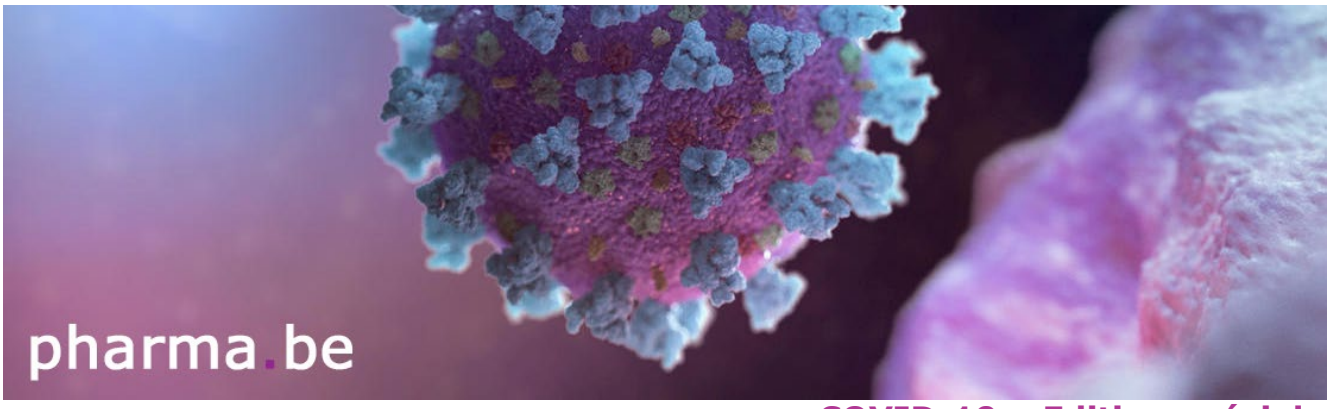
pharma.be
ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE



COVID-19 – Edition spéciale

Mars 2020

#TousEnsembleContreLeCOVID-19

Avant-propos par Catherine Rutten & Ann Adriaensen

En cette période hors du commun, nous souhaitions adresser notre gratitude envers les milliers de travailleurs du secteur des soins de santé ainsi qu'aux dirigeants politiques et scientifiques pour le combat qu'ils mènent contre le virus COVID-19. Le secteur pharmaceutique y contribue aussi, car nous sommes #TousEnsembleContreLeCOVID-19.

Read more

Le secteur pharmaceutique contre le virus COVID-19

Les entreprises en ont fait leur priorité : trouver une solution à la pandémie causée par le virus COVID-19. Découvrez leur travail.

Read more

European pharmaceutical industry response to COVID-19

As the impact of COVID-19 continues to be felt across the world, the biopharmaceutical industry in Europe remains committed to global efforts to care for those affected, contain the outbreak and develop resources to tackle future outbreaks.

Read more

pharma.be vzw | asbl
Algemene Vereniging van de Geneesmiddelenindustrie (A.V.G.I.) | Association générale de l'industrie du médicament (A.G.I.M.)
Terhulpsesteenweg 166 Chaussée de La Hulpe | Brussel 1170 Bruxelles
info@pharma.be | www.pharma.be | tel 02 661 91 11 | fax 02 661 91 99
BTW - TVA BE 0407.622.902 | Ondernemingsnummer - Numéro d'entreprise 0407.622.902 | RPR Brussel

The biopharmaceutical industry is leading the way in developing vaccines and treatments for COVID-19

The rapid spread of the novel coronavirus across the globe is a major public health threat for all, with profound health, social and economic impacts around the world. Discover the press release here.

Read more

Le VIB annonce avoir développé un anticorps capable de neutraliser le virus COVID-19

L'Institut flamand de recherche en biotechnologie (VIB) a annoncé lundi 16 mars 2020 la découverte d'un anticorps capable de neutraliser le virus à l'origine du COVID-19. Des recherches supplémentaires sont toutefois encore nécessaires pour confirmer les résultats.

