to the ongoing pandemic. Our scientists have the experience and expertise required to rapidly test any emerging viral strains in order to assess their potential impact on the effectiveness of COVID-19 vaccines", points out Dr Marc Bailey, Interim Director, NIBSC, UK.

Will the mutant variant throw challenges to vaccine developers?

Genetically, coronavirus (CoV) strains such as SARS-CoV and MERS-CoV are single-stranded, positive-sense RNA virus belonging to the beta-CoV genera in the family Coronaviridae. SARS-CoV-2 like any other RNA corona viruses is prone to evolve by mutation to expand their host range. But its mutation rate is comparatively lesser than other RNA viruses like HIV and influenza and less is transmissible than other diseases like mumps, as stated by the World Health Organisation (WHO).

The virus membrane contains four structural components, namely the spike (S), envelope (E), membrane (M), and nucleocapsid (N) proteins, and five to eight accessory proteins. Currently vaccine developers are targeting the spike protein from the isolates of original dominant D614 strain of SARS-CoV-2 (Wuhan strain). Now it's a requisite to evaluate the immunogenicity of the newly mutated virus and its counter response to the 'approved', 'to be approved' and trial stage vaccines.

Additionally, the immune responses triggered by sub-potent vaccines might provoke the emergence of a mutated virus. Advent of novel subtypes with antigenic changes could be a challenge for COVID-19 vaccine developers.

On December 14, 2020, authorities of the United Kingdom of Great Britain and Northern Ireland reported a new genetically different SARS-CoV-2 variant, G614. Preliminary reports suggest there might be an estimated increase between 40 per cent and 70 per cent in transmissibility with mutation in the spike genomic sequence (S protein). The new strain of the virus has also shown to evade monoclonal antibodies in clinical trials. Researchers at COVID-19 Genomics Consortium UK (COG-UK) are now focusing on new variant's biological properties, virus receptor domain, clinical symptoms, antibody response, transmissibility, virulence and most importantly vaccine interactive properties.

"So far, even though we have seen a number of changes, a number of mutations, none has made a significant impact on either the susceptibility of the virus to any of the currently used therapeutics, drugs or the vaccines under development and one hopes that will continue to be the case."

- Dr Soumya Swaminathan,
Chief Scientist, WHO, Geneva

"We still need to strengthen our pipeline for the next decade and further into the future. We are also looking at acquiring development compounds that have potential sales synergies with our global strategic products."

- Dr Marc Bailey,
Interim Director, NIBSC, UK

"At the moment, there is no indication that this new strain would evade treatments and vaccines. However, the mutation is a reminder of the power of the virus to adapt, and that cannot be ruled out in the future. Acting urgently to reduce transmission is critical."

- Dr Jeremy Farrar,
Director, Wellcome Trust, UK

APAC INITIATIVE TO ENDORSE CEPI

Country	Initiative in collaboration with CEPI
Australia	CEPI, CSL and The University of Queensland (UQ) have partnered to accelerate the development, manufacture and distribution of a COVID-19 vaccine candidate pioneered by researchers at UQ. In May 2020, CEPI announced invest of an initial $3.5 million in a partnering agreement with Clover Biopharmaceuticals AUS Pty Ltd (Clover Australia) a wholly-owned subsidiary of Sichuan Clover Biopharmaceuticals, Inc (China) (Clover Biopharmaceuticals), bringing the organisation's total investment in COVID-19 vaccine research & development to $39.6 million. The Commonwealth Scientific and Industrial Research Organisation (CSIRO) of Australia is also analysing the hCoV-19 sequences in the GISAID EpiCoVTM Database, focusing on the emergence and evolution of Australian isolates. Total sequence analysed : 234170 as of Dec 4.
China	CEPI is funding the development of the protein-based S-Trimer COVID-19 vaccine candidate by China-based Sichuan Clover Biopharmaceuticals.
Hong Kong	CEPI is investing an initial $620,000 in a partnering agreement with The University of Hong Kong (HKU) to rapidly develop a vaccine candidate against COVID-19.
India	In June 2020, AstraZeneca in partnership with India's SII commits to provide 1 billion doses of its AZD1222 vaccine candidate to LMICs. AstraZeneca signed a $750 million supply deal with CEPI and Gavi for its shot. The Department of Biotechnology, through the India Centric Epidemic Preparedness (Ind-CEPI) aims at rapid vaccine development in Indian in alignment with the global initiative at CEPI.
Indonesia	By November 2020, Indonesia contributes $1 million for CEPI vaccine efforts and to promote 'vaccine multilateralism', marking Indonesia's formal membership in the coalition. In its partnership with Indonesia, CEPI has selected state-owned pharmaceutical company Bio Farma to participate in the manufacturing of a COVID-19 vaccine after positive due diligence results.
Japan	By May 2020, Japan contributed approximately $434 million to CEPI and Gavi's vaccine efforts. The Government of Japan will make a total investment of approximately $834 million at local and international platforms to the development and delivery of vaccines.
Korea	The government of the Republic of Korea (ROK) has decided to contribute $3 million for the first time to CEPI. The commitment will be made through the Global Disease Eradication Fund of the Republic of Korea over a three-year period from 2020-2022. Additionally, CEPI announced a collaboration with South Korea-based SK Bioscience to advance the development of a recombinant protein vaccine candidate (GBP510)—manufactured using a nanoparticle platform with a $10 million funding towards phase I/II study and manufacture of clinical trial materials needed for phase I/II and phase III trials. This collaboration represents CEPI's first next-generation or 'Wave 2' vaccine investment.
Malaysia	By 30 November 2020 Malaysia's Ministry of Science, Technology and Innovation (MOSTI) announced funding of $3 million to CEPI, over the next three-year period (2021-2023). The funding will also further CEPI's investments in platform technologies.
New Zealand	New Zealand has joined CEPI Investors' Council with an initial investment of $15 million towards global research efforts. Pledged $37 million to Global COVID-19 Vaccine Search in May 2020. New Zealand has pledged NZ $10 million to the Gavi COVAX AMC, in addition to NZ $7 million pledged earlier this year for the AMC as of Dec 2020.
Singapore	In a Public private partnership The Bioinformatics Institute (a member of Singapore's A*STAR's Research Entities) provides the CoVsurver and FluSurver power the analysis of data in GISAID to highlight mutations relative to reference strains, display them in the 3D protein structure, cross-link with prior literature phenotype information (antiviral susceptibility, host specificity, glycosylation and antigenic properties), view their geographic and temporal frequency of occurrence as well as co-occurrence with other mutations. Singapore has pledged $5 million to the Gavi COVAX AMC.

"COVID-19 vaccine is likely to fight off any mutation because the mutations are only minor mutations which take place at one or two or at the most ten locations but the vaccine or the antibodies that are generated are against the entire vaccine. So, in principle, the vaccine will be as effective even with the mutated virus stream."

- Dr Shekhar Mande,
Director-General, Council of Scientific and Industrial Research, India

"The joint collaboration between CEPI, GISAID, Public Health England, and the National Institute for Biological Standards and Control, fills a key gap in the global outbreak response through acting as a mechanism to both monitor and test emerging viral strains and evaluate whether these circulating strains may impact COVID-19 vaccine development."

- Dr Richard Hatchett,
Chief Executive Officer, CEPI, Norway

Addressing the growing concerns over this new entrant, Dr Jeremy Farrar, Director, Wellcome Trust, UK says, "At the moment, there is no indication that this new strain would evade treatments and vaccines. However, the mutation is a reminder of the power of the virus to adapt, and that cannot be ruled out in the future. Acting urgently to reduce transmission is critical."

