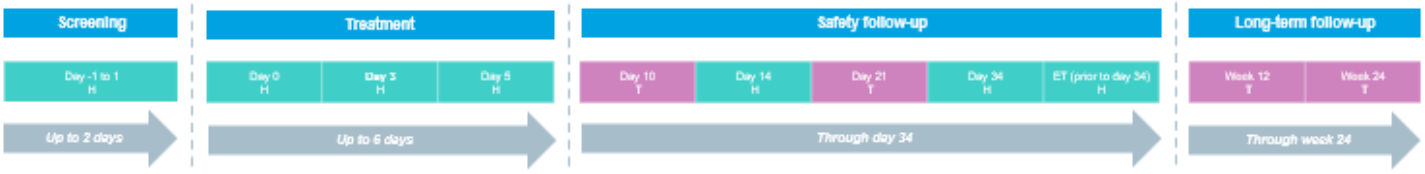
Lightship

COVID-19 Treatment Study

Study Overview:
At present, there are no good treatment options available for mild COVID-19 cases. Lightship is helping a sponsor-partner launch a virtual site for an upcoming clinical research study, testing an oral therapy for mild COVID-19 cases. High-risk study patients must not have received a COVID-19 vaccine and must have a positive COVID-19 test to be enrolled in the study. We would like to offer patients who test positive at your site the opportunity to participate in this trial.

Participation Details:
Participation in this study will be fully remote, which means that study patients can take part via telemedicine for some visits and with a nurse visiting their home for others. After screening, study patients will take an oral antiretroviral therapy for 5 days, then participate in a safety follow-up period for 34 days. There will also be a long-term follow-up period for 24 weeks. The entire study consists of 6 home visits and 4 telemedicine visits in total.



Study Timelines:
- Enrolment period: ~3 weeks (mid-July '21 – August '21)
- Screening: up to 2 days
- Treatment: through day 5
- Follow-up: through day 34
- Long-term follow-up: through week 24

High-Level Inclusion / Exclusion:

Inclusion
Participants ≥18 years of age
Confirmed SARS-CoV-2 infection as determined by RT-PCR in any specimen collected within 5 days prior to randomization
Initial onset of signs / symptoms attributable to COVID-19 within 5 days prior to the day of randomization and at least 1 of the specified signs / symptoms attributable to COVID-19 present on the day of randomization
Has at least 1 characteristic or underlying medical condition associated with an increased risk of developing severe illness from COVID-19 including: • ≥60 years of age • BMI >25 • Current smoker (cigarette smoking within the past 30 days) and history of at least 100 lifetime cigarettes • Immunosuppressive disease (e.g., bone marrow or organ transplantation or primary immune deficiencies) OR prolonged use of immune-weakening medications: ○ Has received corticosteroids equivalent to prednisone ≥20 mg daily for at least 14 consecutive days within 30 days prior to study entry

○ Has received treatment with biologics (e.g., infliximab, ustekinumab), immunomodulators (e.g., methotrexate, 6MP, azathioprine) or cancer chemotherapy within 90 days prior to study entry ○ HIV infection with CD4 cell count <200 mm3 and a viral load less than 400 copies / mL • Chronic lung disease (if asthma, requires daily prescribed therapy) • Known diagnosis of hypertension • CVD, defined as history of any of the following: myocardial infarction, stroke, TIA, HF, angina with prescribed nitroglycerin, CABG, PCI, carotid endarterectomy, and aortic bypass • Type 1 or Type 2 diabetes mellitus • CKD provided the participant is NOT receiving dialysis or has known moderate to severe renal impairment within 6 months of the screening visit • Sickle cell disease • Neurodevelopmental disorders (e.g., cerebral palsy, Down's syndrome) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies) • Active cancer, other than localized skin cancer, including those requiring treatment as long as the treatment is not among the prohibited medications that must be administered/continued during the trial period • Medical-related technological dependence (e.g., CPAP [not related to COVID-19])
Exclusion
History of hospitalization for the medical treatment of COVID-19
Current need for hospitalization or anticipated need for hospitalization within 48 hours after randomization in the clinical opinion of the site investigator
Prior to current diagnosis, any previous laboratory-confirmed SARS-CoV-2 infection, as determined by a molecular test (antigen or nucleic acid) from any specimen collection ≥5 days prior to randomization
Has received or is expected to receive any dose of a SARS-CoV-2 vaccine before the Day 34 visit

Contact:
To refer a patient, please call the following line:
Physician line: (858) 290-6135

Or have a patient call the following line:
Patient line: (858) 290-6133

About Lightship:
Lightship is the virtual-first service provider that is perfecting the way clinical trials get done. Because clinical research plays such a vital role in bringing life-enhancing and life-saving innovations to market, Lightship pursues operational excellence to clinical studies. Our end-to-end hybrid delivery model, our diversity of skillsets, and in-house care team ensure sponsor success and the best possible patient experience. With a problem-solving mindset, we strive to make every clinical trial better than the last. Operational excellence is not a goal, but a way of doing things at Lightship.