Read more

MÉDIA

"Un vaccin contre le coronavirus doit fonctionner"

"Nous pouvons être optimistes quant à la possibilité de développer un vaccin", déclare Johan Van Hoof, directeur de Janssen Vaccines. Découvrez son interview sur la Radio1

L'IMI investit dans la recherche d'un nouveau traitement

Le Innovative Medicines Initiative a lancé un appel pour €90 million d'investissements dans les tests diagnotiques et thérapies pour combattre le COVID-19.

pharma.be
ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

Avant-propos par Catherine Rutten & Ann Adriaensen

En cette période hors du commun, nous souhaitions adresser notre gratitude envers les milliers de travailleurs du secteur des soins de santé ainsi qu'aux dirigeants politiques et scientifiques pour le combat qu'ils mènent contre le virus COVID-19. Le secteur pharmaceutique y contribue aussi, car nous sommes #TousEnsembleContreLeCOVID-19.

La crise du COVID-19 virus qui frappe l'Europe et le monde constitue un défi sans précédent pour le réseau de soins de santé de notre pays. Chaque jour, nous prenons un peu plus conscience de l'ampleur de la situation. Nous souhaitons avant tout exprimer notre solidarité à l'égard des victimes et de leurs familles et adressons notre gratitude aux milliers de travailleurs de la santé qui s'efforcent, de manière altruiste et bienveillante, de contrôler et limiter la propagation de l'épidémie.

Nous sommes également reconnaissants envers les dirigeants politiques, pour leurs actions et leur leadership décisifs en ces temps exceptionnels.

"En plus de veiller au bien-être des 37 000 employés de notre secteur en Belgique et de respecter scrupuleusement les recommandations et ordonnances du gouvernement, le secteur pharmaceutique a également un rôle moteur dans la recherche de solutions. Et il le fait de différentes manières, parmi lesquelles l'approvisionnement en médicaments, la concertation avec les autorités et l'accélération de la Recherche et le Développement de nouveaux vaccins et traitements occupent une place prédominante." - **Ann Adriaensen, Secrétaire générale pharma.be**

- Premièrement, pour assurer la continuité de la **production et de l'approvisionnement en médicaments** des hôpitaux en Belgique et ailleurs. En ces temps spéciaux, l'objectif principal est de maintenir la continuité des activités.
- À côté de cela, **une coopération intensive avec les autorités** est mise en place. Suite à l'épidémie du virus COVID-19, les experts de **l'Agence fédérale des médicaments et des produits de santé** (AFMPS) analysent en permanence l'impact possible sur la disponibilité des médicaments et des dispositifs médicaux en Belgique. En tant qu'organisation coupole, nous soutenons nos membres par une consultation permanente avec le SPF Santé publique et l'AFMPS. Ceci rend possible pour les autorités l'accès aux dernières informations concernant la disponibilité des médicaments en Belgique et leur permet également d'informer la population le plus justement possible.
- Enfin, il y a la **recherche intensive de nouveaux traitements** contre le virus dans laquelle le secteur pharmaceutique est à l'avant-garde. De nombreuses firmes pharmaceutiques ont considérablement augmenté leurs efforts de R&D et ont mis en place des équipes scientifiques qui recherchent, jour et nuit, une solution. Elles vérifient si les molécules existantes peuvent aider à éliminer ou retarder la propagation du virus et explorent de nouvelles voies dans la recherche d'une solution. La collaboration est un mot clé ici. Les firmes se renforcent mutuellement et collaborent avec les universités du monde entier dans leur recherche d'un traitement ou d'un nouveau vaccin.

Dans cette édition spéciale de la newsletter, vous découvrirez comment le secteur pharmaceutique a mis en place un dispositif pour répondre aux besoins les plus urgents et pour accélérer la Recherche et le Développement afin de trouver une solution.

En ces temps de crise, nous réussissons à faire preuve de solidarité et à joindre nos forces. Nous pouvons combattre le virus ensemble.

Nous vous souhaitons une enrichissante lecture,

Catherine Rutten
CEO, pharma.be

Ann Adriaensen
Secrétaire générale, pharma.be

Le secteur pharmaceutique contre le virus COVID-19

Les entreprises en ont fait leur priorité : trouver une solution à la pandémie causée par le virus COVID-19. Découvrez leur travail.

GSK - Mise à disposition de leurs adjuvants

«L'utilisation d'un adjuvant est particulièrement importante dans une situation de pandémie car elle peut réduire la quantité de protéines vaccinales requise par dose, permettant ainsi de produire plus de doses vaccinales et donc de contribuer à protéger davantage de personnes.» a déclaré Thomas Breuer, Chief Medical Officer chez GSK Vaccines.

