COVID-19: WORKING TOGETHER TO FIND TREATMENTS AND VACCINES

The innovative pharmaceutical industry is working around the clock to find solutions to treat those infected by the virus and to prevent it from spreading.

The following are but a few examples of how our member companies are engaged in combatting COVID-19 through research into treatments and vaccines.

Updated December 18, 2020

ABBVIE has announced plans to evaluate its HIV medicine as COVID-19 treatment and has entered into partnerships with health authorities and institutions in various countries to investigate the efficacy and antiviral activity of the medication. Abbvie has also allied with industry partners and the Innovative Medicines Initiative to research and identify targeted medicines against COVID-19.

AMGEN and Adaptive Biotechnologies announced a collaboration aimed at helping address the COVID-19 pandemic. The companies will combine expertise to discover and develop fully human neutralizing antibodies targeting SARS-CoV-2 to potentially prevent or treat COVID-19. The mutually exclusive collaboration brings together Adaptive's proprietary immune medicine platform for the identification of virus-neutralizing antibodies with Amgen's expertise in immunology and novel antibody therapy development. Given the rapidly rising incidence of COVID-19 around the world, the companies will begin work. Neutralizing antibodies defend healthy cells by interfering with the biological function of an invading virus. These antibodies may be used therapeutically to treat someone currently fighting the disease and can be given to people who have heightened risk of exposure to SARS-CoV-2, such as healthcare workers.

The research team based at **AMGEN** British Columbia is actively engaged in anti-COVID 19 therapeutic antibody discovery efforts. They are focused on using antibody-producing B cells derived from patients that have mounted an immune response and recovered from the COVID-19 disease. This research leverages antibody discovery technologies developed by scientists at Amgen British Columbia and their over 20 years of experience in the field of discovery therapeutic antibodies, in collaboration with Amgen's subsidiary deCODE Genetics, Amgen's US-based research sites and external partners at Adaptive Bio.

Biopharmaceutical companies are collaborating to accelerate the development of potential treatments for COVID-19. Recently, **AMGEN** and **LILLY** announced a global partnership to increase manufacturing capacity of the neutralizing antibodies Lilly is developing, one of which was first isolated by Vancouver-based AbCellera. Through this collaboration, Lilly and Amgen hope to have the ability to quickly scale up production for many millions of doses as early as 2021.

ASTRAZENECA is engaging with international health authorities and governments and has provided science and technology expertise to the World Health Organization and the European Federation of Pharmaceutical Industries and Associations. AstraZeneca's Research and Development (R&D) teams have also been working expeditiously to identify monoclonal antibodies to progress towards clinical trial evaluation as a treatment to prevent COVID-19. More than 50 virology, immunology, respiratory, and protein engineering experts across research, clinical, regulatory, and manufacturing are placing the highest priority on developing a treatment to minimize the global impact of the disease.

ASTRAZENECA has initiated two global clinical studies, one of which is being led by the Canadian Global Clinical Hub, to evaluate two of their existing medicines to help alleviate the exaggerated immune response that can result in pneumonia, respiratory failure and death of patients hospitalized with COVID-19 infections. The company is rapidly enrolling patients from a few of the most impacted countries.

ASTRAZENECA recently announced a landmark agreement to collaborate with the University of Oxford on the development and distribution of the University's potential recombinant adenovirus vaccine (AZD1222) aimed at preventing COVID-19 infection. In total, the company has confirmed agreements to supply 1.7 billion doses and is working rapidly to put in place parallel global supply chain agreements that will enable the company to reach all areas of the world at the same time and at no profit.

In Canada, **ASTRAZENECA** recently announced an agreement with the Government of Canada to supply 20 million doses of AZD1222, should clinical trials prove to be successful and authorization be granted by Health Canada. Health Canada has also initiated a rolling review for AZD1222 – marking the beginning of Canada's first authorization review of a COVID-19 vaccine submission.