CEPI has recently partnered with five clinical sample testing laboratories to create a centralised global network to reliably assess and compare the immunological responses generated by COVID-19 vaccine candidates. Located across multiple regions globally, the laboratories initially selected for this vaccine-assessment network are: Nexelis (Canada) and Public Health England (PHE, UK), VisMederi Srl (Italy), Viroclinics-DDL (The Netherlands), icddr,b (formerly International Centre for Diarrhoeal Disease Research, Bangladesh), and Translational Health Sciences and Technological Institute (THSTI, India). Global group will minimise variation between individual lab analyses to enable uniform way of evaluating and identifying the most successful candidates.

"COVID-19 vaccine is likely to fight off any mutation because the mutations are only minor mutations which take place at one or two or at the most ten locations but the vaccine or the antibodies that are generated are against the entire vaccine. So, in principle, the vaccine will be as effective even with the mutated virus stream", mentions Dr Shekhar Mande, Director-General, Council of Scientific and Industrial Research, India.

CEPI is also working with the multiple Asian organisations in a public-private partnership to accelerate R&D programmes for vaccine candidates and to prepare for future outbreaks. CEPI's vaccine development and manufacturing efforts is based on the principles of speed, scale, and access and has provided up to $895 million in funding as of October 2020 to accelerate the development of 10 COVID-19 vaccine portfolios.

"So far, even though we have seen a number of changes, a number of mutations, none has made a significant impact on either the susceptibility of the virus to any of the currently used therapeutics, drugs or the vaccines under development and one hopes that will continue to be the case," says Dr Soumya Swaminathan, Chief Scientist, WHO, Geneva.

Experts believe that its ideal to develop a universal corona vaccine than targeting SARS-CoV-2 spectrum alone. A broad spectrum human coronavirus vaccine can be a boon to provide protection against future pandemic coronaviruses. BS

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10 VACCINE CANDIDATES FUNDED BY CEPI (9 UNDER DEVELOPMENT, AND 7 IN CLINICAL TRIALS)

- AstraZeneca/ University of Oxford (Phase 3)
- Clover Biopharmaceuticals, China (Phase 1)
- CureVac, Germany (Phase 2B/3)
- Inovio, USA (Phase 2)
- Institut Pasteur/Merck/Themis, France/USA/ Austria (Phase 1)
- Moderna, USA (Phase 3)
- Novavax, USA (Phase 3)
- SK Bioscience, South Korea (Preclinical)
- University of Hong Kong, Hong Kong (Preclinical)
- University of Queensland/ CSL, Australia (Phase 1, programme discontinued)

Courtesy: CEPI update as of 18 Dec 2020

"We are confident that Sputnik V will be providing long-term immunization defence against potential new coronavirus infections"

« **Kirill Dmitriev,** CEO, Russian Direct Investment Fund (RDIF), Russia

On December 14, 2020, Moscow's National Research Center for Epidemiology and Microbiology named 'Gamaleya Center' and the Russian Direct Investment Fund (RDIF) announced the efficacy of over 90 per cent of the Russian Sputnik V vaccine in Phase III post-registration clinical trials. RDIF joins partners and manufacturers in ramping up the production of Sputnik V. First batch of 300,000 doses of Sputnik V vaccine has already been delivered to Argentina by RDIF on December 24, 2020. In an interview with BioSpectrum Asia Kirill Dmitriev, CEO, Russian Direct Investment Fund (RDIF), Russia shared more insight on the encouraging efficacy data of the Sputnik V with Biospectrum Asia. ***Edited excerpts;***

Sputnik V Phase 3 trial data are impressive. Can you brief interim efficacy at statistically significant control points justifying the safety and efficacy of this vaccine?

Sputnik V is 91.4 per cent effective in providing protection against COVID-19 based on the final control point analysis and has demonstrated 100 per cent efficacy against severe coronavirus cases. High efficacy rate of above 90 per cent was confirmed at each of the three control points of clinical trials - calculated at three statistically significant representative points - upon reaching 20, 39 and 78 cases of novel coronavirus infection among volunteers both in the placebo group and in the group that received the vaccine. The ratio of the placebo group to the vaccinated group is 1 to 3.

What are the production and distribution highlights of the vaccine and how cost-effective it is for LMIC countries? How quickly APAC countries will receive Sputnik V?

Over 50 countries have expressed interest in obtaining Sputnik V based on its currently known safety and efficacy profile, with preliminary applications already received for over 1.2 billion people (2.4 billion doses). The vaccine for the global market will be produced by RDIF's international partners in India, Brazil, China, South Korea and four other countries.

Existing agreements between RDIF and leading foreign pharmaceutical companies allow the Sputnik V vaccine to be produced abroad for 500 million people per year, starting from 2021. First international deliveries of Sputnik V will be made in January 2021 based on the existing partnerships with foreign manufacturers. Among others, our international production partners include South Korea's GL Rapha (over 150 million doses per year) and India's Hetero (over 100 million doses a year). Sputnik V is also being produced in a number of Russian production sights.

We are currently considering additional applications from a number of countries and companies to further increase production capacity.

The cost of a Sputnik V dose is less than $10 for international markets, making it two or more times cheaper than mRNA vaccines with similar efficacy. Sputnik V is a two dose vaccine.

Under foreign regulatory bodies and international organizations of different

countries how accelerated can the registration process be and what are the challenges (if any)?

Sputnik V is currently registered and being used to vaccinate in Russia, this has been made possible by the granting of an emergency use authorization (EUA). Other countries have made similar EUA, including the UK and US. On December 21, Belarus became the first country other than Russia to register Sputnik V. And on December 23, Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT) followed suit, registering the Russian vaccine under EUA and without conducting additional clinical trials, only using Phase III data from Russia.

EUA allows the use of medical products to diagnose, treat, or prevent serious or life-threatening diseases often before the availability of full Phase III trial data, during a health emergency. EUA can be issued to interventions such as vaccines that have reasonable efficacy and safety, based on the currently available evidence and findings of a risk-benefit analysis. Each country has their own processes and parameters for EUA and Sputnik V's full data is readily available for any government that would like to review it.

Sputnik V has the advantage of being in lyophilized version for efficient storage and transport activities. Strategically how beneficial it is for distribution in international markets?

Sputnik V vaccine is available in two forms, liquid, to be stored at minus 18-degree C, and lyophilised (freeze-dried), that can be stored at 2-degree C to 8-degree C. Use of the freeze-dried version enables easier distribution of the vaccine to remote locations with limited access to modern medical facilities. This is particularly relevant for poor countries and for those with tropical climate. This could make Sputnik V more suitable for many emerging markets in particular in comparison to, for instance, Pfizer vaccine that must be stored at a temperature of minus 70-degree C.

How should be the immunization regimen for medically vulnerable groups who might react to the vaccine unpredictably?

The Phase I-III analysis of Sputnik V has not shown any serious vaccine-related side effects. Given the safety profile demonstrated in the

Sputnik V trials, as well as the long-term safety demonstrated by the human adenovirus-based vector platform used, the safety risk is minimal compared with the risk posed by COVID-19, especially for vulnerable populations. Currently there is no clinical study finding to suggest a different approach to vaccination with Sputnik V for vulnerable groups.

How significant is the role of Russian Direct Investment Fund (RDIF) and Gamaleya Center in progressing overall R&D, manufacturing and global reach target?

The Gamaleya Research Center developed the vaccine and continues to lead its clinical progression. RDIF, working jointly with institutional investors, supports the development of Sputnik V, and is investing in mass production of the vaccine by RDIF portfolio companies and foreign strategic partners.