Lire le communiqué de presse (EN) (https://www.gsk.com/en-gb/media/resource-centre/our-contribution-to-the-fight-against-2019-ncov/)

Pfizer - Un appel à collaborer

La société a publié un plan en cinq points appelant l'industrie biopharmaceutique à se joindre à elle pour s'engager dans une collaboration sans précédent afin de lutter contre le COVID-19.

Lire le communiqué de presse (EN) (https://investors.pfizer.com/investor-news/press-release-details/2020/Pfizer-Outlines-Five-Point-Plan-to-Battle-COVID-19/default.aspx)

Pfizer a également signé une lettre d'intention avec BioNTech SE en Allemagne pour co-développer un vaccin potentiel pour le virus COVID-19 en utilisant la plateforme de développement de médicaments à base d'ADNm de BioNTech.

Lire le communiqué de presse (EN) (https://www.pfizer.com/news/press-release/press-release-detail/pfizer_and_biontech_to_co_develop_potential_covid_19_vaccine)

Eli Lilly - Travail de collaboration avec AbCellera

AbCellera et Eli Lilly sélectionneront parmi plus de 500 anticorps uniques isolés depuis un patient rétabli du COVID-19 pour créer des thérapies d'anticorps en vue de développer un traitement et de prévenir le développement de la maladie.

Lire le communiqué de presse (EN) (https://investor.lilly.com/news-releases/news-release-details/abcellera-and-lilly-co-develop-antibody-therapies-treatment)

Takeda - Lancement du développement d'une thérapie dérivée du plasma

En tant que leader des thérapies dérivées du plasma, Takeda a développé des thérapies dérivées du plasma qui se sont révélées efficaces dans le traitement des infections respiratoires virales aiguës sévères et peuvent être une option de traitement pour COVID-19.

Lire le communiqué de presse (EN) (https://www.takeda.com/newsroom/newsreleases/2020/takeda-initiates-development-of-a-plasma-derived-therapy-for-covid-19/)

Novartis

Novartis annonce un large éventail d'initiatives pour répondre à la pandémie de COVID-19 et créé un fonds mondial de 20 millions USD pour soutenir les communautés touchées.

Lire le communiqué de presse (EN) (https://www.novartis.com/news/media-releases/novartis-announces-broad-range-initiatives-respond-covid-19-pandemic-creates-usd-20-million-global-fund-support-impacted-communities)

Alnylam - progrès dans l'ADNi thérapeutique

Vir et Alnylam étendent leur collaboration pour faire progresser l'ADNi thérapeutique pour le traitement des infections à coronavirus, y compris COVID-19.

Lire le communiqué de presse (EN) (https://investors.alnylam.com/press-release?id=24656)

Janssen Pharmaceutica - Travail de collaboration avec l'Institut Rega

Janssen Pharmaceutica et l'Institut Rega unissent leurs forces pour tester jusqu'à 15 000 composants actifs de médicaments existants pour leur efficacité contre le nouveau virus COVID-19.

Lire l'article Het Laatste Nieuws (NL) (https://pharma.be/nl/component/attachments/?task=download&id=595:De_strijd_om_het_vaccin_-hoe_alle_grote_farmareuzen_vechten_om_de_primeur_HLN)

AstraZeneca

Grâce à leur expertise scientifique dans les maladies infectieuses et à la technologie exclusive de découverte d'anticorps, AstraZeneca a rapidement mobilisé ses efforts de recherche pour découvrir de nouveaux anticorps neutralisant le virus COVID-19 comme traitement pour prévenir la maladie.

Lire le communiqué de presse (EN) (https://www.astrazeneca.com/media-centre/articles/2020/our-update-on-covid-19.html)

pharma.be
ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

European pharmaceutical industry response to COVID-19

As the impact of COVID-19 continues to be felt across the world, the biopharmaceutical industry in Europe remains committed to global efforts to care for those affected, contain the outbreak and develop resources to tackle future outbreaks.

