

Remdesivir Clinical Trials for COVID-19

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Please Note: All newly diagnosed COVID-19 positive patients will be reviewed daily by the study team to determine eligibility for enrollment into clinical trials.

Severe Study 5773 (Amd2)

Inclusion Criteria

- 1) Aged ≥ 12 years
- 2) SARS-CoV-2 infection **confirmed** by **PCR test ≤ 4 days** before randomization
- 3) Currently hospitalized
- 4) **SpO₂ $\leq 94\%$ on room air or requiring supplemental oxygen at screening**
- 5) Radiographic evidence of pulmonary infiltrates
- 6) Men and women of childbearing potential must agree to contraception

Exclusion Criteria

- 1) Participation in any other clinical trial of an experimental treatment for COVID-19
 - 2) **Concurrent treatment** with other agents with actual or possible direct acting antiviral activity against SARS-CoV-2 **< 24 hours** prior to study drug dosing (**including azithromycin, hydroxychloroquine, tocilizumab**)
 - 3) Evidence of **multiorgan failure**
 - 4) **Mechanically ventilated (including V-V ECMO) ≥ 5 days**, or any duration of V-A ECMO
 - 5) **ALT or AST $> 5 \times$ ULN**
 - 6) **Creatinine clearance < 50 mL/min** using the Cockcroft-Gault formula
 - 7) **Positive pregnancy test**
 - 8) Breastfeeding woman
 - 9) Known hypersensitivity to the study drug, the metabolites, or formulation excipient
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Moderate Study 5774 (Amd1)

Inclusion Criteria

- 1) Aged ≥ 12 years
- 2) SARS-CoV-2 infection **confirmed** by **PCR test ≤ 4 days** before randomization
- 3) Currently hospitalized
- 4) **SpO₂ $> 94\%$ on room air at screening**
- 5) Radiographic evidence of pulmonary infiltrates
- 6) Men and women of childbearing potential must agree to contraception

Exclusion Criteria

- 1) Participation in any other clinical trial of an experimental agent treatment for COVID-19
- 2) **Concurrent treatment** with other agents with actual or possible direct acting antiviral activity against SARS-CoV-2 **< 24 hours** prior to study drug dosing (**including azithromycin, hydroxychloroquine, tocilizumab**)
- 3) Requiring **mechanical ventilation** at screening
- 4) **ALT or AST $> 5 \times$ ULN**
- 5) **Creatinine clearance < 50 mL/min** using the Cockcroft-Gault formula
- 6) **Positive pregnancy test**
- 7) Breastfeeding woman
- 8) Known hypersensitivity to the study drug, the metabolites, or formulation excipient