How efficient will Sputnik V be to tackle the mutant strains of coronavirus in the future or is it SARS-CoV-2 specific?

Sputnik V has shown its effectiveness against all existing COVID-19 strains despite all the mutations in the S-protein. We are confident it will be as effective against new mutant strains of the coronavirus, providing long-term immunization defence against potential new coronavirus infections. BS

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“We are planning to launch a new bioprocess controller in Q1 2021”

«
Richard Mirro,
Business Manager, Bioprocess at Eppendorf, Inc., US

Bioprocess engineers develop and produce a multitude of products and ingredients available today. Their applications are diverse, and the products can be found in pharmaceutical, chemical, and nutrition industries. With an integrated portfolio comprising software, instruments, consumables, and services, Eppendorf can satisfy the demands of bioprocess development through production. To find out about what major is in store at Eppendorf Bioprocess, BioSpectrum spoke to Richard Mirro, Business Manager, Bioprocess at Eppendorf, Inc., US. ***Edited excerpts:***

What are the current opportunities and challenges at Eppendorf Bioprocess?

Eppendorf serves the upstream bioprocess market with scalable bioprocess systems, reusable and single-use bioreactors and fermenters, and software solutions. This market is an extremely diverse landscape including therapeutics, food, chemicals, and biofuels. Both challenges and opportunities arise from this diversity. Finding the right balance between dedicated bioreactors serving limited market segments, and supplying flexible bioprocess controllers and software capable of supporting any process requirements is an ongoing challenge. However, serving various segments may compensate market fluctuations. Exponential growth and investment within some biotechnology market areas, particularly vaccine research and development, have significantly increased demand and buffered slowdowns in other market segments. Technology-wise, we observe a trend towards decreasing vessel sizes and single-use solutions, especially in the field of biologics. This clearly favours the Eppendorf single-use bioreactor portfolio, currently covering working volumes up to 50 L, but also our reusable solutions at small and bench scale. As indicated, bioprocess applications and techniques change and so need to do our products. Balancing new product introductions and continuing support of legacy equipment is another challenge.

How is the company responding to the ongoing pandemic? What all steps have been taken so far?

Eppendorf is continuing to strive to meet our customers’ expectations for product supply and availability. Production, employees, supply chain, and service are our pillars for stable business operation. At Eppendorf bioprocess we prioritize COVID-related projects expediting the manufacture and shipment of these opportunities when possible. We monitor and adjust to possible supply shortages and increased lead times from suppliers to ensure continuous production. In addition, we prepare for a possible spike in business as previously locked-down countries and regions come back online. We strive to enable our customers and employees to use the full potential of the remote capabilities of our bioprocess instruments and software. In times of travel restrictions, our technical and application specialists offer remote training and remote service and installation whenever possible. Many of our bioprocess control systems allow for remote system monitoring and control, which can help reducing the time the user needs to spend in the lab. Of course, we implemented safe working conditions for our employees, including restricted travel, working from home, split work shifts, and social distancing for employees continuing to go to the office every day.

What are the strategies in store for the post-COVID era? Anything particular for the APAC region?

We are not making any fundamental changes to our business strategy because of COVID-19, because we believe we have a strong and sustainable long-term strategy. However, some elements of our strategy including digitalization, the introduction of innovative solutions and the expansion of addressable market are being expedited.

What would be the impact of COVID-19 on the bioprocess industry?

I think COVID-19 will impact the bioprocess industry at various levels. Currently, I assume budgets to be redistributed. In some organizations, non-essential product development programs currently may receive reduced funding as budgets get shifted to vaccine-related projects. Economic difficulties may cause the recession of non-COVID related bioprocess industries. As a long-term effect of COVID-19, I expect an increase in local manufacturing capabilities to respond more quickly to future pandemics. Furthermore, new supply chain models for critical consumables are likely to become commonplace. The current pandemic is fostering an increasing acceptance of virtual communication. The trend towards a decreased reliance on and interest in (in-person) industry conferences and tradeshows may continue in the future.

How was the previous FY for the company and what are the expectations from the current one?

Fiscal year 2019 was a strong year for the global life science market, and Eppendorf was able to take advantage of the positive dynamic growth in this sector. Overall, the Eppendorf Group's business development was very good. Nearly all the Group's divisions and all regions developed positively. In comparison with the same period in the previous year, this corresponds to an increase of 10.2 per cent, with prior year at 5.6 per cent. As a result of the rapid spread of the coronavirus since the beginning of 2020, the entire world has been experiencing significant economic upheaval. Even so, Eppendorf is well and strongly positioned with competitive products for a variety of markets and applications. In line with the company's mission, the Eppendorf Group will do its part to support research aiming to combat the corona pandemic through its devices, consumables and services. It is not possible currently to issue a statement projecting the effect of the corona pandemic on the results of the Eppendorf Group.

What are the major investment and expansion plans at Eppendorf Bioprocess?

At Eppendorf Bioprocess we are planning a major product launch in Q1 2021 including a new bioprocess controller and consumables targeting clinical and production-scale upstream bioprocesses. In addition, we are going to present continued product enhancements and new feature releases across the entire product portfolio, including small

scale, bench scale and production scale bioprocess instruments as well as our consumables according to our product agile release strategy. The positive development of the Eppendorf Group during the past fiscal year shows that Eppendorf has succeeded in implementing its growth strategy. Notable examples are Eppendorf's digitalization initiative. Eppendorf again invested heavily in many of its worldwide locations with a view to either expanding or modifying them. A major focus of Eppendorf bioprocess is the ongoing renewal of the product portfolio. As part of the innovation initiative, agile product development was implemented as a standard throughout Eppendorf's global operations in 2019. SciVario twin, the newest bioprocess controller from Eppendorf was one of the first products developed following the agile product development process. New products will be released following an agile process, increasing our innovation pace, response to customer and market needs and ensuring and flexibility. BS

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"Australia has reinforced its standing as a world-class destination for early phase clinical development"

« **Yvonne Lungershausen,** CEO, Avance Clinical, Australia

Avance Clinical, a leading Australian Contract Research Organization (CRO) for biotech firms, and winner of the prestigious Frost & Sullivan 2020 Asia-Pacific CRO Market Leadership Award, has recently partnered with Europe's leading CRO, Cromos Pharma. The collaboration will allow biotech firms to quickly start their pre-IND early phase studies in Australia, thereafter, expanding to Central/Eastern Europe to access the large patient populations for their Phase II and III studies. In an email interaction with BioSpectrum, Yvonne Lungershausen, CEO, Avance Clinical, Australia spoke about the Australian CRO market, and the impact of COVID-19 crisis. ***Edited excerpts:***

As a CRO company, what are your reflections on the COVID-19 situation?

The CRO and biotech sector has been significantly disrupted by the COVID-19 pandemic. Clinical trials around the world have been impacted this year, especially in the USA, which is our main market, where trials have been paused, canceled or delayed. Australia has been recognized globally for its handling of the COVID-19 pandemic with strict quarantine systems and advanced contact tracing, resulting in low numbers of cases and deaths. Therefore we have seen a dramatic increase in the number of USA sponsors moving their trials to Australia.