Brussels, 25 February 2020 - EFPIA members are heavily engaged in the Innovative Medicines Initiative (Call 21) to fast track collaborative research, identifying any suitable assets in their libraries that could be utilised to develop diagnostics and treatments in the fight against COVID-19. In addition, the industry in Europe is providing financial support and in-kind donations to organisations on the ground as well as working closely with European, Chinese, and Global health authorities to combat this global public health emergency.

Many EFPIA members have R&D efforts under way or are providing donations of medicines and critical medical supplies as well as financial support to first responders in addressing this evolving crisis. Here are just a few ways Europe's research-based biopharmaceutical companies are working to combat COVID-19:

R&D Efforts

EFPIA members are engaged in and supporting the development of collaborative research programmes in order to fast-track the development of therapeutics and diagnostics for COVID-19 to complement the ongoing global activities on COVID-19 vaccines. Members have been donating investigational compounds that may have potential to treat COVID-19 for emergency use and clinical trials, including compounds formerly tested on other viral pathogens such as Ebola and HIV. Other members are researching vaccine candidates for prevention and undertaking inventories of existing research portfolio libraries to identify additional potential treatments for research and development.

Partnerships

EFPIA member companies are collaborating with relevant European and global public health authorities including the Innovative Medicines Initiative, the European Medicines Agency, National Health Authorities across Europe as well as the World Health Organization (WHO), Centres for Disease Control and Prevention (CDC), Chinese public health authorities including the Chinese Centre for Disease Control and Prevention and many others to address this public health crisis. These collaborations are focused on all areas of research and development, including evaluating how pandemic preparedness platforms can potentially be tailored to address the COVID-19 emergency, leveraging existing R&D partnerships to accelerate development of antiviral agents against COVID-19, and contribute both resources and expertise to various R&D consortia to address the outbreak.

Monetary and in-kind support

Millions of euros in direct monetary and in-kind contributions are being used to support organizations at the heart of the crisis who are able to have an immediate impact for infected patients and communities in China. EFPIA member companies acted immediately on the ground in China to donate a variety of crucial supplies including advanced surgical equipment, antibiotics, disinfection equipment, batch virus testing devices (e.g., throat swabs), vitamins, protective clothing, goggles, masks, gloves and more.

Supply chain integrity

As the situation evolves, EFPIA member companies are continuing to prioritize the continuity of their supply chains and are working proactively to prevent and mitigate any potential shortages through close coordination with the EMA and other global stakeholders. At this stage, manufacturers have not reported any shortages or delays in production.

Below are just a few of many examples of how EFPIA member companies are supporting efforts in the detection, prevention and treatment of the COVID-19 outbreak.

AbbVie: In late January, the Chinese health authorities identified Aluvia (lopinavir/ritonavir) as a potential treatment for COVID-19 and requested supply. AbbVie donated approximately $2 million (USD) of Aluvia as an experimental option to help address the growing health crisis. AbbVie is also working with the WHO to ensure a coordinated global effort.

AstraZeneca has supported China through financial and medical supplies donations totalling more than US$ 1million. This includes a financial donation to the Red Cross Foundation of China, an employee donation programme, and they are working with suppliers to donate urgently needed supplies to hospitals. AstraZeneca has also donated respiratory and gastrointestinal products to the two newly built specialist hospitals for infectious diseases. Additionally, the company is working with international health authorities to explore ways in which AstraZeneca might be able to support the effort to find measures against the COVID-19 virus outbreak. They have also have mobilised their research efforts to discovering novel coronavirus-neutralising antibodies as a treatment to prevent COVID-19 disease. AstraZeneca teams are now focused on identifying monoclonal antibodies to progress into clinical trial evaluation.

Bayer: Bayer has made substantial financial donations as well as donations of several medicines including an antibiotic to support those affected by the outbreak of COVID-19 in China. The donations have been made to the Chinese Red Cross, which is working with Chinese health authorities to coordinate the deployment of aid measures.

Boehringer Ingelheim: Boehringer Ingelheim (BI) is standing together with all parties to support the fight against the epidemic, making every effort to protect employees' health and safety. BI has made a number of donations totalling more than $1 million (USD) to support the forefront fight against the epidemic in China including: A donation to the China Red Cross Foundation to purchase medical protective materials for hospitals in Wuhan and other cities in Hubei. This helps local frontline medical staff involved in their fight against the epidemic to treat patients more safely. The headquarters of BI also purchased 100,000 protective masks from Germany, which are donated to provide protection for medical staff in hospitals where the patients with the new pneumonia are treated. BI has also donated medicines to help treat patients with new pneumonia in Wuhan.

