



## Press Release by Rhizen

### **Rhizen Pharmaceuticals Announces US FDA Acceptance of its IND Application for RP7214 in SARS-CoV-2 Infection; Phase 1 Clinical Trial of RP7214 Set to Begin Early December 2020**

LA CHAUX DU FONDS, Switzerland dated 1<sup>st</sup> December 2020.

Rhizen Pharmaceuticals, a clinical-stage oncology-focused biopharmaceutical company, today announced the approval of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) to study its oral DHODH inhibitor for SARS-CoV-2 infection. The company announced that initial study shall evaluate single ascending doses of RP7214 in healthy volunteers and that dosing is expected to commence in early December 2020. The company also announces positive feedback from the FDA during its pre-IND discussion on its plans to follow-up this study with a multiple-ascending dose study in Covid-19 patients.

Dihydroorotate dehydrogenase (DHOHD) is a key enzyme involved in pyrimidine biosynthesis in the cell. RP7214 is potentially a best-in-class selective DHODH inhibitor that has shown potent inhibition of Covid-19 viral replication. RP7214 has also been studied extensively across multiple inflammation models where it has demonstrated excellent anti-inflammatory activity. Further, the IND-enabling preclinical studies have shown RP7214 to be orally available, safe and tolerable with predictable dose-linear pharmacokinetics. The host-based mechanism of RP7214 could allow complementary combinations with direct acting anti-viral drugs, while the broad anti-inflammatory action could potentially mitigate the cytokine mediated inflammatory symptoms typically seen in SARS-CoV-2 & other viral infections.

Swaroop Vakkalanka, President & CEO of Rhizen Pharmaceuticals said *“There is an exceptional need for oral antiviral drugs that are suitable for Covid-19 treatment across all hospital and out-patient settings. We are pleased to advance RP7214 into a Phase 1 clinical trial for the treatment of Covid-19 under a US FDA IND. RP7214 has a unique preclinical profile, high oral bioavailability, robust anti-viral potency and broad anti-inflammatory role, that we expect will translate in the clinic and support its eventual development as a potential treatment for Covid-19”*.

#### **About Rhizen Pharmaceuticals S.A.:**

Rhizen Pharmaceuticals is an innovative, clinical-stage biopharmaceutical company focused on the discovery and development of novel onco-therapeutics. Since its establishment in 2008, Rhizen has created a diverse pipeline of proprietary drug candidates targeting several cancers and immune associated cellular pathways. Rhizen is headquartered in La-Chaux-de-Fonds, Switzerland. For additional information, please visit [www.rhizen.com](http://www.rhizen.com)

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