A Study to Learn About a Study Medicine Called Ibuzatrelvir in Adult and Adolescent Patients With COVID-19 Who Are Not Hospitalized But Are at Risk For Severe Disease

Status: RECRUITING

Eligibility Criteria

Age: 12 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. 12 to \<18 years of age, weighing at least 40 kg, or ≥18 years of age of any weight at screening. 2. Presence of risk factors for progression to severe COVID-19 at the time of screening based on age: 1. 12 to 49 years of age with at least two risk factors, where one must be moderate immunocompromise; 2. 50 to 64 years of age with at least two risk factors; 3. 65 to 74 years of age with at least one risk factor; 4. For participants 75 years of age or older, there are no requirements related to risk factors. The list of risk factors includes: BMI ≥35 kg/m2; Current smoker; Chronic lung disease; Cardiovascular disease; Type 1 or Type 2 diabetes mellitus; Mild to moderate renal impairment; Neurodevelopmental disorders; Sickle cell disease; Moderate immunosuppression. 3. Confirmed SARS-CoV-2 infection as determined by RAT in nasal or NP specimen collected within 1 day prior to randomization. Initial onset of symptoms attributable to COVID-19 within 5 days prior to randomization and at least 1 of the specified symptoms attributable to COVID-19 present on the day of randomization. Randomization must occur no later than the 5th day, where the onset of symptoms is the first day. 4. Participants must be unable or unwilling to take nirmatrelvir/ritonavir.

Exclusion Criteria:

1. Current need or anticipated need for hospitalization within 24 hours, due to signs of severe COVID-19 illness (eg, SpO2 \<94% on room air, respiratory rate \>30 breaths/minute, or lung infiltrates \>50%) or due to other medical conditions requiring hospitalization in the opinion of the site investigator. 2. Receiving dialysis or have known severe renal impairment \[ie, eGFR consistently \<30 mL/min/1.73 m2 for adults or CrCl \<30 mL/min for adolescents\], using the serum creatinine-based CKD-EPI formula or the Cockroft Gault, respectively. 3. Active liver disease with AST or ALT \>3 ULN, Total bilirubin ≥2 × ULN (for Gilbert's syndrome, direct bilirubin \>ULN is exclusionary) within the past 3 months, or liver function impairment with Class C per Child Pugh classification. 4. Suspected or confirmed concurrent active systemic infection other than COVID-19 that may interfere with the evaluation of response to the study intervention. 5. Ongoing Long COVID or Post Acute Sequelae of COVID-19 diagnosis. 6. Severely immunocompromised. 7. Any comorbidity requiring hospitalization and/or surgery within 7 days prior to study entry, or that is considered life threatening within 30 days prior to study entry, as determined by the investigator. 8. History of hypersensitivity or other contraindication to any of the components of the study interventions. 9. 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. 10. Current use of any prohibited concomitant medication(s). 10.Has received any other antiviral for the treatment of COVID-19, including remdesivir, nirmatrelvir/ritonavir, molnupiravir, or COVID-19 mAbs within 30 days or 5 half-lives \[whichever is longer\] prior to screening, or received convalescent COVID-19 plasma within 12 months. 12.Received any dose of a COVID-19 vaccine within 4 months of randomization or expected to receive one through Day 34. 13.Previous administration of an investigational product (drug or vaccine) within 30 days or 5 half lives preceding the first dose of study intervention used in this study (whichever is longer). 14.Prior participation in this clinical trial or any other clinical trial of ibuzatrelvir. 15.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: placebo
Conditions:
COVID-19 SARS-CoV-2 Infection
Keywords:
Pneumonia, Viral, Pneumonia, Respiratory Tract Infections, Infections, Virus Diseases, Coronavirus Infections, Coronaviridae Infections, Nidovirales Infections, RNA Virus Infections, Lung Diseases, Respiratory Tract Diseases, COVID-19, Viral Protease Inhibitors, Protease Inhibitors, Enzyme Inhibitors, Molecular Mechanisms of Pharmacological Action, Antiviral Agents, Anti-Infective Agents, ibuzatrelvir

More Information

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