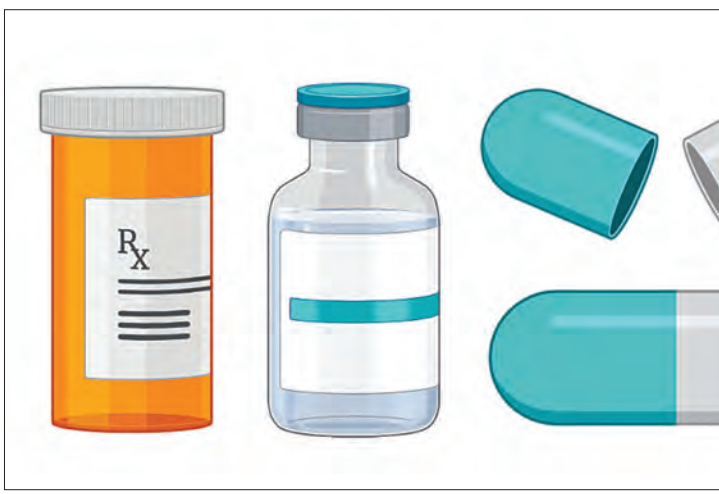
The global disruption presented a number of operational challenges including:

- A need to rapidly pivot to full adoption of eClinical technologies because traditional working practices and methods were no longer practical.
- Initially patient/volunteer participation in clinical trials decreased at some sites because participants were not wanting to attend clinics or hospitals for fear of the virus.
- Some sites in Australia were temporarily closed while they introduced new work practices to protect staff and patients/volunteers.
- COVID-19 studies targeting countries with significant patient populations, rapidly dominated the global sector, resulting in decreased attention, site resources and funding for non-COVID related therapies.
- Employee adaptations to new working environments i.e. working from a home office.
- Conduct of business development activities needed to change as the ability to create new business connections and partnerships via conferences and face to face meetings became no longer possible.

What has been Avance's role in combating COVID-19 and where do you stand in the global race for viable vaccines/treatment?

The Avance Clinical leadership team quickly pivoted the business to address the key challenges and opportunities due to the COVID-19 pandemic. This involved significant investment in the following work practices and resources:

- Quick introduction of new remote working



procedures to allow staff to access site data remotely through coordination with the Information Technology department and providers to ensure all staff had access to a secure private network remotely.

● Launch of new services and significantly increased market positioning and brand awareness during the pandemic including:

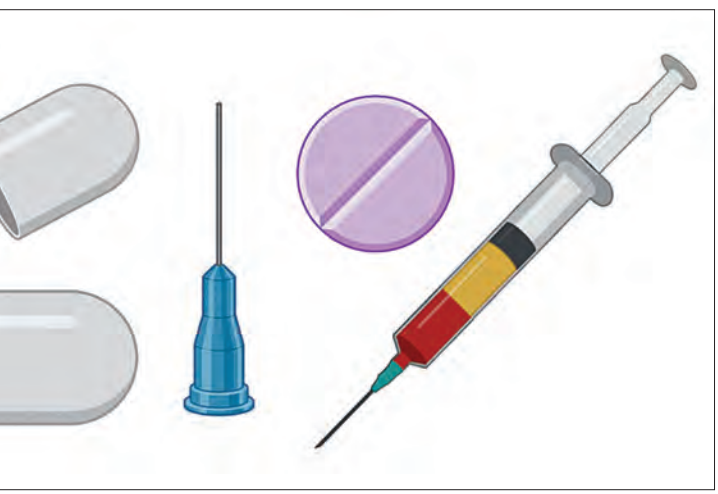
▪ **ClinicReady –** building on the 20-year history of advising biotech clients on their drug development, a dedicated scientific and regulatory affairs service was launched due to increased demand for preclinical study management and scientific and regulatory advice.

▪ **eClinical Solutions –** a suite of the latest eClinical solutions for virtual trials and to maximise the value of study data and deliver real-time visibility on study progress. Working with eClinical industry leaders such as Medrio to offer regulatory compliant and patient centric tools for rapid start-up and continual data flow.

The business development and marketing function quickly pivoted to a targeted, digital campaign to create new business opportunities and partnerships. Our team is also working with biotech companies to deliver early phase clinical trials for COVID-19 treatments and vaccines. For example, we recently announced completion of enrollment in its Phase I clinical study using Atossa's proprietary drug candidate AT-301 administered by nasal spray for the treatment of COVID-19. AT-301 is being developed for at home use enabling management of the infection symptoms with at home quarantine and potentially preventing disease progression.

How has the pandemic affected work at Avance?

There will certainly be some long-term changes in the way we work as a result of the pandemic. Most importantly, it has fast-tracked our investment and adoption of new technology across all operations to accommodate flexible trial environments now and in the future. Virtual or remote trials, eClinical solutions, and sophisticated client and provider information exchange systems have been a key and lasting focus of our COVID-19 response.



While the COVID-19 pandemic has created a significant number of challenges in the CRO and biotech sector, there has also been an upside with the number of opportunities becoming available for Avance Clinical. These opportunities include:

● A significant increase in proposals and study awards as Australia became known globally for good management and control of the virus.

● An increase in hiring for new staff commensurate with the increase in study awards to enable operationalization of the workload.

● An increased focus on readiness to use e-technologies such as e-source, ePRO and e-consent as a remote strategy for clinical trial oversight and as a consequence the organization pivoted quickly to develop new SOPs to support adopting remote strategies for working with sites that were compromised by COVID-19.

● The increased use of digital technologies has further enabled the seamless connectivity with Avance Clinical's global client base.

Do you foresee any long-term consequences for the Australian CRO industry?

At the onset of the pandemic, amidst so much uncertainty, Avance Clinical stood resolute as a company to find solutions to ensure business continuity such that no staff member would lose their job and we achieved this. As the pandemic progressed we embraced the changed world we were forced to operate in and moved quickly to adapt the way we approached our operational functions and also business development and marketing activities. During the crisis, we opted to look for new opportunities and different ways to support our clients and proceeded to launch new services and solutions such as our eClinical technology platform, Clinic Ready service and adopted a strong digital marketing program.

As a consequence of the COVID-19 crisis Australia has reinforced its standing as a world-class destination for early phase clinical development through its stable health system, streamlined regulatory environment and ability to maintain trial continuity. BS

Ayesha Siddiqui

"We plan to launch our prevention and early detection service in India"

« **Sigal Atzmon,** Founder and CEO, Medix Global, UK

London headquartered Medix Global, a provider of innovative, high quality, medical management solutions, is gradually expanding its business in Asia. With its recent entry into India, the company is geared to provide access of its global healthcare services to Indian customers. It has strong credentials for providing customers with fast-tracked and personalized medical solutions, from the right diagnosis to optimized treatment pathways. BioSpectrum Asia spoke to Sigal Atzmon, Founder and CEO, Medix Global, London, UK to find out more about the company's growth plans in Asia.
Edited excerpts:

What are the major offerings at Medix Global for the APAC region?

Medix Global is a leading provider of innovative healthcare management solutions and APAC has been a significant focus of the group in recent years. Rather than focus on expansion in North America and particularly the US, we have decided to deploy an Asia First strategy and have made significant investment and expansion since we first set up our first office in Hong Kong in 2013. Today, our footprint in APAC includes offices in Hong Kong, Shanghai, Singapore, Jakarta, Kuala Lumpur, Bangkok, Melbourne and most recently in Mumbai as well in addition to our offices in London and Tel Aviv. Our service offerings vary slightly depending on the market, but our range of services includes: personal medical case management; disease prevention management services; medical concierge & medical tourism, digital health & AI driven solutions; services for high mobility employees; home care, clinical strategy and medical governance services. It is important to clarify that Medix does not provide any form of treatment and does not replace the customer's treating physician but rather offers value added personalised medical management solutions that empower patients and ensure they are receiving access and implementation of quality care no matter where they live. We pride ourselves in servicing customers in over 90 countries.

How has the pandemic impacted the healthcare services in APAC countries?