GlaxoSmithKline: GlaxoSmithKline (GSK) and the Coalition for Epidemic Preparedness Innovations, formed a new collaboration aimed at helping the global effort to develop a vaccine for the COVID-19. In this new move, GSK will make its established pandemic vaccine adjuvant platform technology available to enhance the development of an effective vaccine against COVID-19. GSK is a leader in the development of innovative vaccines using different adjuvant systems. An adjuvant is added to some vaccines to enhance the immune response, thereby potentially creating a stronger and longer lasting immunity against infections than the vaccine alone. The use of an adjuvant can be of particular importance in a pandemic situation since it can reduce the amount of antigen required per dose, allowing more vaccine doses to be produced and made available to more people.

Johnson & Johnson: Thanks to J&J diversification, size and scale, they have been able to take rapid action across their Pharmaceutical, Consumer and Medical Devices businesses, as well as their Supply Chain and other supporting functions, to help stay ahead of the pandemic. To date their efforts have included: Seeking an optimal vaccine candidate; Making available currently marketed antivirals to test their potential efficacy; Collaborating with industry partners to screen a library of antiviral molecules, with the aim to identify potential treatments; Working with regulators, healthcare organisations, institutions and communities worldwide to maximise their research platforms; Last but not least, supporting healthcare professionals through making available tools, such as personal equipment (for instance via a RMB 1 million donation to the China Red Cross Foundation), a surgical generator and other devices for the newly-built isolation hospitals, protective suits, and a million masks among others.

Lilly: Lilly joined forces with AbCellera Biologics to co-develop antibody products for the treatment and prevention of SARS-CoV-2, the virus that causes COVID-19. The collaboration will leverage AbCellera's rapid pandemic response platform, developed under the DARPA Pandemic Prevention Platform (P3) Program, and Lilly's global capabilities for rapid development, manufacturing and distribution of therapeutic antibodies.

Menarini: Menarini Group decided to dedicate one of its manufacturing plants in Italy (normally operating for topical pharmaceuticals) to the production of hand sanitising gel, to be donated to hospitals and front-line personnel engaged against COVID-19.

Roche and Genentech: Roche and Genentech, a member of the Roche Group, are providing scientific expertise and advice to the WHO and other relevant stakeholders given infectious disease is a key R&D focus area for them. The company is working with Chinese health authorities and the government to help provide screening and health care, including supporting local health officials and hospitals in the Hubei Province. They recently donated diagnostic tests, medical supplies and financial support for the affected region.

Sanofi: Sanofi Pasteur, the vaccines global business unit of Sanofi, will leverage previous development work for a SARS vaccine which may unlock a fast path forward for developing a COVID-19 vaccine. Sanofi is collaborating with BARDA, expanding the company's long-standing partnership with the Authority. Sanofi will use its recombinant DNA platform to produce a 2019 novel COVID-19 vaccine candidate. The recombinant

technology produces an exact genetic match to proteins found on the surface of the virus. The DNA sequence encoding this antigen will be combined into the DNA of the baculovirus expression platform, the basis of Sanofi's licensed recombinant influenza product, and used to rapidly produce large quantities of the COVID-19 antigen which will be formulated to stimulate the immune system to protect against the virus.

EFPIA: EFPIA is in constant dialogue with its members and authorities to ensure the continuity of supply of our medicines and vaccines to patients, in Europe and beyond. To this end, weekly calls have been scheduled with the European Commission to discuss the potential impact of the coronavirus on our supply, along with other priority issues to contain the outbreak.

The biopharmaceutical industry has the capacity and expertise to find and scale solutions to prevent and treat infection of the COVID-19 virus and we will continue to provide updates on the response to the outbreak, and our member companies' contributions, as the situation evolves.

pharma.be
ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

The biopharmaceutical industry is leading the way in developing vaccines and treatments for COVID-19

The rapid spread of the novel coronavirus across the globe is a major public health threat for all, with profound health, social and economic impacts around the world. Discover the press release here.