INNOVATIVE MEDICINES CANADA
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BAYER and the Population Health Research Institute (PHRI) plans to immediately launch a major clinical research program aimed at identifying potential COVID-19 treatments. The two studies will evaluate the safety and efficacy of different combination therapies including Bayer's chloroquine and interferon beta-1b. An outpatient study will evaluate the combination of chloroquine with azithromycin to see if this treatment can prevent deterioration leading to hospital admission, while a second study will evaluate the combination of chloroquine with azithromycin, as well as interferon beta-1b, to prevent admission to intensive care, mechanical ventilation and/or death to combat COVID-19. The goal is to assess the value of these and other therapies rapidly so that the results can inform practice as soon as possible. Bayer will make a financial commitment of $1.5-million (CAD) towards the studies and will supply study drugs to support the research. This adds to the $0.5-million (CAD) committed by the PHRI earlier this month which enabled development of the research program. PHRI plans to enroll 6,000 patients into the two studies from more than 60 contributing research sites across Ontario, Canada, and internationally.

BIOVECTRA is helping reduce the spread of COVID-19 by working with provincial and federal health authorities to support essential services with access to sanitizing agents, manufacturing critical raw materials for COVID-19 diagnostic testing kits, and collaborating with multiple Canadian biopharmaceutical companies and academia on COVID-19 therapeutic products.

BOEHRINGER INGELHEIM is supporting the development of therapies against COVID-19. The company is collaborating with the German Center for Infectious Research and taking part in a fast-track call from the European Union's Innovative Medicines Initiative to develop therapies and diagnostic tools for COVID-19. Their global research team is screening their entire molecule library with more than one million compounds to identify novel small molecules with activity against the virus. The same applies for already existing small molecule compounds from Boehringer Ingelheim's former antiviral research. In addition, Boehringer Ingelheim supports scientists worldwide with its open innovation portal opnMe.com, which offers six anti-viral compounds out of 43 high quality pharmacological tool compounds at no cost for testing of research hypotheses.

BOEHRINGER INGELHEIM is also part of a group of life sciences companies collaborating to accelerate the development, manufacture and delivery of vaccines, diagnostics, and treatments for COVID-19 in response to the pandemic. This work is being done alongside the Bill and Melinda Gates Foundation.

GILEAD has applied decades of expertise in the development of antiviral therapeutics and proactively invested to rapidly develop, evaluate and scale up manufacturing for Veklury® (remdesivir) to address needs today and in the future. Veklury (remdesivir) is the first and only antiviral treatment with an established safety and tolerability profile with a proven efficacy in patients hospitalized with COVID-19.

On July 27, 2020, Health Canada issued a marketing authorization with conditions (Notice of Compliance with conditions, NOC/c) for Veklury (remdesivir). Under this conditional authorization, Veklury (remedesivir) is indicated for the treatment of COVID-19 in adults and adolescents aged 12 years and older and weighing at least 40 kg, with pneumonia requiring supplemental oxygen. Veklury (remdesivir) is the first antiviral treatment for COVID-19 authorized in Canada. **GILEAD** is committed to increasing supply and further researching Veklury (remdesivir) in combination therapies and for outpatient populations to enhance patient outcomes.

GLAXOSMITHKLINE (GSK) is entering into the new collaborative research effort, the COVID-19 Therapeutics Accelerator. The aim of the Accelerator is to bring pharmaceutical companies and expert academic institutions into coordinated research programs, with the aim of bringing the most promising molecules forward that could be used to treat cases of COVID-19. GSK will contribute by making available compounds from its libraries for screening for activity against COVID-19. In addition, GSK is evaluating its marketed pharmaceutical products and medicines in development to determine if any could be used beyond their current indications in response to the pandemic. The company also expanded their vaccine development collaborations and is now working with five partner companies and research groups across the world, including in the USA and China.

GSK and **SANOFI** have joined forces in an unprecedented collaboration to develop an adjuvanted vaccine to fight COVID-19, using innovative technology from both companies. **GSK** will contribute its proven pandemic adjuvant technology. The use of an adjuvant can be of particular importance in a pandemic situation since it may reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced and therefore contributing to protect more people. The companies plan to initiate phase I clinical trials in the second half of 2020 and, subject to regulatory considerations, aim to complete the development required for availability by the second half of 2021.

