Pfizer Logo

Pfizer Starts Global Phase 2/3 EPIC-PEP Study of Novel COVID-19 Oral Antiviral Candidate for Post-Exposure Prophylaxis in Adults

Monday, September 27, 2021 - 06:45am

- *EPIC-PEP (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **P**ost-**E**xposure **P**rophylaxis) is the third study launched in this global clinical research program.*
- *New study will evaluate novel protease inhibitor (PF-07321332, co-administered with a low dose of ritonavir) for prevention of illness in adults living in the same household as someone with COVID-19*
- *PF-07321332 has been specifically designed to be administered orally, so that it can potentially be administered at the first sign of infection with, or exposure to, SARS-CoV-2, without requiring patients to be hospitalized*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced the start of the Phase 2/3 EPIC-PEP (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **P**ost-**E**xposure **P**rophylaxis) study to evaluate the investigational novel oral antiviral candidate PF-07321332, co-administered with a low dose of ritonavir, for the prevention of COVID-19 infection. This Phase 2/3 trial is part of a global clinical research program and is enrolling individuals who are at least 18 years old and live in the same household as an individual with a confirmed symptomatic SARS-CoV-2 infection.

“With the continued impact of COVID-19 around the world, we believe that tackling the virus will require effective treatments for people who contract, or have been exposed to, the virus, complementing the impact that vaccines have had in helping quell infections. If successful, we believe this therapy could help stop the virus early – before it has had a chance to replicate extensively – potentially preventing symptomatic disease in those who have been exposed and inhibiting the onset of infection in others,” said Mikael Dolsten, MD, PhD., Chief Scientific Officer and President, Worldwide Research, Development and Medical of Pfizer. “Given the continued emergence and evolution of SARS-CoV-2 variants and their immense impact, we continue to work diligently to develop and study new ways that our investigational oral antiviral candidate could potentially lower the impact of COVID-19, not only on patients’ lives, but also the lives of their families and household members.”

The Phase 2/3 EPIC-PEP trial is a randomized, double-blind, placebo-controlled study and will enroll up to 2,660 healthy adult participants aged 18 and older. Participants will be randomly assigned (1:1:1) to receive PF-07321332/ritonavir or placebo orally twice daily for 5 or 10 days. The primary objective will assess safety and efficacy for the prevention of confirmed SARS-CoV-2 infection and its symptoms through Day 14. PF-07321332 is an oral antiviral SARS-CoV-2-3CL protease inhibitor, which has an encouraging pre-clinical profile, including potent in vitro antiviral SARS-CoV-2 and broad coronavirus activity. Results from the Phase 1 clinical trial demonstrated that PF-07321332 was safe and well tolerated.

In addition to this study, the global EPIC program consists of multiple ongoing clinical trials, including one in SARS-CoV-2 infected patients who are at high risk of severe illness (including hospitalization or death), which began in July 2021, and another in infected patients who are at standard risk (i.e., do not have risk factors for severe illness), which began in August 2021.

For more information on the EPIC Phase 2/3 clinical trials for PF-07321332, visit clinicaltrials.gov.

About PF-07321332/ritonavir

PF-07321332 isan investigational SARS-CoV-2-3CL protease inhibitor antiviral therapy, specifically designed to be administered orally so that it can potentially be prescribed at the first sign of infection or at first awareness of an exposure, without requiring patients to be hospitalized. 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 active in the body for longer periods of time at higher concentrations to help combat the virus.

In March 2021, Pfizer progressed PF-07321332 to a Phase 1 study in healthy adults to evaluate the safety, tolerability, and pharmacokinetics of the investigational compound. In July, it progressed to a Phase 2/3 trial, EPIC-HR (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **H**igh-**R**isk Patients), to evaluate efficacy and safety, in combination with ritonavir, in participants with a confirmed diagnosis of SARS-CoV-2 infection who are at high risk of progression to severe illness. In August, Pfizer initiated a Phase 2/3 trial, EPIC-SR (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **S**tandard-**R**isk Patients), to evaluate efficacy and safety in participants with a confirmed diagnosis of SARS-CoV-2 infection who are at standard risk (i.e., do not have risk factors for severe illness).

PF-07321332 is the first orally administered coronavirus-specific investigational protease inhibitor to be evaluated in clinical studies.

There is no orally administered therapy currently approved for post-exposure or pre-emptive treatment of 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 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. 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 September 27, 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 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; the risk that demand for any products may be reduced or no longer exist; 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210927005195/en/

Media Contact:
Jerica Pitts
+1 (347) 224-9084
PfizerMediaRelations@pfizer.com

Investor Contact:
Chris Stevo
+1 (212) 733-0437
Christopher.Stevo@pfizer.com

Source: Pfizer Inc.