In the early days of the pandemic, when it started to spread and impact additional countries, we have seen that certain patients and also providers started to cancel or postpone check-ups, tests and elective procedures. Patients were more concerned with visiting a clinic or a hospital than managing their chronic condition and care was being delayed, leading to worse outcomes on the short & long term. But the most significant impact that the pandemic has had on the healthcare landscape is an understanding from regulators, patients, providers and payers both government and private insurers, that there is a strong and immediate need for rapid digitalisation and a fundamental change in the way we consume and provide healthcare services. At Medix, we have been providing remote and digitally enhanced services for many years and during the pandemic, we have seen an unprecedented increase in demand and need from our customers who were seeking support and guidance from the comfort and safety of their home.

How is the company planning its expansion in India? What challenges are you facing with the Indian healthcare system?

We see India as an important and strategic market for us and have a structured roadmap of expansion from both a geographic and services portfolio perspective. We have established our first office in Mumbai in June of this year and are looking forward to working with partners and different stakeholders in the eco-system. We are closely following the recent announcements and plans from both a federal and state level in India focusing on digitalisation of the healthcare sector in India which is very much aligned with our service offering and activities.

How do you foresee the trend of personalised medical case management in India?

We see significant opportunity for personal medical case management in India and over the years, we have had many customers from India who we have provided service to from our office in London and we have seen significant demand and need for our services. In today's medical world, patients dealing with severe medical conditions, face an abundance of options treatments and decision points and simply do not have the tools or knowledge to make the right decision. Further, there is no single solution for a condition or ailment and every patient needs to be seen as a unique individual, taking all of their personal information, family history, genetic information, environmental factors, etc. into account when reviewing their case and through personalised medicine and the Medix personal medical case management service, we apply an holistic and multidisciplinary approach and ensure that a tailored action plan is being implemented. Across India, there are variations and inequalities of care, and access to both quality information and services may be a challenge. In our perspective, it doesn't matter if you are based in Kolkata, Mumbai, Chandigarh or Jaipur, every patient deserves to have personalised and holistic care, with access to the expertise from the best specialists across India and/or globally. It is important that Medix does not provide any form of treatment, nor replace the patient's treating physician but rather provides support and information to empower the patient to make informed decisions and receive access to the best care possible.

Which country in Asia could be the leader of digital and personalised medicine? Why?

Different countries across Asia have different approaches when it comes to the implementation and infrastructure that will enable digitalisation and personalisation of medical care. Singapore is a good example where the government and other stakeholders in the industry have created a sandbox programme to experience new digital health initiatives and given the Singaporean landscape which includes a solid combination of strong IT infrastructure, a robust public and private healthcare system, access to digital medical records under the National Electronic Health Record (NEHR) framework. While Singapore may be a good place to develop and test different solutions as a POC, the real opportunity is to scale them into markets like India, Indonesia, Thailand and others where both the need and market opportunities are significantly greater.

How are you leveraging digitisation across your service offerings?

At Medix, we see digitalisation as a fundamental component of our service offerings as all of our services are delivered remotely by design. By introducing additional digital functionalities and data driven solutions, we are able to offer a more flexible, accessible and enhanced customer experience that enables even greater personalisation. Further, digital tools are also a very good way to increase patient adherence and compliance while enabling remote monitoring of the patient's progress.

Are you planning to launch any new service or solution in the future?

One service that we plan on launching in India and has been active in other markets is the Medix' prevention and early detection service which focuses personalised assessment and tools to manage one's risk to develop and/or early detect and prevent cancer, cardiovascular, stroke and diabetes. With the prevalence of diabetes and cardiovascular conditions in India, often referred to as the diabetes capital of the world, we see significant potential for this service which will provide tangible and actionable added value to both individuals and communities.

What are your major plans for 2021?

The pandemic has created even further demand for digital health solutions and for Medix services in particular. Specifically, for India, we see 2021 as a very important year for us and are looking forward to setting up additional offices in India and launching additional digital health services specifically focused on the Indian market. We see services that focus on prevention as a major opportunity. BS

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John Davison steps in as Vice-Chairman at Hello Health Group

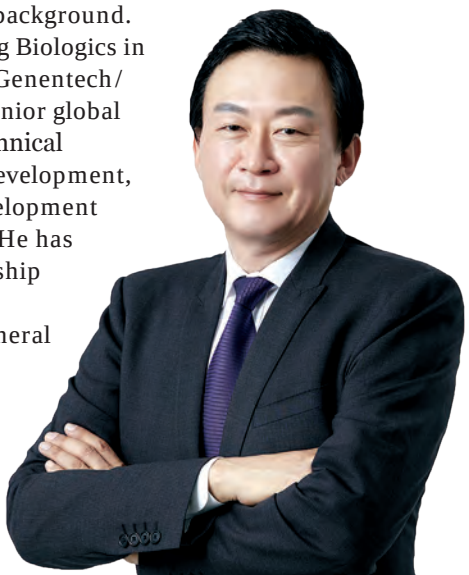
Singapore based Hello Health Group has announced the appointment of John Davison as Vice-Chairman. Davison, a graduate of Cambridge University and Harvard Business School, has had an illustrious 30-year career spanning all six continents of the world, mainly in the emerging markets of Asia, Middle East, Africa & Latin America. He is the recently retired Chief Executive Officer (CEO) of Zuellig Pharma. He led a major turnaround over the past 6 years, re-energising the core distribution business, creating two new fast-growth divisions and driving the full digital transformation of the company. Prior to this, he orchestrated turnarounds and delivered transformational growth in leading consumer products companies Danone (Dairy), Royal Numico (Infant/Clinical Nutrition) and Diageo (Drinks). He also enjoyed successful stints at B2B supply chain technology startup eSkye Solutions, leading management consulting firm McKinsey and top European business school INSEAD.

CANbridge Pharma appoints Justin Lu as GM of China

CANbridge Pharmaceuticals Inc. has appointed Justin Lu to the position of General Manager (GM) of China, responsible for setting up and operating commercial operations in China. Lu will be based in Shanghai. Lu comes to CANbridge with an impressive pharmaceutical industry track record. Immediately prior to this position, he was Head of Hemophilia and Rare Disease at Takeda Pharmaceutical China. Before then, he was at Celgene Pharmaceutical, in Shanghai, where he held the position of Associate Marketing Manager, and led the taskforce that set up the launch of Revlimid. Prior to that, he was Senior Regional Sales Manager at Bayer Healthcare, in Shanghai, where he worked in specialty healthcare and was responsible for Nexavar in Eastern China. Earlier, he was the Senior Regional Sales Manager at Bayer Healthcare and Senior Regional Sales Manager at Beijing Novartis Pharma. Lu started his career at Eli Lilly, Asia, where he was a Medical Specialist in oncology.

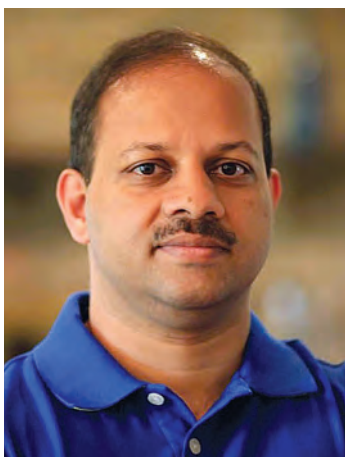
Samsung Biologics names John Rim as President & CEO

South Korean firm Samsung Biologics has announced John Rim as its President and Chief Executive Officer (CEO). Prior to being appointed CEO, Rim served as Executive Vice President at Samsung Biologics for the past three years and was a key senior leadership contributor in driving the company's success through a strong focus on client satisfaction and global business acumen. He was also instrumental in rapidly expanding the manufacturing portfolio across Samsung Biologics and for the continuous operational excellence in Plant 3, the world's largest manufacturing capacity at a single site. As CEO, he will continue to serve on the company's board as an inside director offering his in-depth industry experience and global background. Before joining Samsung Biologics in 2018, Rim worked for Genentech/ Roche in a variety of senior global leadership roles in Technical Operations, Product Development, and Research and Development in the US and Europe. He has also held senior leadership roles with Astellas Pharmaceuticals in General Management, Sales & Marketing, Technical Operations, Customer Service, Business Development, and Strategic Planning.



