



First Participant Dosed in Phase 2/3 Study of Oral Antiviral Candidate in Non-Hospitalized Adults with COVID-19 Who Are at Low Risk of Severe Illness

New York, N.Y., September 1, 2021 – [Pfizer Inc.](https://www.pfizer.com) (NYSE:PFE) today shared that the first participant has been dosed in a pivotal Phase 2/3 clinical trial to evaluate the safety and efficacy of PF-07321332 – an investigational orally administered protease inhibitor antiviral therapy designed specifically to combat COVID-19 – in non-hospitalized, symptomatic adult participants who have a confirmed diagnosis of SARS-CoV-2 infection and are not at increased risk of progressing to severe illness, which may lead to hospitalization or death.

The randomized, double-blind trial will enroll approximately 1,140 participants, who will receive PF-07321332/ritonavir or placebo orally every 12 hours for five days.

Protease inhibitors, like PF-07321332, are designed to block the activity of the main protease enzyme that the coronavirus needs to replicate. Co-administration with a low dose of ritonavir is expected to help slow the metabolism, or breakdown, of PF-07321332 in order for it to remain in the body for longer periods of time at higher concentrations, thereby working continuously to help combat the virus. Ritonavir has previously been used in combination with other antivirals to similarly inhibit metabolism.

This study is part of a global clinical development program, consisting of multiple ongoing and planned clinical trials to evaluate this early-intervention, outpatient therapeutic candidate for potential use in a broad population of patients. The first registrational trial in this program, a pivotal Phase 2/3 study of PF-07321332/ritonavir in non-hospitalized, symptomatic adult participants who have been diagnosed with SARS-CoV-2 infection and are at increased risk of progressing to severe illness, began enrollment in July 2021.

If successful, PF-07321332/ritonavir has the potential to address a significant unmet medical need, providing patients with a novel oral therapy that could be prescribed at the first sign of infection, without requiring hospitalization.

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](https://twitter.com/Pfizer) and [@Pfizer News](https://twitter.com/PfizerNews), [LinkedIn](https://www.linkedin.com/company/pfizer), [YouTube](https://www.youtube.com/channel/UCv31111111111111111111) 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 September 1, 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 and Pfizer's oral antiviral clinical candidate PF-07321332, an investigational SARS-CoV2-3CL protease inhibitor, 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 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 including efficacy, safety and tolerability profile observed to date, in additional studies or in larger, more diverse populations following commercialization; 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 may be filed in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications for PF-07321332, 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, 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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