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In July 2020, **GSK** and **MEDICAGO** announced a collaboration to develop and evaluate a COVID-19 candidate vaccine combining Medicago's recombinant Coronavirus Virus-Like Particles with GSK's pandemic adjuvant system. Subject to successful clinical development and regulatory considerations, the companies aim to complete development and manufacture approximately 100 million doses by the end of 2021. By the end of 2023, a large-scale facility under construction in Quebec City is expected to deliver up to 1 billion doses annually. The manufacturing platform has been used to produce a seasonal VLP flu vaccine and the license application is under review with Canadian authorities.

JOHNSON & JOHNSON (J&J) announced the selection of a lead COVID-19 vaccine candidate from constructs it has been working on, through its **JANSSEN** Pharmaceutical Companies, since January 2020. J&J expects to initiate human clinical studies of its lead vaccine candidate at the latest by September 2020 and anticipates the first batches of a COVID-19 vaccine could be available for emergency use authorization in early 2021, a substantially accelerated timeframe in comparison to the typical vaccine development process. Through a landmark new partnership, BARDA, which is part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services, and Johnson & Johnson, through its Janssen Pharmaceutical Companies, together have committed more than $1-billion of investment to co-fund vaccine research, development, and clinical testing. J&J will use its validated vaccine platform and is allocating resources to focus on these efforts. As part of its commitment, J&J is also expanding the Company's global manufacturing capacity, including through the establishment of new U.S. vaccine manufacturing capabilities and scaling up capacity in other countries. In addition to Janssen's efforts to develop a vaccine candidate, it is working closely with global partners to screen its library of antiviral molecules to accelerate the discovery of potential COVID-19 treatments and provide relief for people around the world.

LILLY entered into an agreement with AbCellera to co-develop antibody products for the treatment and prevention of COVID-19. The collaboration will leverage AbCellera's rapid pandemic response platform, developed under the DARPA Pandemic Prevention Platform (P3) Program, along with Lilly's global capabilities for rapid development, manufacturing and distribution of therapeutic antibodies.

LILLY has entered into an agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to study baricitinib, a treatment for adults with moderately to severely active rheumatoid arthritis, as an arm in NIAID's Adaptive COVID-19 Treatment Trial. The study will investigate the efficacy and safety of baricitinib as a potential treatment for hospitalized patients diagnosed with COVID-19, beginning this month in the U.S. with a planned expansion to additional sites including Europe and Asia. Results are expected within the next two months. Lilly also announced that it will advance LY3127804, an investigational selective monoclonal antibody against Angiopoietin 2 (Ang2), to Phase 2 testing in pneumonia patients hospitalized with COVID-19 who are at a higher risk of progressing to acute respiratory distress syndrome (ARDS). Ang2 is known to be elevated in ARDS patients and Lilly will test whether inhibiting the effects of Ang2 with a monoclonal antibody can reduce the progression to ARDS or the need for mechanical ventilation in COVID-19 patients. This trial will begin later this month at several U.S. centers.

A Phase 2 clinical trial will evaluate the safety and efficacy of potential new therapeutics for COVID-19, with the first therapeutic to be tested being LY-CoV555, an investigational monoclonal antibody made by **LILLY**. LY-CoV555 emerged from Lilly's collaboration with AbCellera Biologics. Researchers sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, are working with clinical sites to identify potential patient volunteers currently infected with SARS-CoV-2, the virus which causes COVID-19, who have mild to moderate disease not requiring hospitalization. They will be invited to take an experimental therapy or a placebo as part of a rigorously designed randomized clinical trial. The trial, which is known as ACTIV-2, also may investigate other experimental therapeutics later under the same trial protocol.

