

Early treatment with upamostat reduces COVID-19 symptoms, hospitalizations

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March 09, 2022

Upamostat reduced hospitalizations for COVID-19 by 100% and significantly reduced the development of new, severe symptoms when administered early to symptomatic patients, according to a press release from the manufacturer.

“The treatment has excellent safety and tolerability, and its convenient once-daily dosing positions oral upamostat (RedHill Biopharma Ltd.) as a potential highly beneficial treatment for COVID-19 patients early in the course of the disease,” **Gilead Rada**y, the chief operating officer at RedHill Biopharma, told Healio.

Outcomes among nonhospitalized patients with symptomatic COVID-19 who received upamostat or placebo early in the disease course:



RedHill announces positive phase 2 study results with oral RHB-107 in non-hospitalized COVID-19. <https://www.redhillbio.com/news/news-details/2022/RedHill-Announces-Positive-Phase-2-Study-Results-with-Oral-RHB-107-in-Non-Hospitalized-COVID-19/default.aspx>.

Published March 1, 2022. Accessed March 3, 2022.

The new findings are from the phase 2 part of a phase 2/3 multicenter, randomized, double-blind, placebo-controlled, parallel-group study of upamostat, an investigational antiviral serine protease inhibitor.

For the phase 2 component, researchers evaluated two different dose levels of upamostat in 41 adult outpatients and compared their outcomes with 20 additional patients who received placebo. The dose levels were 200 mg or 400 mg administered for 14 days. In total, 60 patients were in the U.S. and one patient was in South Africa. Patients must have either become symptomatic or tested positive with a PCR or antigen test within 5 days of randomization. The last individual was enrolled on Nov. 12, 2021. Among the patients, 62.5% had the delta variant, according to RedHill Biopharma.

The company reported that upamostat demonstrated favorable safety and tolerability in patients. Although this phase was not powered to assess the efficacy of the treatment, researchers observed “highly promising results,” the press release said. No patients in the treatment arm were hospitalized for COVID-19, compared with a 15% hospitalization rate among patients in the control arm ($P = .0317$). Also, there was an 87.8% reduction in new, severe COVID-19 symptoms among patients in the treatment arm compared with a 20% reduction in new symptoms among patients in the control arm ($P = .036$).

The antiviral targets human serine proteases that have a role in preparing the spike protein for viral entry into target cells, according to Raday.

RedHill Biopharma is also investigating opaganib, a sphingosine kinase-2 selective inhibitor, for COVID-19. A recent phase 2/3 trial showed significant reductions in mortality and improved time to recovery among patients hospitalized for severe COVID-19 who also received remdesivir and corticosteroids, Healio previously reported.

Both upamostat and opaganib target host cells, whereas other available antivirals target viral enzymes and RNA, according to the company. However, the two drugs differ in their “mechanism of action.”

“Opaganib, because it has anti-inflammatory as well as antiviral properties, may work both late and early in the course of the disease,” Raday said. Comparatively, upamostat is expected to be most useful early in the course of COVID-19 because it “blocks viral entry into cells, thus blocking viral replication.”

RedHill Biopharma is submitting the phase 2 data to regulators, Raday said. “We are eager to get this treatment to patients who need it as soon as possible,” he added.

References:

RedHill announces positive phase 2 study results with oral RHB-107 in non-hospitalized COVID-19. <https://www.redhillbio.com/news/news-details/2022/RedHill-Announces-Positive-Phase-2-Study-Results-with-Oral-RHB-107-in-Non-Hospitalized-COVID-19/default.aspx>. Published March 1, 2022. Accessed March 3, 2022.

Updates on regulatory discussions and plans in multiple countries. <https://www.redhillbio.com/news/news-details/2022/RedHill-Biopharmas-Oral-Opaganib-Reduces-Mortality-by-70-Given-on-Top-of-Remdesivir-and-Corticosteroids-in-Severe-COVID-19/default.aspx>. Published. Feb. 7, 2022. Accessed March 3, 2022.