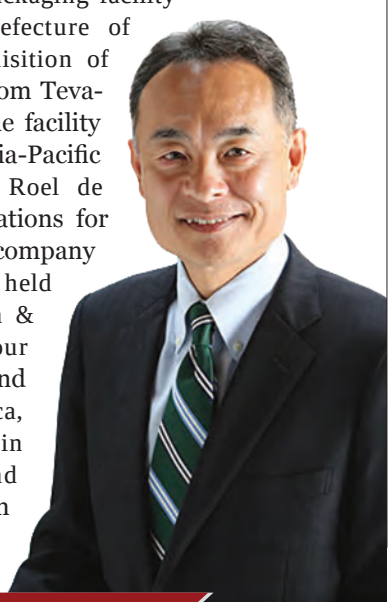
Agilent honours biopharma scientist from India

Agilent Technologies has honoured Prof. Anurag Rathore, a scientist at the Indian Institute of Technology Delhi (IIT-D), with an Agilent Thought Leader Award, for his contributions to the field of biopharmaceutical research and his work with advanced methods for molecular characterisation of biosimilars. He is the first researcher in India to receive this award. The work at Prof. Rathore's lab focuses on the best practices towards molecular characterisation of monoclonal antibody-based biosimilars. Monoclonal antibodies (mAbs) include an important and growing group of biopharmaceutical drugs used to treat several diseases and conditions. Their activity, stability, and other physicochemical and toxicological characteristics are heavily influenced by the level and position of their amino acid modifications. He is an active member of the Parenteral Drug Association (PDA) and American Chemical Society (ACS) and have authored more than 400 publications and presentations in these areas. He obtained his PhD from Yale University, US, in 1998 and then worked in the Process Development groups at Pharmacia Corporation and Amgen before joining the Department of Chemical Engineering, IIT-D in 2009.



Nakaya Matsumaru to lead Catalent's new facility in Japan

Catalent has announced the appointment of Nakaya "Nick" Matsumaru as General Manager of its new clinical packaging facility in Minakuchi, located in the Shiga prefecture of Japan. Catalent had completed the acquisition of the 60,000-square-foot facility in Shiga from Teva-Takeda Pharmaceuticals in July 2020. The facility is the latest in Catalent's expanding Asia-Pacific clinical supplies network. Reporting to Roel de Nobel, Catalent's Vice President of Operations for Europe and Asia-Pacific, Nick joins the company from SymBio Pharmaceuticals, where he held the role of Senior Director Supply Chain & Quality Assurance. Prior to this, he spent four years in vice president, executive officer and head of operations posts with AstraZeneca, and seven years in Japan-based supply chain management with Johnson & Johnson and Janssen. He holds a bachelor's degree in sociology from Keio University in Tokyo.



Waters Corporation announces CFO transition

Waters Corporation has announced that Sherry Buck has stepped down as Chief Financial Officer (CFO), effective December 31, 2020, in order to pursue another opportunity at a privately held company. Upon her departure, Michael F Silveira, Vice President and Corporate Controller of Waters, will assume the role of interim Chief Financial Officer. Buck will work alongside Silveira in order to facilitate a smooth transition. Waters has been actively working with a leading search firm to identify a permanent CFO, and the process is advancing well with several strong internal and external candidates. Silveira joined Waters in 2004 as Assistant Corporate Controller. He was appointed Vice President & Corporate Controller in 2013, and, in 2018, gained increased responsibilities including oversight of treasury, tax and corporate financial planning and analysis. He is a Certified Public Accountant and has held several senior financial management positions with Astro-Med, Inc (nka AstroNova), Textron, Inc and KPMG. Silveira received a BS in Accounting from Providence College.

Australia undertakes clinical studies of needle-free vaccine patch

Researchers at the University of Sydney, Australia have been awarded $1.12 million in a funding via the Innovative Manufacturing CRC (IMCRC) to undertake independent clinical research studies to understand the potential of needle-free vaccine delivery for at-risk groups. This grant reflects matched funding from Commonwealth Government funded IMCRC and Vaxxas, an Australian biotechnology company. The two upcoming clinical studies are designed to evaluate the safety, feasibility, acceptability and usability of self-administration of Vaxxas' vaccine delivery technology using an inactive substance. They will focus on older adults and healthcare professionals, who are more likely to be impacted by pandemic influenza and SARS-COV-2. The device is a one square-centimetre of biocompatible polymer, smaller than a postage stamp, covered in thousands of micro-projections, which are invisible to the naked eye. These are coated with a vaccine formulation, with the goal of penetrating the protective outer layer of the skin to deliver the vaccine to cell layers immediately under the skin, rich in immune cells. The device is applied to the skin using a disposable applicator that contains the product. The vaccine technology is still under development and has not yet been approved for use.

Japan makes way to rapidly measure eye lens opacity

A team of scientists at Kyushu University in Japan has developed a new system through which objective measurement of the opacity and transmittance of the lens in the human eye may one day become a simple and rapid process routinely performed at eye clinics. As we age, the crystalline lenses in our eyes gradually become opaque, leading to a decrease in the light transmitted into the eye. However, no simple methods currently exist to simultaneously measure lens opacity also referred to as optical density, and spectral transmittance without first extracting the lens from the eye. Researchers now report that they have developed a new system that can measure both properties safely, easily, and rapidly without disturbing the eye. Developed in collaboration with researchers at the Singapore Eye Research Institute, the system can take measurements in about four seconds using only a light source, an imaging device, and computer for analysis. The system works by analyzing images formed by the reflection of different wavelengths of light at the interface between the lens and the gel-like vitreous humor inside the eye.

China develops novel microrobotic diagnostic system

The Chinese University of Hong Kong (CUHK) has recently developed a fully automated, low cost and rapid microrobotic diagnostic system with comparable sensitivity and specificity to clinical detection methods. The research team is now studying the application of this microrobotic system for multiple pathogens including the COVID-19. The team has developed the innovative microrobotic detection system integrating the novel fluorescent microrobots with an external magnetic actuation system to accurately detect specific pathogens in a short time. The microrobotic sensing probes are G. lucidum spores coated by a layer of iron oxide nanoparticles and functionalised with carbon dots. By analysing the changes in the fluorescence signal of the microrobots under green light excitation, the system can determine the presence of pathogen in patients' samples. In addition, the system uses an external magnetic field to remotely actuate the microrobots, speeding up the fluorescence quenching and thus shortening the detection time.

