A Study to Learn About the Study Medicine Ibuzatrelvir in Adults With COVID-19 Who Are Severely Immunocompromised

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. 18 years of age or older at screening who are non-hospitalized or hospitalized for observation or with the intent of administering the study intervention. 2. Confirmed SARS-CoV-2 infection as determined by RAT (or other locally approved test) collected within 2 days prior to randomization. Initial onset of symptoms attributable to COVID-19 within 5 days prior to the day of randomization and at least 1 of the specified symptoms attributable to COVID-19 present on the day of randomization. 3. Severely immunocompromised due to: * Solid organ or islet cell transplant recipient who is receiving immunosuppressive therapy; * Active hematologic malignancy (eg, chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia); * Receipt of CAR-T-cell therapy or HCT either within 2 years of transplantation or who are receiving immunosuppressive therapy; * Currently receiving or recently received B-cell depleting therapies (eg, rituximab), where the immunosuppressive effect is still ongoing.

Exclusion Criteria:

1. Severe COVID-19, or current need for supplemental oxygen for treatment of COVID-19. 2. Receiving dialysis or have current kidney failure (ie, eGFR consistently \<15 mL/min/1.73 m2) 3. Active liver disease 4. History of hypersensitivity or other contraindication to any of the components of the study interventions, as determined by the investigator 5. Suspected or confirmed concurrent active systemic infection other than COVID-19 that may interfere with the evaluation of response to the study intervention. 6. Life expectancy less than 30 days at study entry due to an underlying condition, in the judgement of the investigator. 7. Any medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study. 8. Has received any other antiviral for the treatment of the current COVID-19 infection 9. Current use of any prohibited concomitant medication(s) or unwillingness or inability to use a required concomitant medication(s). 10. Current or previous administration of an investigational product (drug or vaccine) within 30 days (or as determined by local requirement) or 5 half lives preceding the first dose of study intervention used in this study (whichever is longer). Authorized or products with conditional approval are not considered investigational. 11. Prior participation in this trial or any clinical trial of ibuzatrelvir. 12. Females who are pregnant, breastfeeding, or who are planning to become pregnant within the timeframe of the study. 13. Investigator site staff directly involved in the conduct of the study and their family members, site staff otherwise supervised by the investigator, and sponsor and sponsor delegate employees directly involved in the conduct of the study and their family members.

Conditions & Interventions

Interventions:
DRUG: ibuzatrelvir, DRUG: remdesivir, DRUG: placebo for ibuzatrelvir, DRUG: placebo for remdesivir
Conditions:
COVID-19 Infection
Keywords:
COVID-19 infection, pneumonia, respiratory tract infections, coronavirus infection, RNA virus infection, lung disease, pneumonia, viral, infections, virus, viral protease inhibitor, protease inhibitor, enzyme inhibitor, severe immunocompromise, anti-viral agents, anti-infectives, ibuzatrelvir, remdesivir, COVID-19

More Information

Contact(s): Pfizer CT.gov Call Center - ClinicalTrials.gov_Inquiries@pfizer.com
Principal Investigator:
IRB
Number:
System ID: NCT07013474
