NIH Remdesivir ACCT-3 Inclusion and Exclusion Criteria (8.13.20)

Patients with COVID pneumonia (same criteria as ACTT-1 and 2) are randomized 1:1 to receive: Remdesivir + either Interferon beta-1a (Rebif) or matching placebo (SC). Steroids are allowed per NIH guidelines and Montefiore protocol. Convalescent plasma is an exclusion.
To refer a patient who may be eligible please email: COVID-NIH-AdaptiveTreatmentTrial-StudyTeam-MOSES@montefiore.org

Full inclusion and exclusion criteria are below:

**INCLUSION CRITERIA**

2. Subject (or legally authorized representative) provides informed consent prior to initiation of any study procedures.
3. Subject (or legally authorized representative) understands and agrees to comply with planned study procedures.
4. Male or non-pregnant female adults ≥ 18 years of age at time of enrollment.
5. Has laboratory-confirmed SARS-CoV-2 infection as determined by PCR or other commercial or public health assay (e.g., NAAT and antigen tests) in any respiratory specimen, as documented by either of the following:
   - PCR or other assay positive in sample collected < 72 hours prior to randomization; OR
   - PCR or other assay positive in sample collected ≥ 72 hours but < 7 days prior to randomization AND progressive disease suggestive of ongoing SARS-CoV-2 infection. Note: if written documentation of the positive test result is not available at enrollment (e.g. report from other institution), the subject may be enrolled but the PCR should be repeated at the time of enrollment.
6. Illness of any duration, and at least one of the following:
   - Radiographic infiltrates by imaging (chest x-ray, CT scan, etc.), OR
   - SpO2 ≤ 94% on room air, OR
   - Requiring supplemental oxygen, OR
   - Requiring mechanical ventilation.
7. Women of childbearing potential must agree to either abstinence or use at least one primary form of contraception not including hormonal contraception from the time of screening through Day 29.
8. Agrees to not participate in another clinical trial (both pharmacologic and other types of interventions) for the treatment of COVID-19 through Day 29.

**EXCLUSION CRITERIA**

1. Anticipated discharge from the hospital or transfer to another hospital which is not a study site within 72 hours.
2. Subject is on or being prepared to go on ECMO at the time of screening.
3. Subjects with an estimated glomerular filtration rate (eGFR) < 30 mL/min are excluded unless in the opinion of the PI, the potential benefit of receiving remdesivir outweighs the potential risk of study participation.
4. ALT or AST > 5 times the upper limits of normal.
5. Total white cell blood cell count (WBC) <1500 cells/μL.
6. Platelet count <50,000/μL.
7. History of chronic liver disease (e.g., jaundice, ascites, hepatic encephalopathy, history of bleeding esophageal or gastric varices). No laboratory testing is needed.
8. Pregnancy or breast feeding (lactating women who agree to discard breast milk from Day 1 until two weeks after the last study product is given are not excluded).
9. Allergy to any study medication including history of hypersensitivity to natural or recombinant interferon beta or human albumin.
10. Patient has a chronic or acute medical condition or is taking a medication that cannot be discontinued at enrollment, that in the judgement of the PI, places them at unacceptable risk for a poor clinical outcome if they were to participate in the study.
11. Received three or more doses of remdesivir, including the loading dose, outside of the study for COVID-19.
12. Received convalescent plasma or intravenous immunoglobulin [IVIg]) for the treatment of COVID-19.
13. Received any interferon product within two weeks of screening, either for the treatment of COVID-19 or for a chronic medical condition (e.g., multiple sclerosis, HCV infection)
14. Received any of the following in the two weeks prior to screening as treatment of COVID-19:
   • small molecule tyrosine kinase inhibitors (e.g. baricitinib, imatinib, gefitinib, acalabrutinib, etc.);
   • monoclonal antibodies targeting cytokines (e.g., TNF inhibitors, anti-interleukin-1 [IL-1], anti-IL-6 [tocilizumab or sarilumab], etc.);
   • monoclonal antibodies targeting T-cells or B-cells as treatment for COVID-19