Last updated: 16 March 2020

As a science-driven industry that aims to address some of the world's biggest healthcare challenges, the research-based biopharmaceutical industry is uniquely positioned to respond rapidly to COVID-19. It has deep scientific knowledge gained from decades of experience working on developing solutions for combatting a range of infectious diseases such as MERS, SARS, Ebola and influenza, as well as experience working with health authorities and regulators to find a fast-tracked approach to bringing safe and effective medicines to market for patients.

Biopharmaceutical companies are committed to developing solutions to help diagnose, treat and prevent COVID-19.

Sharing the novel COVID-19 virus sequence helped to galvanise the research community

The rapid virus sequencing by the scientific community enabled researchers to characterize and begin to understand the new threat posed by COVID-19. Biopharmaceutical companies with potentially relevant knowhow were thereby enabled to get their scientists to check their R&D libraries for potential assets that could fight coronaviruses. "Open Access" data-sharing channels are the backbone to securing a response capacity and have proven their worth with influenza networks. This speedy sharing of the novel coronavirus pathogen sequence was instrumental in galvanising global collaboration with the private and public sector: a pre-requisite for timely development of vaccines and treatments. The Global Initiative on Sharing All Influenza Data or GISAID Initiative, an open access platform partly funded by the private sector, played a critical role in sharing the first genome sequences of the novel coronavirus and centralizing their collection. This has proven vital in speeding up the sharing of information among scientists as well as public health authorities.

Accelerating research and innovation for novel coronavirus (COVID-19)

The rapid pace with which researchers have been able to understand this novel strain of virus and get medicines into human clinical trials is a testament to the lessons learned from past public health emergencies.

IFPMA members have been manufacturing thousands of doses of investigational and previously approved medicines that could treat coronavirus for emergency use and for use in clinical trials around the globe, including compounds formerly tested on other viral pathogens such as Ebola and HIV.

As of March 2020, there are a number of therapeutics currently in clinical trials and more than 20 vaccines in development for COVID-19.

Scientists checking libraries of assets – From the outset of the epidemic (and now pandemic), member companies reviewed their drug and vaccine portfolios to see if there is any research that could be of help. Analysis of drugs and vaccines portfolios involved scientists searching for potentially useful assets that could help with the development of new or repurposed treatments or vaccines to fight against the novel coronavirus. Relevant assets include diagnostics and biomarkers, approved therapies or compounds in

development which could be repurposed. In addition, member companies undertook to identify any ACE inhibitors, protease inhibitors or immunotherapies that could be relevant in the context of novel coronavirus.

No time wasted in engaging in R&D collaboration – R&D biopharmaceutical companies are part of a wider research community which is collaborating to fast-track the development of therapeutics, diagnostics and new vaccines. R&D biopharmaceutical companies are already engaging with existing networks such as CEPI (Coalition for Epidemic Preparedness Innovations) and Europe's IMI (Innovative Medicines Initiative).

Several biopharmaceutical companies are researching vaccine candidates for prevention and collaborating in the share of existing technologies that can be leveraged to allow a rapid upscale of production once a vaccine candidate is identified. IFPMA members are also sharing technologies that act as an adjuvant that can boost the effectiveness of a potential vaccine.

Collaborating in this way could hasten development of resources to tackle this outbreak. It creates networks of centres of excellence that can deliver a real impact and a preparedness infrastructure which can be mobilized for future outbreaks.

Biopharmaceutical industry leads the way in making diagnostics kits, developing new vaccines and treatments to contain COVID-19

There are companies working on phase I studies for both vaccines and treatments, and one potential treatment already being tested for another disease is now in Phase III clinical trials. Potential treatments include both antiviral medicines and immunotherapies. It is estimated that there are as of now (March 2020) nearly 80 clinical trials for experimental new treatments and vaccines in development for coronaviruses including COVID-19, Novel Coronavirus Pneumonia, SARS and MERS.

Treatment development

As of March 2020, there are at least: 14 companies with a medicine in early phase research, 4 companies with a medicine in Phase I of development and 3 in Phase II, and one company has a medicine in Phase III trials. Listed below is a snapshot of the different areas of research focused on finding a new treatment.

- **AbbVie** announced it is partnering with global authorities to determine the effectiveness of HIV drugs in treating COVID-19. AbbVie is supporting clinical studies and basic research with lopinavir/ritonavir, working closely with European health authorities and the U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention, National Institutes of Health and the Biomedical Advanced Research and Development Authority to coordinate these efforts.

