A Study to Evaluate the Safety and Efficacy of Razuprotafib, a Novel Tie 2 Activator, in Hospitalized Subjects With Moderate to Severe Coronavirus Disease 2019 (COVID-19)

**Status:** Recruiting

### Eligibility Criteria

**Sex:** All  
**Age:** 18 Years and over  
**Healthy Volunteers:** This study is NOT accepting healthy volunteers

#### Inclusion Criteria:

1. Ability to understand and provide informed consent;  
2. Males and non-pregnant females 18 years of age or older at the time of Screening;  
3. Laboratory-confirmed active SARS-CoV-2 infection within 72 hours prior to randomization, or (if testing results cannot be obtained) by evidence of progressive disease suggestive of ongoing SARS-CoV-2 infection;  
4. Females of childbearing potential must be willing to completely abstain or agree to use a highly effective method of contraception through Day 28; and have a negative urine pregnancy test during Screening;  
5. Currently hospitalized, receiving standard of care therapy for COVID-19, and meets the criteria for moderate or severe COVID-19, as follows: Moderate = symptoms of moderate illness with COVID-19, which could include any symptom of mild illness or shortness of breath with exertion and with respiratory rate at 20 or greater breaths/min, SpO2 >93% on room air at sea level, or heart rate at 90 or greater beats/min; Severe = symptoms suggestive of severe systemic illness with COVID-19, which could include any symptom of moderate illness, shortness of breath at rest, or respiratory distress, and respiratory rate at 30 or greater breaths/min, heart rate at 125 or greater beats/min, or SpO2 >93% on room air at sea level or PaO2:FiO2 <300.

#### Exclusion Criteria:

1. Inability to initiate study drug within 12 hours after randomization;  
2. Female of childbearing potential who is unable or unwilling to forego breastfeeding through Day 28;  
3. Systolic blood pressure <100 mmHg;  
4. In shock or requiring pressor support;  
5. Respiratory failure, defined as subjects who are on mechanical ventilation; receiving oxygen delivered by high-flow nasal cannula (heated, humidified, oxygen delivered via reinforced nasal cannula at flow rates >20 L/min with fraction of delivered oxygen of 0.5 or greater), noninvasive positive pressure ventilation, or extracorporeal membrane oxygenation (ECMO); or have a clinical diagnosis of respiratory failure (ie, clinical need for 1 of the preceding therapies, but preceding therapies not able to be administered in setting of resource limitation);  
6. Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >3 × the upper limit of normal (ULN);  
7. Total bilirubin >2 × ULN;  
8. Estimated glomerular filtration rate <30 mL/min or receiving hemodialysis or hemofiltration;  
9. Moribund subject not expected to survive 24 hours in the opinion of the treating clinical team;  
10. Any concurrent serious medical condition (eg, active malignancies on chemotherapy, post organ transplant, end stage congestive heart failure) or not likely to respond to treatment;  
11. Decision to withhold life-sustaining treatment; Note: In the event of cardiac arrest, the decision to withhold cardiopulmonary resuscitation only does not fulfill this exclusion criterion.  
12. Use of cytochrome P450 (CYP) 2C8 substrates (eg, repaglinide, paclitaxel, or cerivastatin) or CYP3A4 substrates (eg, amiodipine, budesonide, dasabuvir, enzanlutamide, imatinib, lopinavir, loperamide, saquinavir, sildenafil, midazolam, or montelukast);  
13. Use of CYP2C8 inhibitors (eg, gemfibrozil, fluvoxamine, or ketoconazole);  
14. Participation in another investigational study during the present study through the last visit (Day 28); or  
15. Previous randomization in this study.

### Conditions & Interventions

**Interventions:**  
Drug: Razuprotafib Subcutaneous Solution, Drug: Placebo Subcutaneous Solution

**Conditions:**  
COVID-19, Acute Respiratory Distress Syndrome

**Keywords:**  
COVID-19, ARDS, Coronavirus SARS-CoV-2

### More Information

**Contact(s):** sfinder@umn.edu  
**Phase:** Phase 2  
**IRB Number:**  
**System ID:** NCT04511650

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