Pfizer to Provide New Zealand with 60,000 Treatment Courses of Investigational Oral Antiviral Candidate to Help Combat COVID-19

- *If approved, PF-07321332 in combination with ritonavir would be the first oral antiviral of its kind, a 3CL protease inhibitor specifically designed to combat SARS-CoV-2.*
- *Courses are expected to be delivered over 2022, subject to Medsafe approval.*
- *Pfizer has begun a rolling regulatory submission in New Zealand to Medsafe.*

AUCKLAND, NEW ZEALAND, 6 December 2021 — Pfizer New Zealand announced today an agreement with the New Zealand Government to supply 60,000 treatment courses of its investigational COVID-19 oral antiviral candidate, PF-07321332; ritonavir, subject to regulatory approval from Medsafe. If approved or authorised, PF-07321332; ritonavir would be the first oral antiviral of its kind, a 3CL protease inhibitor specifically designed to combat SARS-CoV-2. A rolling regulatory submission has commenced in New Zealand for provisional approval by Medsafe.

Under the terms of the agreement, the New Zealand Government will acquire an initial quantity of 60,000 treatment courses, subject to approval by Medsafe, to be delivered to New Zealand over the course of 2022. Pricing for PF-07321332; ritonavir, is based on the principles of advance commitment, volume, equity and affordability.

“We are honored to work with the New Zealand Government toward achieving our shared goal of addressing this public health crisis,” said Anne Harris, Pfizer New Zealand Managing Director. “If approved , oral protease inhibitor antiviral therapies may help to reduce the severity or onset of illness in adults who contract, or have been exposed to, COVID-19. An oral treatment option may thus be an important potential tool to help address the ongoing global impact of the COVID-19 pandemic,” Ms. Harris said.

“We were very encouraged by the recent results of our Phase 2/3 interim analysis, which showed overwhelming efficacy of PF-07321332; ritonavir in reducing the risk of hospitalisation compared to placebo among high-risk patients adults treated within three days of symptom onset by almost 90% and with no deaths, with similar results seen with those treated within five days, and are pleased that the New Zealand Government recognises this potential.

“It is promising to see a growing understanding of the valuable role that oral therapies may play in combatting COVID-19, and we look forward to continuing our discussions with the New Zealand Government to help ensure broad access for New Zealanders”, Ms Harris said.

PF-07321332; ritonavir is designed to block the activity of the SARS-CoV-2-3CL protease, an enzyme that the coronavirus needs to replicate, at a stage known as proteolysis – which occurs before viral RNA replication. 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. In preclinical studies, PF-07321332 did not demonstrate evidence of mutagenic DNA interactions. If authorised or approved, PF-07321332; ritonavir will be administered at a dose of 300mg (two 150mg tablets) of PF-07321332 with one 100mg tablet of ritonavir, given twice-daily for five days.

Our Commitment to Equitable Access
Pfizer is committed to working toward equitable access to PF-07321332; ritonavir for all people, aiming to deliver safe and effective antiviral therapeutics as soon as possible and at an affordable price. If authorised or approved, during the pandemic, Pfizer will offer our 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.

Pfizer will continue to invest up to approximately US$1 billion to support the manufacturing and distribution of this investigational treatment candidate, including exploring potential contract manufacturing options. It has entered into agreements with several countries and has initiated bilateral outreach to approximately 100 countries around the world. Additionally, Pfizer has signed a voluntary licensing agreement with the Medicines Patent Pool (MPP) to help expand access, pending regulatory authorisation or approval, in 95 low-and middle-income countries that account for approximately 53% of the world's population.

About the Phase 2/3 EPIC-HR Study Interim Analysis
In July 2021, Pfizer initiated 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-hospitalised 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 29 September, 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 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 randomised (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 hospitalisation or death from any cause compared to placebo in adults treated within three days of symptom onset (primary endpoint); 0.8% of patients who received PF-07321332; ritonavir were hospitalised through Day 28 following randomisation (3/389 hospitalised with no deaths), compared to 7.0% of patients who received placebo and were hospitalised or died (27/385 hospitalised with 7 subsequent deaths). The statistical significance of these results was high ($p<0.0001$). Similar reductions in COVID-19-related hospitalisation or death were observed in adults treated within five days of symptom onset; 1.0% of patients who received PF-07321332; ritonavir were hospitalised through Day 28 following randomisation (6/607 hospitalised, with no deaths), compared to 6.7% of patients who received a placebo (41/612 hospitalised 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 adult 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 adults dosed with PF-07321332; ritonavir compared to placebo, respectively.

About the EPIC Development Program
The EPIC (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19) Phase 2/3 development program for PF-07321332; ritonavir consists of three clinical trials spanning a broad spectrum of patients, including adults who have been exposed to the virus through household contacts, as well as adults at both standard risk and high risk of progressing to severe illness.

In July 2021, Pfizer initiated the first of these trials, known as EPIC-HR, a randomised, double-blind study of non-hospitalised adult patients with COVID-19, who are at high risk of progressing to severe illness. At the recommendation of an independent Data Monitoring Committee and in consultation with the U.S. FDA, Pfizer has ceased further enrollment into the study due to the overwhelming efficacy demonstrated in these results.

In August 2021, Pfizer began 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 adults 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 adults 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. These trials are ongoing.

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

About Pfizer New Zealand: Breakthroughs That Change Patients' Lives™
At Pfizer, we apply science and our global resources to improve health and wellbeing at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines. Our diversified global health care portfolio includes biologic and small molecule medicines and vaccines.

Consistent with our responsibility as one of the world's leading biopharmaceutical companies, we also collaborate with healthcare 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. To learn more, please visit us on www.pfizer.co.nz and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice

The information contained in this release is as of 6 December 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 COVID-19 oral antiviral clinical candidate, PF-07321332 in combination with ritonavir (including qualitative assessments of available data, potential benefits, expectations for clinical trials, an agreement with the New Zealand Government and the timing of delivery of courses thereunder, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorisations 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 for any potential indications for PF-07321332 or any other protease inhibitors may be filed in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications for PF-07321332 or any other protease inhibitors, 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 any other protease inhibitors, including development of products or therapies by other companies; risks related to the availability of raw materials to manufacture PF-07321332 or any other protease inhibitors; 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 for PF-07321332 or any other protease inhibitors, which would negatively impact our ability to supply the estimated numbers of courses of PF-07321332 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 31 December, 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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