Pfizer Logo

Pfizer Initiates Phase 1 Study of Novel Oral Antiviral Therapeutic Agent Against SARS-CoV-2

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- *In-vitro studies conducted to date show that the clinical candidate PF-07321332 is a potent protease inhibitor with potent anti-viral activity against SARS-CoV-2*
- *This is the first orally administered coronavirus-specific investigational protease inhibitor to be evaluated in clinical studies, and follows Pfizer's intravenously administered investigational protease inhibitor, which is currently being evaluated in a Phase 1b multi-dose study in hospitalized clinical trial participants with COVID-19*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) announced today that it is progressing to multiple ascending doses after completing the dosing of single ascending doses in a Phase 1 study in healthy adults to evaluate the safety and tolerability of an investigational, novel oral antiviral therapeutic for SARS-CoV-2, the virus that causes COVID-19. This Phase 1 trial is being conducted in the United States. The oral antiviral clinical candidate PF-07321332, a SARS-CoV2-3CL protease inhibitor, has demonstrated potent *in vitro* anti-viral activity against SARS-CoV-2, as well as activity against other coronaviruses, suggesting potential for use in the treatment of COVID-19 as well as potential use to address future coronavirus threats.

"Tackling the COVID-19 pandemic requires both prevention via vaccine and targeted treatment for those who contract the virus. Given the way that SARS-CoV-2 is mutating and the continued global impact of COVID-19, it appears likely that it will be critical to have access to therapeutic options both now and beyond the pandemic," said Mikael Dolsten, MD, PhD., Chief Scientific Officer and President, Worldwide Research, Development and Medical of Pfizer. "We have designed PF-07321332 as a potential oral therapy that could be prescribed at the first sign of infection, without requiring that patients are hospitalized or in critical care. At the same time, Pfizer's intravenous antiviral candidate is a potential novel treatment option for hospitalized patients. Together, the two have the potential to create an end to end treatment paradigm that complements vaccination in cases where disease still occurs."

Protease inhibitors bind to a viral enzyme (called a protease), preventing the virus from replicating in the cell. Protease inhibitors have been effective at treating other viral pathogens such as HIV and hepatitis C virus, both alone and in combination with other antivirals. Currently marketed therapeutics that target viral proteases are not generally associated with toxicity and as such, this class of molecules may potentially provide well-tolerated treatments against COVID-19.

The Phase 1 trial is a randomized, double-blind, sponsor-open, placebo-controlled, single- and multiple-dose escalation study in healthy adults evaluating the safety, tolerability and pharmacokinetics of PF-07321332.

Initiation of this study is supported by preclinical studies that demonstrated the antiviral activity of this potential first-in-class SARS-CoV-2 therapeutic designed specifically to inhibit replication of the SARS-CoV2 virus. The

structure of PF-07321332, together with the pre-clinical data, will be shared in a COVID-19 session of the Spring American Chemical Society meeting on April 6.

Pfizer is also investigating an intravenously administered investigational protease inhibitor, PF-07304814, which is currently in a Phase 1b multi-dose trial in hospitalized clinical trial participants with COVID-19.

About Pfizer: 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 170 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. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: *The information contained in this release is as of March 23, 2021. 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 information about Pfizer's efforts to combat COVID-19, Pfizer's oral antiviral clinical candidate PF-07321332, a SARS-CoV2-3CL protease inhibitor, and Pfizer's intravenously administered investigational protease inhibitor, PF-07304814, involving 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 the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including the in vitro data), including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when any drug applications for any potential indications for PF-07321332 or PF-07304814 may be filed in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any applications for PF-07321332 or PF-07304814, 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 and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of PF-07321332 or PF-07304814, including development of products or therapies by other companies; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; 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, 2020 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 www.sec.gov and www.pfizer.com.

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