A Study of LY3819253 (LY-CoV555) and LY3832479 (LY-CoV016) in Participants With Mild to Moderate COVID-19 Illness

Status: Recruiting

Eligibility Criteria

Age: 0 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

• Are currently not hospitalized. (Not applicable to participants in treatment arm 22.)

• Have one or more mild or moderate COVID-19 symptoms: Fever, cough, sore throat, malaise, headache, muscle pain, gastrointestinal symptoms, or shortness of breatl with exertion. (Not applicable to participants in treatment arm 22.)

• Must have sample taken for test confirming viral infection no more than 3 days prior to starting the drug infusion

• Are males or females, including pregnant females who agree to contraceptive requirements

• Understand and agree to comply with planned study procedures

• Agree to the collection of nasopharyngeal swabs and venous blood. (Not applicable to participants in treatment arms 20-21.)

• The participant or legally authorized representative give signed informed consent and/or assent Participants in treatment arms 7-9, 13-14, and 18-21 ONLY

• Are greater than or equal to (≥)18 years of age and must satisfy at least one of the following at the time of screening

• Are pregnant

• Are ≥65 years of age

• Have a body mass index (BMI) ≥35

• Have chronic kidney disease (CKD)

• Have type 1 or type 2 diabetes

• Have immunosuppressive disease

• Are currently receiving immunosuppressive treatment or

• Are ≥55 years of age AND have:

• cardiovascular disease (CVD), OR

• hypertension, OR

• chronic obstructive pulmonary disease (COPD) or other chronic respiratory disease

• Are 12-17 years of age (inclusive) AND satisfy at least one of the following at the time of screening

• Are pregnant

• Have a body mass index (BMI) ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm

• Have sickle cell disease

• Have congenital or acquired heart disease

• Have neurodevelopmental disorders, for example, cerebral palsy

• Have a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)

• Have asthma or reactive airway or other chronic respiratory disease that requires daily medication for control

• Have type 1 or type 2 diabetes

• Have chronic kidney disease

• Have immunosuppressive disease, or

• Are currently receiving immunosuppressive treatment Participants in treatment arm 22 ONLY

•Are 0 (≥ 32 weeks gestational age AND ≥ 1.5 kilograms [kg]) to 17 years of age (inclusive) AND satisfy at least one of the following risk factors at the time of screening

• Are pregnant

• Have a BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm

• Have sickle cell disease

• Have congenital or acquired heart disease

• Have neurodevelopmental disorders, for example, cerebral palsy, autism, or Down syndrome (FAIR Health 2020; Spreat et al. 2020)

• Have a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)

• Have asthma, cystic fibrosis, reactive airways disease or other chronic respiratory disease that requires daily medication for control

• Have type 1 or type 2 diabetes

• Have chronic kidney disease

• Have immunosuppressive disease, or

• Are currently receiving immunosuppressive treatment, or

• Are less than (<) one year of age.

• Have one or more COVID-19 symptoms

• Shortness of breath/difficulty breathing

• Fever

• Sore throat

• Nausea

• Diarrhea

• Tiredness

• Headache

• New loss of taste

• Nasal congestion/runny nose

• Chills

• Stomachache

• Vomiting

• Cough

• Muscle/body aches and pain

• New loss of smell

• Poor appetite or poor feeding (in babies) Participants in treatment arm 23 ONLY: Must have first positive result sample of current SARS-CoV-2 viral infection ≤3 days prior to start of treatment administration. Participant can have COVID previously and still meet criteria for this addendum. Positive result needs to be from a current infection. Are 0 (≥ 38 weeks gestational age and ≥ 3.3 kg) to <12 years of age at the time of screening, or are 12 to 17 and weighing <40 kg; and

• Have mild to moderate COVID-19 disease, including one or more COVID-19 symptoms within the last 7 days

