First shipment of PAXLOVID, Pfizer's novel COVID-19 oral treatment arrives in New Zealand

- *PAXLOVID™ (nirmatrelvir [PF-07321332] tablets and ritonavir tablets) is the first oral treatment of its kind; it includes nirmatrelvir, a 3CL (or main) protease inhibitor specifically designed to combat SARS-CoV-2.*
- *Medsafe gave provisional consent for PAXLOVID for supply to New Zealand in early March 2022.*
- *Data demonstrated an 89% and 88% reduction in risk of COVID-19-related hospitalisation or death from any cause in adults treated with PAXLOVID within three and five days of symptom onset, respectively, compared to placebo.*

AUCKLAND, NEW ZEALAND, 31 March 2022 – Pfizer announced today that New Zealand has received its first delivery of PAXLOVID™ (nirmatrelvir [PF-07321332] tablets and ritonavir tablets), providing an important oral treatment for adults with COVID-19. This follows Medsafe's provisional consent for the supply and use of PAXLOVID in New Zealand in early March 2022. PAXLOVID has provisional consent for the treatment of coronavirus disease 2019 (COVID-19) in adults 18 years of age and older, who do not require initiation of supplemental oxygen due to COVID-19 and are at increased risk of progression to hospitalisation or death.

PAXLOVID is an oral treatment and should be taken within the first five days of symptomatic infection. Data demonstrated an 89% reduction in risk of COVID-19-related hospitalisation or death from any cause in adults treated with PAXLOVID compared to placebo in those treated within three days of symptom onset, with no deaths in the treatment group.

PAXLOVID is the first oral treatment of its kind; it includes nirmatrelvir, a 3CL protease (also known as Main protease or M^{pro}) inhibitor that was specifically developed in Pfizer's laboratories to combat SARS-CoV-2.

"This milestone in New Zealand is an important moment in our continued fight against COVID-19, paving the way for use of PAXLOVID as cases continue to rise and we address the threat of the current variant of concern, Omicron," said Anne Harris, Pfizer New Zealand Managing Director.

"Whilst vaccination remains the most effective way to help prevent COVID-19, this oral treatment provides us with another important line of defence - to reduce hospitalisations and save lives. PAXLOVID has the potential to transform COVID-19 treatment and help lessen the devastating impact of the virus that has now claimed nearly six million lives globally", Ms Harris said.

In December 2021, Pfizer announced an agreement with Pharmac to supply 60,000 treatment courses of PAXLOVID to New Zealand over 2022.

Medsafe based its decision on positive results from the Phase 2/3 EPIC-HR (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **H**igh-**R**isk Patients) interim analysis, which enrolled non-hospitalised adults aged 18 and older with confirmed COVID-19 who are at increased risk of progressing to severe illness. The data showed that PAXLOVID reduced the risk of hospitalisation or death by 89% (within three days of symptom onset) and 88% (within five days of symptom onset) compared to placebo, with no deaths observed in the treatment group. Treatment-emergent adverse events were comparable between PAXLOVID (23%) and placebo (24%), most of which were mild in intensity. These data were recently published in the *New England Journal of Medicine*. Additional Phase 2/3 clinical trials are ongoing in adults at standard risk (i.e., low risk of hospitalisation or death) of progressing to severe illness, and in those who have been exposed to the virus through household contacts.

About PAXLOVID™ (nirmatrelvir tablets and ritonavir tablets)
PAXLOVID is a SARS-CoV-2 main protease (M^{pro}) inhibitor (also known as SARS-CoV-2 3CL protease inhibitor) therapy. It was developed to be administered orally so that it can be prescribed at the first sign of infection or, pending clinical success of the rest of the EPIC development program and subject to regulatory authorisation, at first awareness of an exposure – potentially helping patients

avoid severe illness (which can lead to hospitalisation and death) or avoid disease development following contact with a household member who contracts COVID-19. Nirmatrelvir [PF-07321332], which originated in Pfizer laboratories, is designed to block the activity of the M^{pro}, an enzyme that the coronavirus needs to replicate. Co-administration with a low dose of ritonavir helps slow the metabolism, or breakdown, of nirmatrelvir in order for it to remain active in the body for longer periods of time at higher concentrations to help combat the virus.

Nirmatrelvir is designed to inhibit viral replication at a stage known as proteolysis, which occurs before viral RNA replication. In preclinical studies, nirmatrelvir did not demonstrate evidence of mutagenic DNA interactions.

Current variants of concern can be resistant to treatments that work by binding to the spike protein found on the surface of the SARS-CoV-2 virus. PAXLOVID, however, works intracellularly by binding to the highly conserved M^{pro} of the SARS-CoV-2 virus to inhibit viral replication. Nirmatrelvir has shown consistent *in vitro* antiviral activity against earlier and current variants of concern (i.e., Alpha, Beta, Delta, Gamma, Lambda, Mu, and Omicron).

PAXLOVID is generally administered at a dose of 300 mg (two 150 mg tablets) of nirmatrelvir with one 100 mg tablet of ritonavir, given twice-daily for five days. One carton contains five blister packs of PAXLOVID, as co-packaged nirmatrelvir tablets with ritonavir tablets, providing all required doses for a full five-day treatment course.