Korea discovers key indicators for Alzheimer's disease

Korean researchers at the Center for Cognition and Sociality, within the Institute for Basic Science (IBS) and Korea Institute of Science and Technology (KIST) have announced the discovery of key indicators for neurodegeneration in Alzheimer's disease (AD). Though AD is a common and fatal neurodegenerative brain disorder, most of AD treatments seem to not be making much headway to unravel the mystery of its cause. Many AD drugs have targeted the elimination of beta-amyloid (Aβ) or amyloid plaques, which block cell-to-cell signaling at synapses. But some AD patients continue to show neurodegeneration and cognitive decline even after the removal of the amyloid plaques. The research team has demonstrated that the severity of reactive astrocytes is a key indicator for the onset of AD, raising profound implications of the current theory of AD mechanism. In its toxin-receptor-based animal model, the research team fine-tuned astrocytic reactivity in vivo. They found that the mild reactive astrocytes can naturally reverse its reactivity, whereas severe reactive astrocytes can cause irreversible neurodegeneration, brain atrophy and cognitive deficits, all within 30 days. These results indicate that severe reactive astrocytes are sufficient for neurodegeneration.

India builds germicidal fabric technology for face masks

An innovative germicidal fabric technology developed at the Institute for Stem Cell Science and Regenerative Medicine in India has been used to coat fabric that has been launched as face masks. The research group intensified the development of the germicidal coating in April of 2020, as part of the national effort towards the current COVID-19 pandemic. This technology has been shown to inactivate viruses and bacteria upon contact. In the laboratory, the G-fab technology achieved a 99.99 per cent reduction rate against a wide range of enveloped viruses, including SARS-CoV-2, the causative agent of COVID-19, the influenza virus (H1N1 flu), as well as both gram-negative and gram-positive bacteria. A non-exclusive license to Color Threads, a company based in Tirupur, and an incubate at the Centre for Cellular and Molecular Platforms (C-CAMP), has enabled the rapid transfer of this technology, and the development of a germicidal fabric called, G-fab 99+ antiviral.

Singapore designs foldable tent for safe dental care

Dental treatments are performed at close proximity to the mouths and noses of the patients, and the procedures are often related to the generation of aerosols as well as handling of oral fluids and blood. This puts dentists at a high risk of exposure to COVID-19, and other critical infectious diseases. Now, researchers from the National University of Singapore (NUS) have invented a portable tent-like shield to prevent the spread of saliva and aerosols generated during dental procedures. The Dental Droplet and Aerosol Reducing Tent (Dental DART) can be placed around the patient's head to serve as a barrier to protect dentists, nurses and patients from direct and indirect exposure to infectious diseases such COVID-19. In addition, the Dental DART limits the spread of aerosols onto environmental surfaces, decreasing pathogen availability and potential cross-contamination. This device is an adaptation of DART, an earlier NUS innovation that protects healthcare workers when they perform procedures that generate droplets and aerosols, such as intubation and extubation.

Wipro GE Healthcare partners with IIT Madras

Wipro GE Healthcare (WGE) has announced a fellowship partnership with the Indian Institute of Technology Madras (IIT-M), Chennai, to provide increased opportunities for research scholars to build and further improve the innovation ecosystem. Under this programme, Wipro GE Healthcare will also provide financial aid and industrial expertise to chosen Masters (MS) in research scholars at IIT-M. Wipro GE Healthcare aims to develop an innovation mindset in students with engineering skills by providing industrial exposure in healthcare domain and other technology areas of the company through close collaboration with technical experts. Research Scholars of this MS programme shall also be offered nine-month long internship opportunity at WGE. The partnership will further evangelise the concept of local innovation in affordable medical technology and other related areas through activities such as student hackathons, guest lectures, product tear-downs and lecture demonstrations.

Monash University receives over $44M research funding

Monash University has been awarded more than $44 million in funding for 49 research projects in the latest round of National Health and Medical Research Council (NHMRC) Ideas Grants, the most of any Australian university. The major Monash projects that received funding include $1 million for soft wearable patches for stillbirth prevention where the project aims to directly tackle this unmet clinical challenge by revolutionising the way fetal movements are evaluated; $1.1 million for new therapeutics for neurodegenerative disorders like Alzheimer's disease where the project aims to decipher the best way to inhibit glutamate receptors as a new therapeutic strategy to optimally treat symptoms as well as slow down brain degeneration. Likewise, $1.3 million has been granted for developing new therapies for autoimmune disease; and $816,000 for a sutureless cannula for rapid implantation of mechanical heart pumps for which the team will use engineering software usually used for designing rockets to optimise blood flow as well as tissue engineering to better integrate the devices within patients.

Varian inks MoU with Yonsei University for cancer research

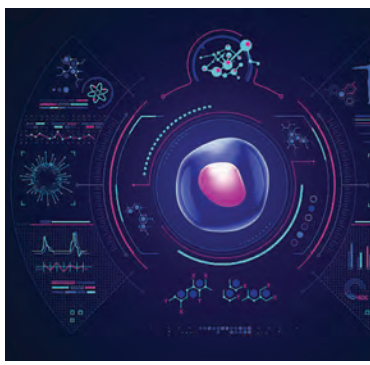
US based Varian has announced that it has entered into a three-year agreement with Yonsei Cancer Center, Yonsei University Health System in South Korea to collaborate on research and development projects in the field of radiation therapy and oncology. Yonsei Cancer Center is Korea's first cancer hospital established in 1969, and it is one of the leading cancer centers in the world. The signing of this MoU with Varian is a step forward in the fight against cancer. Yonsei University is particularly interested in working with Varian on artificial intelligence (AI) solutions, which have shown to improve early detection of cancer by more accurately identifying at-risk patients, improving treatment planning, and predicting patient outcomes.

Medit picks Straumann as distributor for intraoral scanners

Medit and Straumann have entered a global distribution partnership for intraoral scanners effective as of January 1, 2021. This agreement leverages the existing partnership of the two companies for dental lab scanners. The distribution agreement includes South Korean firm Medit's highly popular intraoral scanner, the i500. The scanner delivers excellent performance for a wide range of applications and last month the company had released a software update, further enhancing the i500's capabilities. Straumann Group is a global leader in tooth replacement and orthodontic solutions that develops, manufactures, and supplies innovative global brands for replacement, corrective, and digital dentistry. With Medit's strong presence as an open system provider, and Straumann Group's large digital ecosystem, the partnership is based on powerful synergies and the common goal of driving the adoption of digital dentistry. With the distribution agreement, the Medit i500 will be integrated in Straumann's prosthetic and clear aligner workflow solutions, such as ClearCorrect. The alliance will also include the workflow between Medit's open collaboration platform, Medit Link, and Straumann Group's open software platforms for surgical planning, prosthetics, and treatment services.

RoosterBio inks agreement with Sartorius Korea Biotech

US based RoosterBio Inc. has entered into an exclusive agency agreement with Sartorius Korea Biotech, a subsidiary of the Sartorius Group, a leading international partner of the biopharmaceutical and life science research sectors. This strategic partnership combines Sartorius' proven expertise in providing high-caliber bioprocess testing, technical and customer services to the local South Korean market, as well as its global reach, and RoosterBio's advanced platform of RUO and cGMP-grade human mesenchymal stem/stromal cell (hMSC) working cell banks, optimized paired media, and hMSC bioprocess systems. This winning combination sets the stage for accelerating the development of new, effective medical treatments and expands RoosterBio's footprint into Asia, especially in South Korea. Under the terms of the agreement, Sartorius Korea Biotech will engage with its customers as an exclusive agent for RoosterBio to facilitate sales operations and increase the market potential for RoosterBio products on an exclusive basis in South Korea.



