

# Pfizer Advances Battle Against COVID-19 on Multiple Fronts

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- *Anti-viral compounds show activity against SARS-CoV-2 in preclinical screening*
- *Pfizer and BioNTech enter into collaboration agreement to co-develop potential COVID-19 vaccine*
- *Company shares additional data and analysis of azithromycin*
- *Launch of two new studies to provide insights on the interaction between *S. pneumoniae* and SARS-CoV-2*
- *Pfizer explores studies of JAK inhibitor tofacitinib in patients with COVID-19-related pneumonia*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced important advances in the battle against the global COVID-19 pandemic.

As outlined in Pfizer's five-point plan, the company has been collaborating across the healthcare innovation ecosystem ranging from large pharmaceutical companies to the smallest of biotech companies, from government agencies to academic institutions to address the COVID-19 global health care crisis. Researchers and scientists have been relentlessly working to develop an investigational antiviral compound to treat SARS-CoV-2, which causes the current pandemic of coronavirus infections (COVID-19), a vaccine to prevent infection as well as evaluating other therapies that have scientific potential to help infected patients fight the virus.

"We are committed to making the impossible possible," said Dr. Albert Bourla, Chairman and CEO. "In the spirit of the Five Point Plan that Pfizer issued, we are facing this public health challenge head on by collaborating with industry partners and academic institutions to develop potential novel approaches to prevent and treat COVID-19. Our researchers and scientists also have been exploring potential new uses of existing medicines in Pfizer's portfolio to help infected patients globally. We are leaving no stone unturned as we explore every option to help provide society with a treatment or cure."

Pfizer announced key advances in its commitment to protect humankind from this escalating pandemic and prepare the industry to better respond to future global health crises.

## ***Anti-Viral Compound Screening***

Pfizer confirmed a lead compound and analogues are potent inhibitors of the SARS-CoV-2 3C-like (3CL) protease, based on the results of initial screening assays. In addition, preliminary data suggest the lead protease inhibitor shows antiviral activity against SARS-CoV-2. Consequently, Pfizer will perform pre-clinical confirmatory studies, including further anti-viral profiling and assessment of the suitability of the lead molecule for IV administration clinically. In parallel, the company is also investing in materials that will accelerate the start of a potential clinical study of the lead molecule to third quarter 2020, three or more months in advance of earlier estimates, subject to positive completion of the pre-clinical confirmatory studies.

## ***Applying Pfizer's Long History in Vaccine Research Development Expertise to Finalize Our Agreement with BioNTech***

Pfizer Inc. and BioNTech SE have entered into a global collaboration agreement to co-develop BioNTech's potential first-in-class, mRNA-based coronavirus vaccine program aimed at preventing COVID-19 infection. In March 2020, the companies announced a letter of intent to collaborate and began working together at that time. The two companies plan to jointly conduct clinical trials for the COVID-19 vaccine candidates initially in the United States and Europe across multiple research sites. BioNTech and Pfizer intend to initiate clinical trials as early as the end of April 2020, assuming regulatory clearance. The companies estimate that there is potential to supply millions of vaccine doses by the end of 2020 subject to technical success of the development program and approval of regulatory authorities and then rapidly scale up to capacity to produce hundreds of millions of doses in 2021. For the terms of the agreement, please see the press release page of [Pfizer's website](#).

## ***Analysis of Azithromycin as an Agent with Antiviral Activity***

In an effort to share information that could benefit COVID-19 mitigation efforts, Pfizer researchers will publish a review in *Clinical Pharmacology and Therapeutics* which assesses published in vitro and clinical data regarding azithromycin as an agent with antiviral properties. This open access review may serve to facilitate the use of azithromycin in future research on COVID-19. Azithromycin is not approved for the treatment of viral infections.