Our 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. During the pandemic, Pfizer will offer its oral therapy through a tiered pricing approach, pending country authorisation or approval, 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 continues to invest to support the manufacturing and distribution of PAXLOVID, including exploring potential contract manufacturing options. As a result of these efforts, Pfizer has raised its production projections, with the ability to produce up to 120 million courses of treatment by the end of 2022, pending global demand.

The company has initiated bilateral outreach to more than 100 countries around the world and has entered into agreements with multiple countries. Additionally, Pfizer has signed a voluntary license agreement with the Medicines Patent Pool (MPP) for its oral treatment to help expand access, pending country regulatory authorisation or approval, in 95 low- and middle-income countries that account for approximately 53% of the world's population.

About the EPIC Development Program
The EPIC (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19) Phase 2/3 development program for PAXLOVID consists of four clinical trials spanning a broad spectrum of participants, including adults who have been exposed to the virus through household contacts, adults at both standard risk and high risk of progressing to severe illness, and children under the age of 18 at risk of progressing to severe disease.

In July 2021, Pfizer initiated the first of these trials, known as EPIC-HR (**E**valuation of **P**rotease **I**nhibition for **C**OVID-19 in **Hi**gh-**R**isk Patients), a randomised, double-blind study of non-hospitalised adults 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 ceased further enrollment into the study in early November 2021 due to the overwhelming efficacy demonstrated in these results. Findings from the EPIC-HR final analysis were published online in *The New England Journal of Medicine* on February 16, 2022.

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) study 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 hospitalisation or death). Interim data from this study have been reported. Pfizer is currently expanding the population of the ongoing EPIC-SR study by approximately 800 participants and expects to share results later this year.

In September 2021, 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) study to evaluate efficacy and safety in adults exposed to SARS-CoV-2 by a household member. This trial is also ongoing, and Pfizer expects to share results later this year.

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

About the EPIC-HR Final Results
In the final analysis of the primary endpoint from all patients enrolled in EPIC-HR, an 89% reduction in COVID-19-related hospitalisation or death from any cause compared to placebo in patients treated within three days of symptom onset was observed, consistent with the interim analysis. In addition, a consistent safety profile was observed.

0.7% of patients who received PAXLOVID were hospitalised through Day 28 following randomisation (5/697 hospitalised with no deaths), compared to 6.5% of patients who received placebo and were hospitalised or died (44/682 hospitalised with 9 subsequent deaths). The statistical significance of these results was high ($p<0.0001$). In a secondary endpoint, PAXLOVID reduced the risk of hospitalisation or death from any cause by 88% compared to placebo in patients treated within five days of symptom onset; 0.8% of patients who received PAXLOVID were hospitalised or died through Day 28 following randomisation (8/1039 hospitalised with no deaths), compared to 6.3% of patients who received placebo (66/1046 hospitalised with 12 subsequent deaths), with high statistical significance ($p<0.0001$). In the overall study population through Day 34, no deaths were reported in patients who received PAXLOVID as compared to 13 deaths in patients who received placebo.
In the EPIC-HR trial, in a secondary endpoint, SARS-CoV-2 viral load at baseline and Day 5 have been evaluated for 1574 patients. After accounting for baseline viral load, geographic region, and serology status, PAXLOVID reduced viral load by approximately 10-fold relative to placebo when treatment was initiated within three days of symptom onset, indicating robust activity against SARS-CoV-2 and representing the strongest viral load reduction reported to date for an oral COVID-19 agent.

Treatment-emergent adverse events were comparable between PAXLOVID (23%) and placebo (24%), most of which were mild in intensity. Fewer serious adverse events (1.6% vs. 6.6%) and discontinuation of study drug due to adverse events (2.1% vs. 4.2%) were observed in patients dosed with PAXLOVID, compared to placebo, respectively.

All other secondary endpoints for this study, which are available on clinicaltrials.gov (NCT04960202) and EudraCT (2021-002895-38), were not yet available for this review.

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. For more information, please visit: www.pfizer.co.nz

Disclosure Notice
The information contained in this release is as of 31 March 2022. 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 statement contains forward-looking information about Pfizer's efforts to combat COVID-19 and PAXLOVID (including a Phase 2/3 study in pediatric patients, a potential age-appropriate formulation for three additional planned cohorts of younger than 6 years old, qualitative assessments of available data, potential benefits, expectations for clinical trials, advance purchase agreements and an agreement with MPP, efforts toward equitable access, the anticipated timing of data readouts, regulatory submissions, regulatory approvals or authorisations, potential to maintain antiviral activity

against current variants of concern, 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, including the risk that final results from EPIC-SR could differ from the interim 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 commercialisation; the ability of PAXLOVID to maintain efficacy against emerging virus variants; the risk that serious and unexpected adverse events may occur that have not been previously reported with PAXLOVID use; 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 authorisation for any potential indications for PAXLOVID may be filed in particular jurisdictions and if obtained, whether or when such emergency use authorisation or licenses will expire or terminate; whether and when regulatory authorities in any jurisdictions may approve any applications or submissions for PAXLOVID that may be pending or filed (including a potential new drug application submission in the U.S. and submissions in other jurisdictions), 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, 2021 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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Pfizer Media Relations Contacts:

New Zealand Media Contact
mediaANZ@pfizer.com
+64 275 540 500

Asia Media Contacts
Trupti Wagh
+65 9187 3247
trupti.wagh@pfizer.com

Roma Nair
+91 99870 08170
roma.nair@pfizer.com