• Shortness of breath/difficulty breathing

• Fever

• Sore throat

• Nausea

• Diarrhea

• Tiredness

• Headache

• New loss of taste

• Nasal congestion/runny nose

• Chills

• Malaise

• Vomiting

• Cough

• Muscle/body aches and pain

• New loss of smell

• Poor appetite or poor feeding (in babies under 1 year old)

Exclusion Criteria:

• Have oxygen saturation (SpO2) less than or equal to (≤)93 percent (%) on room air at sea level or ratio of arterial oxygen partial pressure (PaO2 in millimeters of mercury) to fractional inspired oxygen (FiO2) less than (<)300, respiratory rate greater than or equal to (≥)30 per minute, heart rate ≥125 per minute due to COVID-19

• Require mechanical ventilation or anticipated impending need for mechanical ventilation due to COVID-19

• Have known allergies to any of the components used in the formulation of the interventions

• Have hemodynamic instability requiring use of pressors within 24 hours of randomization

• Suspected or proven serious, active bacterial, fungal, viral, or other infection (besides COVID-19) that in the opinion of the investigator could constitute a risk when taking intervention

• Have any co-morbidity requiring surgery within <7 days, or that is considered life-threatening within 29 days

• Have any serious concomitant systemic disease, condition or disorder that, in the opinion of the investigator, should preclude participation in this study

• Have a history of a positive SARS-CoV-2 test prior to the one serving as eligibility for this study

• Have received an investigational intervention for SARS-CoV-2 prophylaxis within 30 days before dosing

• Have received treatment with a SARS-CoV-2 specific monoclonal antibody

• Have received convalescent COVID-19 plasma treatment

• Have participated in a previous SARS-CoV-2 vaccine study or have received a SARS-CoV-2 vaccine

• Have participated, within the last 30 days, in a clinical study involving an investigational intervention. If the previous investigational intervention has a long half-life, 5 half-lives or 30 days, whichever is longer, should have passed

• Are concurrently enrolled in any other type of medical research judged not to be scientifically or medically compatible with this study

• Mothers who are breast feeding Participants in Treatment Arm 22 ONLY

• Have a diagnosis of Multisystem Inflammatory Syndrome in Children (MIS-C) in the opinion of the investigator

• Are currently hospitalized for treatment of COVID-19. Other reasons for hospitalization are acceptable. Participants in treatment arm 23 ONLY

• SpO2 ≤ 93% on room air at sea level, or while on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity, respiratory rate ≥30 per minute, and heart rate ≥125 per minute due to COVID-19 (FDA February 2021)

• Require mechanical ventilation or anticipated impending need for mechanical ventilation due to COVID-19

• Have known allergies to any of the components used in the formulation of the interventions

• Have hemodynamic instability requiring use of pressors within 24 hours of randomization

• Suspected or proven serious, active bacterial, fungal, viral, or other infection (besides COVID-19) that in the opinion of the investigator could constitute a risk when taking intervention

• Have any co-morbidity requiring surgery within 7 days, or that is considered life-threatening within 29 days

• Have any serious concomitant systemic disease, condition or disorder that, in the opinion of the investigator, should preclude participation in this study.

• Have received treatment with a SARS-CoV-2 specific monoclonal antibody or remdesivir within 90 days before dosing.

• Have received convalescent COVID-19 plasma treatment within 90 days before dosing

• Have participated, within the last 30 days, in a clinical study involving an investigational intervention. If the previous investigational intervention has a long half-life, 5 half-lives or 30 days, whichever is longer, should have passed

• Are concurrently enrolled in any other type of medical research judged not to be scientifically or medically compatible with this study

• Are currently pregnant or breast feeding

Conditions & Interventions

Interventions:
Drug: LY3819253, Drug: LY3832479, Drug: LY3853113, Drug: Placebo
Conditions:
COVID-19

More Information

Contact(s): There may be multiple sites in this clinical trial. 1-877-CTLILLY (1-877-285-4559) or - ClinicalTrials.gov@lilly.com
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Phase: Phase 2/Phase 3
IRB
Number: HM20022495
System ID: NCT04427501