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Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries

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- *Agreement builds on Pfizer's comprehensive strategy to work toward equitable access to COVID-19 vaccines and treatments for all people, particularly those living in the poorest parts of the world*
- *Agreement will enable qualified sub-licensees to supply countries comprising approximately 53% of the world's population*
- *Interim data from the Phase 2/3 EPIC-HR study demonstrated an 89% reduction in risk of COVID-19-related hospitalization or death compared to placebo in non-hospitalized high-risk adults with COVID-19 within three days of symptom onset with similar results seen within five days of symptom onset*

NEW YORK & GENEVA--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and the Medicines Patent Pool (MPP), a United Nations-backed public health organization working to increase access to life-saving medicines for low- and middle-income countries, today announced the signing of a voluntary license agreement for Pfizer's COVID-19 oral antiviral treatment candidate PF-07321332, which is administered in combination with low dose ritonavir (PF-07321332; ritonavir). The agreement will enable MPP to facilitate additional production and distribution of the investigational antiviral, pending regulatory authorization or approval, by granting sub-licenses to qualified generic medicine manufacturers, with the goal of facilitating greater access to the global population.

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Under the terms of the head license agreement between Pfizer and MPP, qualified generic medicine manufacturers worldwide that are granted sub-licenses will be able to supply PF-07321332 in combination with ritonavir to 95 countries, covering up to approximately 53% of the world's population. This includes all low- and lower-middle-income countries and some upper-middle-income countries in Sub-Saharan Africa as well as countries that have transitioned from lower-middle to upper-middle-income status in the past five years. Pfizer will not receive royalties on sales in low-income countries and will further waive royalties on sales in all countries covered by the agreement while COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization.

"Pfizer remains committed to bringing forth scientific breakthroughs to help end this pandemic for all people. We believe oral antiviral treatments can play a vital role in reducing the severity of COVID-19 infections,

decreasing the strain on our healthcare systems and saving lives," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "We must work to ensure that all people – regardless of where they live or their circumstances – have access to these breakthroughs, and we are pleased to be able to work with MPP to further our commitment to equity."

"This license is so important because, if authorized or approved, this oral drug is particularly well-suited for low- and middle-income countries and could play a critical role in saving lives, contributing to global efforts to fight the current pandemic," said Charles Gore, Executive Director of MPP. "PF-07321332 is to be taken together with ritonavir, an HIV medicine we know well, as we have had a license on it for many years, and we will be working with generic companies to ensure there is enough supply for both COVID-19 and HIV."

"Unitaid, a global health agency, created MPP ten years ago for this exact purpose – to secure licenses that enable and accelerate access to affordable quality treatments for people in resource-limited settings," said Dr Philippe Duneton, Executive Director, Unitaid. "During a pandemic, saving time means saving lives. This agreement could help us to reach more people more quickly as soon as the medicine is approved and, when coupled with increased access to testing, bring benefits to millions."

Access the license agreement.

MPP invites Expressions of Interest (EoI) from potential sublicensees based anywhere in the world for sublicences to manufacture and sell the co-pack of PF-07321332; ritonavir in the licensed territory:

Access the EoI portal

More information about the EoI process

Deadline for applying: 6 December 2021, 6pm CET

About PF-07321332; ritonavir
PF-07321332 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.

About Pfizer's Commitment to Equitable Access
Pfizer is committed to working toward equitable access of PF-07321332; ritonavir for all people, aiming to deliver safe and effective antiviral therapeutics as soon as possible and at an affordable price. If authorized or approved, 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, which will pay a not-for-profit price.

Pfizer has also begun and will continue to invest up to approximately $1 billion to support the manufacturing and distribution of this investigational treatment candidate, including exploring potential contract manufacturing options. It has entered into advance purchase agreements with several countries and has initiated bilateral outreach to approximately 100 countries around the world.

About the Phase 2/3 EPIC-HR Study Interim Analysis
In July 2021, Pfizer initiated the Phase 2/3 EPIC-HR (Evaluation of Protease Inhibition for COVID-19 in High-Risk Patients) randomized, double-blind study of non-hospitalized adult patients with COVID-19, who are at high risk of progressing to severe illness. The primary analysis of the interim data set evaluated data from 1,219 adults who were enrolled by September 29, 2021. At the time of the decision to stop recruiting patients, enrollment was at approximately 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 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 PF-07321332; ritonavir or placebo orally every 12 hours for five days.

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 PF-07321332; ritonavir 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 PF-07321332; ritonavir 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 PF-07321332; ritonavir as compared to 10 (1.6%) deaths in patients who received placebo.

The review of safety data included a larger cohort of 1,881 patients in EPIC-HR, whose data were available at the time of the analysis. Treatment-emergent adverse events were comparable between PF-07321332; ritonavir (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 PF-07321332; ritonavir compared to placebo, respectively.

About MPP
The Medicines Patent Pool (MPP) is a United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organizations, industry, patient groups, and other stakeholders, to prioritize and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, MPP has signed agreements with eleven patent holders for thirteen HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, a long-acting technology and two experimental oral antiviral treatments for COVID-19. MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC). MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government and SDC. More information at https://medicinespatentpool.org/ and follow us on Twitter, LinkedIn and YouTube.

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.

Pfizer Disclosure Notice
The information contained in this release is as of November 16, 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 PF-07321332 (including qualitative assessments of available data, potential benefits, expectations for clinical trials, advanced purchase agreements and an agreement with MPP, efforts toward equitable access, 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 PF-07321332; ritonavir may be filed in particular 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 or submissions for PF-07321332; ritonavir, 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; ritonavir, including development of products or therapies by other companies; risks related to the availability of raw materials for PF-07321332; ritonavir; 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 PF-07321332; ritonavir 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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