- **Eli Lilly and AbCellera** (Canadian biotech firm) have entered into an agreement to codevelop 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, and Lilly's global capabilities for rapid development, manufacturing and distribution of therapeutic antibodies.

- **EFPIA** is working with the Innovative Medicines Initiative (IMI) on potential actions to support collaborative research programs in order to fast-track the development of therapeutics.

- **Gilead** is working with the Chinese health authorities to set up clinical trials to test the effectiveness of an experimental antiviral (remdesivir) aimed at treating Ebola and SARS.

- **Johnson & Johnson**, in partnership with the Rega Institute for Medical Research, University of Leuven (Belgium), are working to identify existing or new compounds with antiviral activity against COVID-19 that could contribute to providing immediate relief to the current outbreak.

- **Pfizer** announced that it completed a preliminary assessment of certain antiviral compounds that were previously in development and that inhibited the replication of coronaviruses similar to the one causing COVID-19 in cultured cells. Pfizer is engaging with a third party to screen these compounds under an accelerated timeline and expects to have the results back by the end of March.

- **Pfizer** also outlined a detailed 5-point action plan to battle COVID-19. The plan includes a commitment to sharing its clinical development and regulatory expertise to support other smaller biotech companies that are screening compounds or existing therapies for activity against the virus causing COVID-19.

- **Regeneron Pharmaceuticals** announced an expanded agreement with the U.S. Department of Health and Human Services (HHS) to develop new treatments combating the novel coronavirus.

- **Regeneron Pharmaceuticals and Sanofi SA** are racing to launch clinical trials exploring whether their arthritis drug could treat symptoms of the novel coronavirus infections.

- **Roche**'s Actemra was approved by China on March 5 to treat Covid-19 patients with lung complications. Roche has donated nearly $2m-worth of Actemra to China to help the country manage the COVID-19 outbreak". Actemra has been on the European market since 2010 for treatment of several kinds of arthritis.

- **Takeda** announced that it is initiating the development of a drug to treat people infected with the novel coronavirus. The experimental drug would be derived from the blood of coronavirus patients who have recovered from the respiratory disease. In parallel, Takeda is also exploring whether currently marketed and pipeline products may be an effective treatment option for infected patients.

Vaccine development

While vaccines and small molecule treatments are approved through different regulatory pathways and their development programs vary, they generally both must complete three phases of clinical trials. However, there are differences in the data required to show the safety of vaccines and the size of clinical trials for vaccines relative to small molecules. Experts are hoping it will take as little as 12 to 18 months before there is a vaccine available. This is a best-case estimate that assumes one or two of the first few vaccines that enter development will be successful. Typically, only approximately one in ten experimental vaccines make it all the way through to regulatory approval. Therefore, the more companies taking different approaches to find a vaccine, the more "shots on goal" and significantly greater chances of success.

- **CEPI** and **GSK** will collaborate to help the global effort to develop a vaccine for the novel coronavirus. GSK is making its adjuvant technology available to support rapid development of candidate vaccines and is working with The University of Queensland, Australia.

- **CSL Limited** partnered with the University of Queensland's COVID-19 vaccine development program. They will provide technical expertise as well as a donation of Seqirus' proprietary adjuvant technology, MF59®, to their pre-clinical development program.

- **GSK** announced it would partner with the Chinese biotech company Clover Biopharmaceuticals. Under the partnership, GSK will provide Clover with its proprietary adjuvants – compounds that enhance the effectiveness of vaccines.

- **Johnson & Johnson** expanded its collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of U.S. Department of Health & Human Services (HHS), to accelerate development of a potential novel coronavirus vaccine.

- **Pfizer** and **BioNTech** have entered into a partnership to jointly develop BioNTech's mRNA-based vaccine candidate BNT162 to prevent COVID-19 infection. The collaboration aims to accelerate global development of BNT162, which is expected to enter clinical testing by the end of April 2020.

- **Sanofi** announced it will work with the U.S. Department of Health & Human Services (HHS) to develop a coronavirus vaccine.

