A Study of PF-07321332/Ritonavir in Nonhospitalized High Risk Adult Participants With COVID-19

ClinicalTrials.gov Identifier: NCT04960202

Recruitment Status : Recruiting
First Posted : July 13, 2021
Last Update Posted : September 21, 2021

See Contacts and Locations

Sponsor:
Pfizer

Information provided by (Responsible Party):
Pfizer

Study Description

Go to

Brief Summary:
The purpose of this study is to determine whether PF-07321332/ritonavir is safe and effective for the treatment of adults who are ill with COVID-19 and do not need to be in the hospital, but are at an increased risk of developing severe illness. Throughout the study period, provision will be made to allow study visits to be conducted at a participant's home or another non-clinic location if available. The total study duration is up to 24 weeks.

Condition or disease	Intervention/treatment	Phase
COVID-19	Drug: PF-07321332	Phase 3

	Drug: Ritonavir Drug: Placebo	

Study Design

Go to

Study Type :
Interventional (Clinical Trial)

Estimated Enrollment :
3000 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

Intervention Model Description:
Eligible participants with a confirmed diagnosis of SARS-CoV-2 infection will be randomized (1:1) to receive PF-07321332/ritonavir or placebo orally every 12 hours for 5 days (10 doses total).

Masking:
Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose:
Treatment

Official Title:
AN INTERVENTIONAL EFFICACY AND SAFETY, PHASE 2/3, DOUBLE-BLIND, 2-ARM STUDY TO INVESTIGATE ORALLY ADMINISTERED PF-07321332/RITONAVIR COMPARED WITH PLACEBO IN NONHOSPITALIZED SYMPTOMATIC ADULT PARTICIPANTS WITH COVID-19 WHO ARE AT INCREASED RISK OF PROGRESSING TO SEVERE ILLNESS

Actual Study Start Date :
July 16, 2021

Estimated Primary Completion Date :
November 26, 2021

Estimated Study Completion Date :
April 8, 2022

Resource links provided by the National Library of Medicine

Drug Information available for: Ritonavir

U.S. FDA Resources

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: PF-07321332/ritonavir Orally administered PF-07321332+ritonavir	Drug: PF-07321332 PF-07321332 (tablet) Drug: Ritonavir Ritonavir (capsule)
Placebo Comparator: Placebo Orally administered placebo	Drug: Placebo Placebo (tablet or capsule)

Outcome Measures

Go to

Primary Outcome Measures :

1. Proportion of participants with COVID-19 related hospitalization or death from any cause [Time Frame: Day 1 through Day 28]

Secondary Outcome Measures :

1. Incidence of Adverse Events (AEs) and Serious Adverse Events (SAEs)of PF-07321332/ritonavir relative to placebo [Time Frame: Day 1 through Day 34]
2. Incidence of Treatment-emergent Adverse Events (TEAEs) of PF-07321332/ritonavir relative to placebo of PF-07321332/ritonavir relative to placebo [Time Frame: Day 1 through Day 34]
3. Duration of each targeted COVID-19 sign/symptom [Time Frame: Day 1 through Day 28]
4. Severity of each targeted COVID-19 sign/symptom [Time Frame: Day 1 through Day 28]
5. Proportion of participants with death (all cause) [Time Frame: Day 1 through Week 24]
6. To determine the pharmacokinetics (PK) in plasma and whole blood of PF-07321332 in nonhospitalized symptomatic adult participants with COVID 19 who are at increased risk of progression to severe disease [Time Frame: Day 1 through Day 5]
7. Viral titers measured by Reverse Transcription Polymerase Chain Reaction (RT-PCR) in nasal swabs [Time Frame: Day 1 through Day 14]
8. Number of COVID-19 related medical visits other than hospitalization [Time Frame: Day 1 through Day 34]
9. Number of days in hospital and intensive care unit for the treatment of COVID-19 [Time Frame: Day 1 through Day 34]

Eligibility Criteria

Go to

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Confirmed SARS-CoV-2 infection within 5 days prior to randomization
- Initial onset of COVID-19 signs/symptoms within 5 days prior to the day of randomization and at least 1 of the specified COVID-19 signs/symptoms present on the day of randomization
- Fertile participants must agree to use a highly effective method of contraception
- Has at least 1 characteristic or underlying medical condition associated with an increased risk of developing severe illness from COVID-19

Exclusion Criteria:

- History of or need for hospitalization for the medical treatment of COVID-19
- Prior to current disease episode, any confirmed SARS-CoV-2 infection
- Known medical history of active liver disease
- Receiving dialysis or have known moderate to severe renal impairment
- Known human immunodeficiency virus (HIV) infection with a viral load greater than 400 copies/mL or taking prohibited medications for HIV treatment
- Suspected or confirmed concurrent active systemic infection other than COVID-19
- History of hypersensitivity or other contraindication to any of the components of the study intervention
- Current or expected use of any medications or substances that are highly dependent on CYP3A4 for clearance or are strong inducers of CYP3A4
- Has received or is expected to receive convalescent COVID-19 plasma

- Has received or is expected to receive any dose of a SARS-CoV-2 vaccine before the Day 34 visit
- Participating in another interventional clinical study with an investigational compound or device, including those for COVID-19 through the long-term follow-up visit
- Known prior participation in this trial or other trial involving PF-07321332
- Oxygen saturation of <92% on room air, or on their standard home oxygen supplementation for those who regularly receive chronic supplementary oxygen for an underlying lung condition
- Females who are pregnant or breastfeeding

Contacts and Locations

Go to

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04960202***

Contacts

Contact: Pfizer CT.gov Call Center 1-800-718-1021 ClinicalTrials.gov_Inquiries@pfizer.com

Locations

Show 283 study locations

Sponsors and Collaborators

Pfizer

Investigators

Study Director: Pfizer CT.gov Call Center Pfizer

More Information

Go to

Additional Information:

To obtain contact information for a study center near you, click here. EXIT

Responsible Party:

Pfizer

ClinicalTrials.gov Identifier:

NCT04960202 History of Changes

Other Study ID Numbers:

C4671005

2021-002895-38 (EudraCT Number)

First Posted:

July 13, 2021 Key Record Dates

Last Update Posted:

September 21, 2021

Last Verified:

September 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

Yes

Plan Description:

Pfizer will provide access to individual de-identified participant data and related study documents (e.g. protocol, Statistical Analysis Plan (SAP), Clinical Study Report (CSR)) upon request from qualified researchers, and subject to certain criteria, conditions, and exceptions. Further details on Pfizer's data sharing criteria and process for requesting access can be found at: https://www.pfizer.com/science/clinical_trials/trial_data_and_results/data_requests.

URL:

https://www.pfizer.com/science/clinical_trials/trial_data_and_results/data_requests

Studies a U.S. FDA-regulated Drug Product:

Yes

Studies a U.S. FDA-regulated Device Product:

No

Keywords provided by Pfizer:

SARS-CoV-2

Additional relevant MeSH terms:

COVID-19
Respiratory Tract Infections
Infections
Pneumonia, Viral
Pneumonia
Virus Diseases
Coronavirus Infections
Coronaviridae Infections
Nidovirales Infections
RNA Virus Infections
Lung Diseases
Respiratory Tract Diseases
Ritonavir
HIV Protease Inhibitors
Viral Protease Inhibitors
Protease Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Anti-HIV Agents
Anti-Retroviral Agents
Antiviral Agents
Anti-Infective Agents
Cytochrome P-450 CYP3A Inhibitors
Cytochrome P-450 Enzyme Inhibitors