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Pfizer's Novel COVID-19 Oral Antiviral Treatment Candidate Reduced Risk of Hospitalization or Death by 89% in Interim Analysis of Phase 2/3 EPIC-HR Study

Friday, November 05, 2021 - 06:45am

- PAXLOVID™ (PF-07321332; ritonavir) *was found to reduce the risk of hospitalization or death by 89% compared to placebo in non-hospitalized high-risk adults with COVID-19*
- *In the overall study population through Day 28, no deaths were reported in patients who received* PAXLOVID™ *as compared to 10 deaths in patients who received placebo*
- *Pfizer plans to submit the data as part of its ongoing rolling submission to the U.S. FDA for Emergency Use Authorization (EUA) as soon as possible*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced its investigational novel COVID-19 oral antiviral candidate,PAXLOVID™, significantly reduced hospitalization and death, based on an interim analysis of the Phase 2/3 EPIC-HR (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **H**igh-**R**isk Patients) randomized, double-blind study of non-hospitalized adult patients with COVID-19, who are at high risk of progressing to severe illness. The scheduled interim analysis showed an 89% reduction in risk of COVID-19-related hospitalization or death from any cause compared to placebo in patients treated within three days of symptom onset (primary endpoint); 0.8% of patients who received PAXLOVID™ were hospitalized through Day 28 following randomization (3/389 hospitalized with no deaths), compared to 7.0% of patients who received placebo and were hospitalized or died (27/385 hospitalized with 7 subsequent deaths). The statistical significance of these results was high ($p<0.0001$). Similar reductions in COVID-19-related hospitalization or death were observed in patients treated within five days of symptom onset; 1.0% of patients who received PAXLOVID™ were hospitalized through Day 28 following randomization (6/607 hospitalized, with no deaths), compared to 6.7% of patients who received a placebo (41/612 hospitalized with 10 subsequent deaths), with high statistical significance ($p<0.0001$). In the overall study population through Day 28, no deaths were reported in patients who received PAXLOVID™ as compared to 10 (1.6%) deaths in patients who received placebo.

At the recommendation of an independent Data Monitoring Committee and in consultation with the U.S. Food and Drug Administration (FDA), Pfizer will cease further enrollment into the study due to the overwhelming efficacy demonstrated in these results and plans to submit the data as part of its ongoing rolling submission to the U.S. FDA for Emergency Use Authorization (EUA) as soon as possible.

"Today's news is a real game-changer in the global efforts to halt the devastation of this pandemic. These data suggest that our oral antiviral candidate, if approved or authorized by regulatory authorities, has the potential to save patients' lives, reduce the severity of COVID-19 infections, and eliminate up to nine out of ten hospitalizations," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "Given the continued global impact of COVID-19, we have remained laser-focused on the science and fulfilling our responsibility to help healthcare systems and institutions around the world while ensuring equitable and broad access to people

everywhere."

If approved or authorized, PAXLOVID™, which originated in Pfizer's laboratories, would be the first oral antiviral of its kind, a specifically designed SARS-CoV-2-3CL protease inhibitor. Upon successful completion of the remainder of the EPIC clinical development program and subject to approval or authorization, it could be prescribed more broadly as an at-home treatment to help reduce illness severity, hospitalizations, and deaths, as well as reduce the probability of infection following exposure, among adults. It has demonstrated potent antiviral in vitro activity against circulating variants of concern, as well as other known coronaviruses, suggesting its potential as a therapeutic for multiple types of coronavirus infections.

"All of us at Pfizer are incredibly proud of our scientists, who designed and developed this molecule, working with the utmost urgency to help lessen the impact of this devastating disease on patients and their communities," said Mikael Dolsten, MD, PhD., Chief Scientific Officer and President, Worldwide Research, Development and Medical of Pfizer. "We're thankful to all of the patients, investigators, and sites around the world who participated in this clinical trial, all with the common goal of bringing forth a breakthrough oral therapy to help combat COVID-19."

The Phase 2/3 EPIC-HR study began enrollment in July 2021. The Phase 2/3 EPIC-SR (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **S**tandard-**R**isk Patients) and EPIC-PEP (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **P**ost-**E**xposure **P**rophylaxis) studies, which began in August and September 2021 respectively, were not included in this interim analysis and are ongoing.