## ***Studying Pfizer's Existing Medicines for Critical Patient Populations in Need***

Pfizer Inc. and the Liverpool School of Tropical Medicine's Respiratory Infection Clinical Research Group are launching two new studies to provide insights on the interaction between *S. pneumoniae* and SARS-CoV-2. Pfizer is expected to finalize in the coming days, a research collaboration agreement with Liverpool to provide funding and in-kind laboratory testing support for this research. The studies (SAFER study (SARS-CoV-2 Acquisition in Frontline Health Care Workers – Evaluation to Inform Response) and the FASTER study (Facilitating A SARS CoV-2 Test for Rapid triage)) will help demonstrate whether patients infected with COVID-19 have a higher risk of also developing pneumococcal pneumonia and if having both infections leads to more severe disease and poorer outcomes. The SAFER study will enroll 100 healthcare workers at the Royal Liverpool Hospital and examine rates of SARS-CoV-2 acquisition and dynamics of pneumococcal colonization. The FASTER study will recruit 400 patients from the infectious disease ward at the Royal Liverpool Hospital suspected of having coronavirus. Enrollment has already begun, and data are expected over the next few months.

An independent Phase 2 investigator-initiated study for the use of tofacitinib, an oral Janus Kinase (JAK) inhibitor, in patients with SARS-CoV-2 interstitial pneumonia is planned to be initiated in Italy later this week. The study is supported by a Pfizer grant. For more details about the study, please see [clinicaltrials.gov](#).

Pfizer is also in discussions with other institutions about additional studies involving tofacitinib and potentially other immune modulators in our portfolio. This research is based on the hypothesis that JAK inhibition could mitigate systemic and alveolar inflammation in patients with COVID-19-related pneumonia by inhibiting essential cytokine signaling involved in immune-mediated inflammatory response that could lead to damage of the lungs, resulting in acute respiratory distress syndrome in patients with COVID-19-related pneumonia. It is important to note, tofacitinib is not currently approved for this use and should not be used in patients with an active serious infection.

“While this work can generally take years, we are working to find opportunities to save time wherever we can and work in parallel rather than in a linear capacity,” said Mikael Dolsten, Chief Scientific Officer and President, Worldwide Research, Development & Medical, Pfizer. “This pursuit requires a crucial multi-pronged approach

with a deep collaboration and partnership across the health innovation ecosystem – from the academic community, industry partners, policymakers and regulatory bodies. We announced in March that we are collaborating with BioNTech to co-develop a potential first-in-class, mRNA-based COVID-19 vaccine. A public threat like coronavirus COVID-19 pushes each of us to urgently bring forward our resources and expertise to overcome this most challenging moment in the medical history of this century.”

The company will continue to share information from its portfolio and emerging candidates that could benefit the many companies and organizations who are working quickly to provide solutions to combat this unprecedented healthcare crisis.

### **Pfizer Inc.: Breakthroughs That Change Patients’ Lives**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at [www.Pfizer.com](http://www.Pfizer.com). In addition, to learn more, please visit us on [www.Pfizer.com](http://www.Pfizer.com) and follow us on Twitter at [@Pfizer](https://twitter.com/Pfizer) and [@Pfizer News](https://twitter.com/PfizerNews), [LinkedIn](https://www.linkedin.com/company/pfizer), [YouTube](https://www.youtube.com/user/Pfizer) and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

### **Disclosure Notice:**

The information contained in this release is as of April 9, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking statements about Pfizer’s efforts to battle COVID-19, including potential clinical trial timing, potential timing of vaccine availability and potential of the various candidates being studied, that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including uncertainties regarding the results of screening and the ability to meet anticipated pre-clinical and clinical endpoints, commencement and/or completion dates for our pre-clinical and clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable pre-clinical or clinical data; the risk that pre-clinical and clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications for any potential antiviral compounds, vaccines or other candidates may be filed or approved in any jurisdictions, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any such products, including development of products or therapies by other companies; our manufacturing capabilities and capacity; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and

Exchange Commission and available at <http://www.sec.gov> and [www.pfizer.com](http://www.pfizer.com).

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