The ACTIV-3 study of the National Institute of Allergy and Infectious Diseases (NIAID) will study the investigational monoclonal antibody LY-CoV555, developed and manufactured by **LILLY** in partnership with AbCellera, for their ability to reduce the severity and/or duration of illness among hospitalized patients. Antibodies are infection-fighting proteins made by the immune system that can bind to the surface of viruses and prevent them from infecting cells. Synthetic versions of antibodies can be reproduced in a laboratory. These manufactured antibodies are known as monoclonal antibodies.

LILLY announced the initiation of BLAZE-2, a Phase 3 trial studying LY-CoV555 for the prevention of SARS-CoV-2 infection and COVID-19 in residents and staff at long-term care facilities in the U.S. LY-CoV555, the lead antibody from Lilly's collaboration with AbCellera, is a neutralizing antibody against SARS-CoV-2, the virus that causes COVID-19. The rapid spread of SARS-CoV-2 among residents of long-term care facilities combined with the higher mortality rate for the elderly creates the urgent need for therapies to prevent COVID-19 in this vulnerable population.

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medicago

MEDICAGO announced the production of a viable vaccine candidate for COVID-19 which is undergoing preclinical testing for safety and efficacy. Funding received from the Government of Canada's COVID-19 Response Fund for coronavirus research and the Government of Quebec, as announced on March 23, will allow Medicago to rapidly move forward on clinical trials to assess the safety and efficacy of the vaccine candidate and then quickly shift to scaling up production for pandemic response.

In July 2020, **MEDICAGO** and **GSK** announced a collaboration to develop and evaluate a COVID-19 candidate vaccine combining Medicago's recombinant Coronavirus Virus-Like Particles with GSK's pandemic adjuvant system. Subject to successful clinical development and regulatory considerations, the companies aim to complete development and manufacture approximately 100 million doses by the end of 2021. By the end of 2023, a large-scale facility under construction in Quebec City is expected to deliver up to 1 billion doses annually. The manufacturing platform has been used to produce a seasonal VLP flu vaccine and the license application is under review with Canadian authorities.

MEDICAGO and Dynavax Technologies Corporation, a biopharmaceutical company focused on developing and commercializing novel vaccines, announced their collaboration to investigate an adjuvanted vaccine candidate to protect against COVID-19. The collaboration is evaluating the combination of Medicago's Coronavirus Virus-Like Particle (CoVLP) with Dynavax's advanced adjuvant, CpG 1018™. Adding CpG 1018, the adjuvant contained in Dynavax's U.S. FDA-approved adult hepatitis B vaccine, is intended to enhance the immune response of Medicago's COVID-19 vaccine which may decrease the total amount of antigen needed per dose, providing more doses to help protect a greater number of people.

MERCK INVENTING FOR LIFE

In research, building on their enormous experience with antivirals and vaccines, **MERCK** has embarked upon a broad-based development program for antiviral and vaccine approaches for SARS-CoV-2. Merck has teams of scientists researching COVID-19 and assessing their available antiviral candidates and vaccine assets for potential to impact the pandemic. They are also engaged with a range of research organizations on collaborative efforts to accelerate the development of medicines and vaccines for COVID-19.

MERCK has announced that they are participating in a new research collaboration with the Institute for Systems Biology to investigate and define the molecular mechanisms of SARS-CoV-2 infection and COVID-19 and identify targets for medicines and vaccines, as well as the NIH-led Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV consortium). ACTIV is a partnership that aims to develop a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials and regulatory processes, and/or leveraging assets among all partners to rapidly respond to the COVID-19 and future pandemics.

MERCK knows from our experience in HIV and Ebola that science and collaboration are both essential to develop medicines and vaccines in a global public health emergency like the one we are facing now. They also know that the path to a new medicine or vaccine is not fast, nor is it easy. As was the case with many diseases, they are optimistic that our industry's efforts will create new tools to combat this coronavirus. This pandemic underscores the need for their company and the industry to continue to invest in research for the greatest health threats.

More recently, **MERCK** announced two COVID-19 vaccine development efforts—a collaboration with IAVI and acquiring Themis Bioscience, a company focused on vaccines and immune-modulation therapies for infectious diseases, including COVID-19. Merck has also announced a research collaboration with Ridgeback Biotherapeutics to develop a novel antiviral candidate.