Olympus expands respiratory portfolio with new acquisition

Japan's Olympus Corporation has announced that it has entered into an agreement to acquire Veran Medical Technologies, Inc. (VMT), a leading provider of advanced medical devices specializing in interventional pulmonology based in the US, for up to $340 million. The acquisition will be implemented through Olympus subsidiary Olympus Corporation of the Americas (OCA), and will be the latest in a series of strategic acquisitions designed to strengthen Olympus' position as a leading global medical device company. As part of Olympus' corporate strategy, the company vowed to focus and scale its therapeutic solutions division. To accelerate the process and provide greater agility, Olympus made OCA the company's therapeutic division headquarters, recognizing the significant growth opportunities in North America. The company also identified three core medical fields to prioritize - gastroenterological endotherapy devices, urological devices, and respiratory devices. The VMT acquisition is centered on respiratory devices and will position Olympus as a leader in this field. Already a leader in bronchoscopy systems, Olympus' endoscope technologies will combine perfectly with VMT's navigation products to develop solutions for improved diagnosis of peripheral lung cancer.

Thermo Fisher launches high-precision isotope ratio MS system

A new inductively coupled plasma mass spectrometry (ICP-MS) instrument has been designed to enable scientists working in earth sciences, nuclear safeguards and biomedical research to conduct reliable, high-precision isotope ratio analysis across a wide range of applications, without compromising sensitivity, stability or ease-of-use. The Thermo Fisher Scientific Neoma Multicollector ICP-MS (MC-ICP-MS) system combines innovative features from the field-proven technology of existing variable multi-collector instrumentation. A new level of automation with the integration of peripherals makes access to reliable, high-precision isotope ratio data easier and more efficient, leading to enhanced research productivity and novel applications. The new instrument offers the flexibility to quickly change between a broad range of isotopic systems, which is a key consideration for productivity in multi-user facilities.

HiMedia gets multiple nods for COVID-19 products

HiGenoMB, the molecular biology division of Indian firm HiMedia Laboratories has received the CE/IVD approval and a nod from the Indian Council of Medical Research (ICMR) for its COVID-19 range of products. Hi-PCR Coronavirus (COVID-19) Multiplex Probe PCR Kit is capable of detecting 4 different genes- N gene, E gene, RdRp gene and RPPH1 (Endogenous Internal Control) in the same assay. On the other hand, HiPurA Viral RNA Purification Kit has been the front runner amongst the COVID products for HiGenoMB. HiPurA Viral RNA Purification Kit – Magnetic Bead Based product was approved from ICMR-approved site National Institute of Virology in Pune along with its use with HiMedia's Automated DNA/RNA Instrument- InstaNX Mag96. HiMedia Labs has also successfully launched the InstaNX Mag Series of Automated DNA/RNA Extraction Platforms viz InstaNX Mag32 capable of processing 32 samples & InstaNX Mag96, the high throughput version capable of processing 96 samples.

Agilent receives approval for postnatal assay in Japan

Agilent Technologies has obtained clearance from the Ministry of Health, Labour and Welfare (MHLW) in Japan for the GenetiSure Dx Postnatal Assay, a microarray-based assay for diagnostic use. This assay enables clinical geneticists to detect genetic aberrations associated with developmental delay, intellectual disabilities, congenital anomalies, and unexplained dysmorphic features. The company also announced that it has registered its microarray scanner, SureScan Dx Scanner, as a Class I medical device in Japan, intended for use with the assay. Based on Agilent's proprietary microarray for comparative genomic hybridization (CGH), the GenetiSure Dx Postnatal Assay is a qualitative assay for the postnatal diagnosis of copy-number alterations (CNVs) and copy-neutral loss of heterozygosity (cnLOH) from genomic DNA (gDNA), obtained from the peripheral whole blood in patients who have been referred for chromosomal testing based on clinical presentation. The GenetiSure Dx Postnatal Assay is the result of a clinical validation utilizing 900 samples and brings CGH technology into a diagnostic setting in Japan. Available since 2017 as an in vitro diagnostic assay (IVD) in Europe and the United States, Japanese clinical geneticists can now have access to this assay to help identify a definitive genetic diagnosis for their patients.

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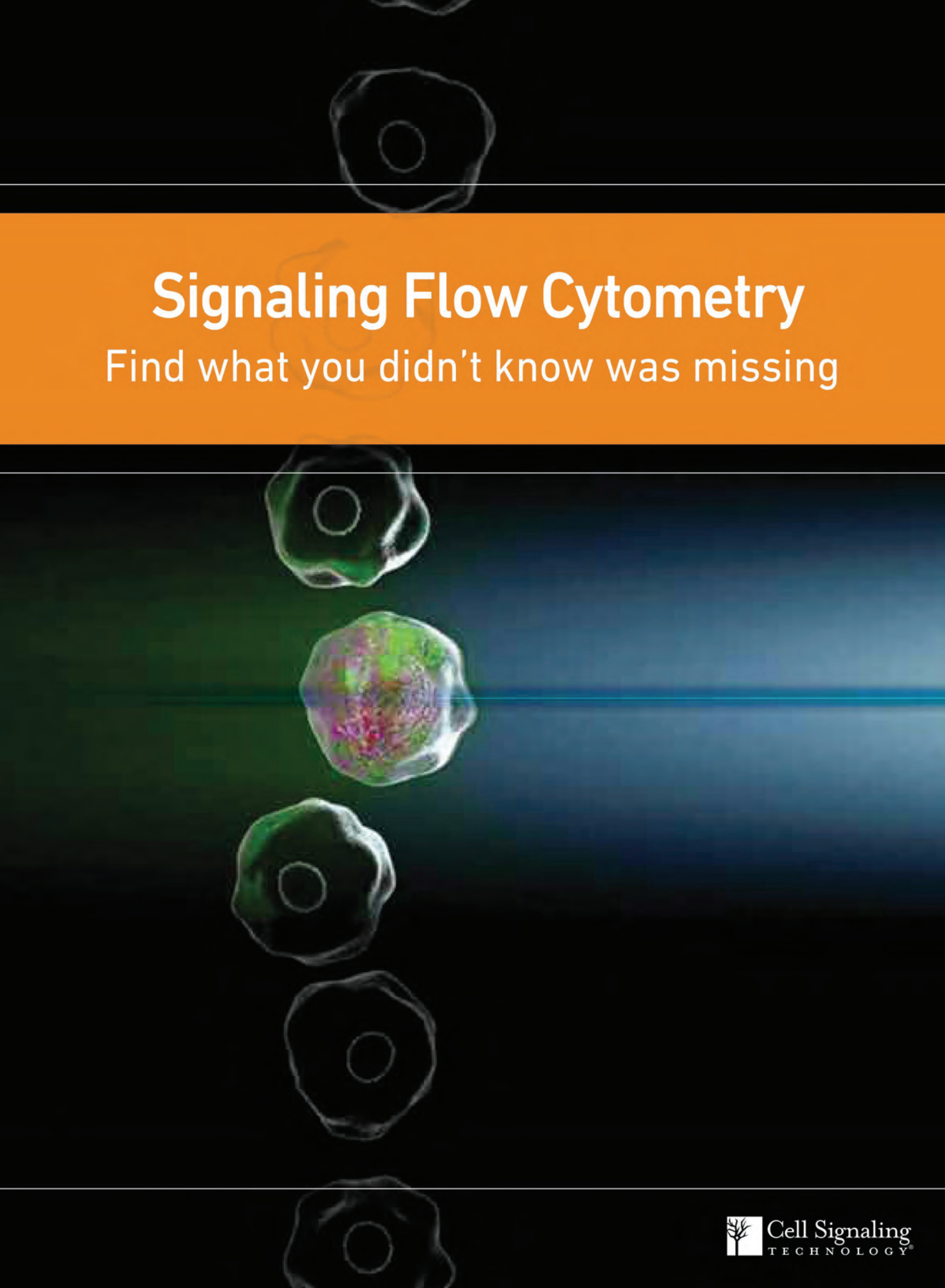

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