Diagnostics

Rolling out diagnostics to detect whether patients are genuinely infected with the new coronavirus is a key step in preventing or slowing its spread. However, the rapid spread of COVID-19 has drastically increased the demand for testing kits around the world, especially in the United States and Europe, and governments are trying to ramp up their testing capacities.

- **Roche** announced that the FDA issued an Emergency Use Authorization for its diagnostic kit cobas® SARS-CoV-2 Test, advancing coronavirus testing to meet urgent medical needs. Roche is committed to delivering as many tests as possible and is going to the limits of production capacity.

- **Takeda** is partnering with public entities and other pharmaceutical companies through the Innovative Medicines Initiative (IMI) in Europe to leverage collective expertise in the hope of developing diagnostics for COVID-19 as well as inhibitors to help prevent future outbreaks.

Pharmaceutical manufacturing supply chain

IFPMA and its member companies are monitoring the coronavirus situation closely. Currently, IFPMA member companies are not aware of any near-term impacts on the availability of medicines and vaccines. They are continuously monitoring and proactively handling the situation as it develops and do not expect, furthermore, any long-term impact on the availability of medicines and vaccines, unless any disruption caused by the pandemic is sustained over the next several months.

R&D biopharmaceutical companies are working to prevent and mitigate any shortages through close coordination with national regulatory authorities and other global stakeholders, including the World Health Organization.

Le VIB annonce avoir développé un anticorps capable de neutraliser le virus COVID-19

L'Institut flamand de recherche en biotechnologie (VIB) a annoncé lundi 16 mars 2020 la découverte d'un anticorps capable de neutraliser le virus à l'origine du COVID-19. Des recherches supplémentaires sont toutefois encore nécessaires pour confirmer les résultats.

VIB achieves important milestone in the development of a COVID-19 drug - 16 March 2020

Earlier this year, the lab of Xavier Saelens (VIB-UGent) announced the discovery of a unique antibody that is capable of binding the virus that causes COVID-19 (SARS-CoV-2). The antibody was developed in collaboration with two research groups in the US. The team has now established that the antibody can neutralize a lab variant of the virus, an important step forward in the development of a potential antiviral drug against the new coronavirus. This progress was made possible thanks to the intensive efforts of various teams in the VIB-UGent Center for Medical Biotechnology.

An antibody against COVID-19

Since the start of the COVID-19 outbreak, the team of professor Xavier Saelens has been working relentlessly on a potential treatment for the viral infection. Earlier work of the scientists identified an antibody that binds an important part of the SARS-CoV-2 virus.

Today, the lab announces new findings, in cooperation with the labs of Jason McLellan (University of Texas at Austin, US) and Markus Hoffmann and Stefan Pöhlmann (German Primate Center – Leibniz Institute for Primate Research, Göttingen, Germany). These findings show that the antibody can neutralize the virus. This is an important step forward in the pursuit of an antiviral drug against the new coronavirus.

En route to protection

The new results provide the first evidence that the antibody could prevent the new coronavirus from infecting human cells. Importantly, the antibody can also be produced at large-scale using production processes that are common in the biopharmaceutical industry.

Prof. Saelens emphasizes: "This important step forward in the fight against COVID-19 is the result of great teamwork by members of my lab and professor Nico Callewaert's research group (VIB-UGent Center for Medical Biotechnology)."

Dr. Bert Schepens, staff scientist in the team of Prof. Saelens: "Good teamwork is crucial. We can count on the expertise in the research center, colleagues from VIB Discovery Sciences and the VIB Innovation & Business team. We will continue these collaborations, also with academic experts outside VIB. The moment we observed virus neutralization in these experiments really felt like a collective victory."

In contrast to vaccines, an antibody offers immediate protection – though of shorter duration. The advantage of this approach over vaccines is that patients don't need to produce their own antibodies. The most vulnerable groups, such as the elderly, often mount a modest response to vaccines, which means that their protection may be incomplete. Healthcare workers or people at increased risk of exposure to the virus can also benefit from an immediate protection. This type of medicine can therefore be an important tool in fighting the current pandemic.

The next steps

It remains important to note that confirmation of these results using the pathogenic coronavirus strain is needed – experiments which are currently ongoing. The VIB researchers are also preparing the preclinical test phase for a coronavirus treatment. Although these first results are highly promising, further research is necessary to confirm the full potential of this antibody-based drug directed against COVID-19.