MERCK is also pleased to work with the Bill & Melinda Gates Foundation and its industry peers during this challenging period. As part of Merck's commitment of expertise and assets, the company will be actively participating in the Therapeutics, Vaccines Manufacturing, and Clinical & Regulatory workstreams.

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NOVARTIS is joining collaborative R&D efforts with the Bill & Melinda Gates Foundation, Wellcome, and Mastercard-supported COVID-19 Therapeutics Accelerator and a partnership with the Innovative Medicines Initiative (IMI). Novartis has also announced plans to initiate a Phase III clinical trial in collaboration with Incyte to evaluate the use of Jakavi for treatment of a type of severe immune overreaction called cytokine storm that can lead to life-threatening respiratory complications in patients with COVID-19. The proposed trial will assess Jakavi in patients with severe COVID-19 pneumonia as a result of SARS-CoV-2 infection. Given the rapid spread of the pandemic, and as plans for the study are finalized, Novartis also has set up an international compassionate use program for eligible patients, subject to local regulations, while ensuring there is enough Jakavi to go around for approved indications.

PFIZER has outlined a five-point plan calling on the biopharmaceutical industry to collaborate to combat COVID-19. The plan is intended to help scientists bring forward therapies and vaccines to help protect humankind from the pandemic and prepare the industry to respond to future global health crises. As part of that plan, Pfizer and BioNTech are currently carrying out a Phase 2b/3 clinical trial for BioNTech's mRNA-based vaccine candidate BNT162b2, which is being developed to help prevent COVID-19 infection. The trial is operating in more than 120 sites around the world and will enroll 44,000 individuals including those as young as the age of 12-years-old. On August 5, Pfizer and BioNTech announced an agreement with the Canadian government to supply their mRNA-based vaccine candidate against SARS-CoV-2, subject to clinical success and regulatory approval, over the course of 2021. Pfizer Canada is currently working in parallel with Canadian stakeholders to define how this vaccine can be brought to the Canadian population.

On October 9, **PFIZER CANADA** and BioNTech SE announced the initiation of a rolling submission under Health Canada's Interim Order Regulatory pathway for BNT162b2, the lead candidate from the companies' vaccine development program against COVID-19.

Recently, alongside leading biopharmaceutical companies who are also conducting vaccine research and development, **PFIZER** announced a historic pledge that outlines a united commitment to uphold the integrity of the scientific process as we work towards developing a potential vaccine for COVID-19 that puts patient safety and public health as top priorities.

Additionally, **PFIZER** is actively involved in the research of potential antiviral therapies

ROCHE CANADA has been selected as a participant in a Phase III clinical trial studying the safety and efficacy of one of Roche's portfolio medicines in hospitalized adult patients with severe COVID-19 pneumonia. In addition, Roche is collecting and compiling data from other, independently-led clinical trials that are taking place around the world.

ROCHE launched a COVID-19 Open Innovation Challenge in late March to encourage Canadians to help develop solutions to the challenges we face from the COVID-19 pandemic. Roche received over 840 high quality applications demonstrating the amazing skill and talent we have in Canada. All submissions were reviewed by a Roche Canada Steering Committee, and the chosen winning submissions will receive funds to support the development of the innovative solution.

ROCHE has also assembled a group of like-minded public and private organizations with a common mission and vision to bring actionable COVID-19 intelligence to patients, frontline healthcare providers, institutions, supply chains, and government. The group is called the Roche Data Science Coalition and has developed a centralized location, housed by ThinkData Works' Namara platform, for curated publicly available population datasets which will be gathered from sources across the globe. The data collected through the Coalition will be used to enhance COVID-19 research datasets focused on informing the management of the global COVID-19 pandemic and will provide the scientific and research community with a robust foundation for current and future COVID-19 patient-level data work. The Roche Data Science Coalition collaborators, as well as patients, clinicians, infectious disease specialists, epidemiologists and data scientists will use this data to accelerate research efforts, evaluate solutions and ensure knowledge mobilization globally. The Coalition is also making available a patient self-assessment tool, supported through their collaborator, Self Care Catalysts and their free app Health Storylines, that can be used by anyone suspected to have, or has been diagnosed (currently being treated or recovered) with COVID-19.