About the Phase 2/3 EPIC-HR Study Interim Analysis

The primary analysis of the interim data set evaluated data from 1219 adults who were enrolled by September 29, 2021. At the time of the decision to stop recruiting patients, enrollment was at 70% of the 3,000 planned patients from clinical trial sites across North and South America, Europe, Africa, and Asia, with 45% of patients located in the United States. Enrolled individuals had a laboratory-confirmed diagnosis of SARS-CoV-2 infection within a five-day period with mild to moderate symptoms and were required to have at least one characteristic or underlying medical condition associated with an increased risk of developing severe illness from COVID-19. Each patient was randomized (1:1) to receive PAXLOVID™ or placebo orally every 12 hours for five days.

About the Phase 2/3 EPIC-HR Study Safety Data

The review of safety data included a larger cohort of 1881 patients in EPIC-HR, whose data were available at the time of the analysis. Treatment-emergent adverse events were comparable between PAXLOVID™ (19%) and placebo (21%), most of which were mild in intensity. Among the patients evaluable for treatment-emergent adverse events, fewer serious adverse events (1.7% vs. 6.6%) and discontinuation of study drug due to adverse events (2.1% vs. 4.1%) were observed in patients dosed with PAXLOVID™ compared to placebo, respectively.

About PAXLOVID™ (PF-07321332; ritonavir) and the EPIC Development Program

PAXLOVID™ is an investigational SARS-CoV-2 protease inhibitor antiviral therapy, specifically designed to be administered orally so that it can be prescribed at the first sign of infection or at first awareness of an exposure, potentially helping patients avoid severe illness which can lead to hospitalization and death. PF-07321332 is designed to block the activity of the SARS-CoV-2-3CL protease, an enzyme that the coronavirus needs to replicate. Co-administration with a low dose of ritonavir helps 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.

PF-07321332 inhibits viral replication at a stage known as proteolysis, which occurs before viral RNA replication. In preclinical studies, PF-07321332 did not demonstrate evidence of mutagenic DNA interactions.

Pfizer initiated the EPIC-HR study in July 2021 following positive Phase 1 clinical trial results and continues to evaluate the investigational antiviral in additional EPIC studies. In August 2021, Pfizer initiated the Phase 2/3 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 patients with a confirmed diagnosis of SARS-CoV-2 infection who are at standard risk (i.e., low risk of hospitalization or death). EPIC-SR includes a cohort of vaccinated patients who have an acute breakthrough symptomatic COVID-19 infection and who have risk factors for severe illness. In September, Pfizer initiated the Phase 2/3 EPIC-PEP (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **P**ost-**E**xposure **P**rophylaxis) to evaluate efficacy and safety in adults exposed to SARS-CoV-2 by a household member.

For more information on the EPIC Phase 2/3 clinical trials for PAXLOVID™, visit clinicaltrials.gov.

About Pfizer's Commitment to Equitable Access

Pfizer is committed to working toward equitable access to PAXLOVID™ for all people, aiming to deliver safe and effective antiviral therapeutics as soon as possible and at an affordable price. If our candidate is successful, during the pandemic, Pfizer will offer our investigational oral antiviral therapy through a tiered pricing approach based on the income level of each country to promote equity of access across the globe. High and upper-middle income countries will pay more than lower income countries. The company has entered into advance purchase agreements with multiple countries and is in negotiations with several others. Pfizer has also begun and will continue to invest up to approximately $1 billion to support the manufacturing and distribution of this investigational treatment, including exploring potential contract manufacturing options to help ensure access across low- and middle-income countries, pending regulatory authorization.

The company is working to ensure access for its novel antiviral candidate for those most in need around the world, pending successful trial results and regulatory approval.

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 November 5, 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 investigational oral antiviral candidate PAXLOVID™ (including qualitative assessments of available data, potential benefits, expectations for clinical trials, advanced purchase agreements, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorizations, planned investment and anticipated manufacturing, distribution and supply), 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 or submissions to request emergency use or conditional marketing authorization for any potential indications for PAXLOVID™ may be filed in any jurisdictions and if obtained, whether or when such emergency use authorization or licenses will expire or terminate; whether and when regulatory authorities in any jurisdictions may approve any such applications for PAXLOVID™, 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 PAXLOVID™, including development of products or therapies by other companies; risks related to the availability of raw materials for PAXLOVID™; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand, which would negatively impact our ability to supply the estimated numbers of courses of PAXLOVID™ within the projected time periods; whether and when additional purchase agreements will be reached; 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.

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Source: Pfizer Inc.