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SANOFI

SANOFI PASTEUR, the vaccines global business unit of **SANOFI**, is leveraging previous development work for a SARS vaccine as part of its goal to unlock a fast path forward for developing a COVID-19 vaccine. Sanofi is collaborating with the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services, expanding the company's longstanding partnership with BARDA. That partnership includes an agreement signed last year to establish state of the art facilities in the United States for the sustainable production of an adjuvanted recombinant vaccine, the technology platform that will be used for the COVID-19 program. Additionally, Sanofi is researching whether some on-market products may be a potential treatment option and are also sharing their expertise in an advisory capacity to various global governments and health agencies, including the World Health Organization, the U.S. National Institutes of Health, and the U.S. Centers for Disease Control.

In addition, **SANOFI** has started a global clinical trial program with Regeneron evaluating Kevzara(r) (sarilumab) in patients hospitalized with severe COVID-19. This global clinical program began in the U.S. at medical centers in New York, one of the epicenters of the U.S. COVID-19 outbreak, and is quickly recruiting across the country where COVID-19 is most prevalent. Canada one of the participating countries in the Phase 2/3 trial with patient enrollment starting shortly. Sanofi is also collaborating with Translate Bio, a clinical-stage messenger RNA (mRNA) therapeutics company, where Sanofi is combining its deep vaccine expertise and support with Translate Bio's messenger RNA platform to discover, design, and manufacture a number of SARS-CoV-2 vaccine candidates.

SANOFI and **GSK** have joined forces in an unprecedented collaboration to develop an adjuvanted vaccine to fight COVID-19, using innovative technology from both companies. **SANOFI** will contribute its S-protein COVID-19 antigen, which is based on recombinant DNA technology. This technology has produced an exact genetic match to proteins found on the surface of the virus, and the DNA sequence encoding this antigen has been combined into the DNA of the baculovirus expression platform, the basis of Sanofi's licensed recombinant influenza product in the US.

Takeda

TAKEDA is developing an investigational Hyperimmune globulin (H-IG). H-IG has been found to be effective in the treatment of severe acute respiratory infections of viral etiology and may present a potential treatment option for high-risk COVID-19 patients, as well as the prevention of infection in healthcare workers at high risk of exposure to SARS-CoV-2. In addition, Takeda is exploring whether select marketed therapies and molecules in its drug library could be viable candidates for the effective treatment of COVID-19. These efforts are at an early stage but being given a high priority within the company.

TAKEDA is part of an alliance of world-leading plasma companies partnering to develop a potential plasma-derived therapy for treating COVID-19. The alliance will begin immediately with the investigational development of one, unbranded anti-SARS-CoV-2 polyclonal hyperimmune immunoglobulin medicine with the potential to treat individuals with serious complications from COVID-19. The collaboration will leverage leading-edge expertise and work that the companies already have underway. Experts from the alliance will begin collaborating across key aspects such as plasma collections, clinical trial development and manufacturing.

MULTIPLE MEMBERS

A CONSORTIUM OF LIFE SCIENCES COMPANIES announced an important collaboration to accelerate the development, manufacture and delivery of vaccines, diagnostics, and treatments for COVID-19 in response to the pandemic alongside Bill & Melinda Gates Foundation. The industry brings a range of assets, resources, and expertise needed to identify effective and scalable solutions to the pandemic that is affecting billions worldwide. The impact on health systems, economies, and livelihoods are significant, and effective response requires an unprecedented collaboration across government, academia, private sector, and philanthropy. As a first step, 15 companies have agreed to share their proprietary libraries of molecular compounds that already have some degree of safety and activity data-with the COVID-19 Therapeutics Accelerator launched by the Gates Foundation, Wellcome, and Mastercard two weeks ago to quickly screen them for potential against COVID-19. Successful hits would move rapidly into in vivo trials in as little as two months.

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