

Kinarus Therapeutics initiates KIN001 Phase II KINFAST clinical trial in COVID-19 outpatients

- **KINFAST to evaluate ability of KIN001 to reduce severity and duration of symptoms in ambulatory COVID-19 patients**
- **Interim data from ongoing Phase 2 KINETIC trial in hospitalized Covid-19 patients expected in late Q3 2022**

Basel, Switzerland, 29 August 2022 -- Kinarus Therapeutics Holding AG (SIX: KNRS) ("Kinarus"), a clinical-stage biopharmaceutical company developing novel therapeutics to treat viral, respiratory, and ophthalmic diseases today announced that the first patient has been dosed in the Phase 2 KINFAST trial, a multicenter placebo-controlled trial evaluating KIN001 in mild or moderate COVID-19 patients in an outpatient setting. The trial will enroll patients at clinical trial sites in Switzerland and Germany. The KINFAST trial is partly supported by a non-diluting grant from the Programme for COVID-19 medicines of the Swiss Federal Office of Public Health.

KIN001 is an orally administered combination of two drugs that have demonstrated synergistic antiviral and anti-inflammatory activity, as well as ability to reduce tissue fibrosis. In contrast to other antivirals and monoclonal antibody therapies, which target SARS-Cov2 directly, KIN001 targets human host cell pathways required for SARS-Cov2 viral replication, blocking the virus' ability to replicate and reducing potential for the emergence of escape mutants. Kinarus and its collaborators recently published data in the peer-reviewed *International Journal of Molecular Sciences* demonstrating KIN001's strong antiviral efficacy and equal potency against the original SARS-CoV-2 strain and variants of concern (VOC), including delta and omicron.

"This important milestone demonstrates the potential of KIN001 to address all severities of COVID-19 with potential for wide use in early and later stages of the disease," said Thierry Fumeaux M.D., MBA, Chief Medical Officer of Kinarus Therapeutics, and former Head of the Clinical Expert Group on the COVID-19 Task Force mandated by the Swiss Federal Council. "With the initiation of this global Phase 2 program, we are one step closer to achieving our goal of providing an easily administered oral drug with multiple synergistic mechanisms that fight and treat SARS-Cov2 infection, independent of the variant. KIN001 aims to prevent disease progression thereby reducing disease severity as well as hospitalizations."

Kinarus previously provided an update on progress of its first Phase 2 clinical trial of KIN001 to treat hospitalized COVID-19 patients ("KINETIC"). KINETIC had enrolled 131 patients as of June 6, 2022, and interim data are expected to be available late in Q3 2022.

Last week, Kinarus held and published on its website a webinar on [KIN001's potential to treat COVID-19 infection](https://ir.kinarus.com/reports-presentations/#presentations) (<https://ir.kinarus.com/reports-presentations/#presentations>).

KINFAST is a Phase 2 multicenter, randomized, double-blind, placebo-controlled, outpatient study to evaluate the efficacy, safety, and pharmacokinetic profile of KIN001 in patients with mild or moderate COVID-19. The study is expected to enroll approximately 400 non-hospitalized patients with confirmed mild to moderate symptoms and confirmed SARS-CoV-2 infection with an interim assessment after enrolling about 140 patients. Patients will be randomized within 5 days of symptom onset. The primary endpoint is the time to recovery, based on the daily symptoms' evaluation by the patient (patient-reported outcome developed by the FDA). Other efficacy endpoints will include number of patients requiring hospitalization for COVID-19, as well as the total burden of symptoms (severity and duration), as assessed by the patient.

KIN001 is a patented combination of pamapimod, a highly selective investigational small molecule inhibitor of p38 mitogen-activated protein kinase (p38 MAPK), and pioglitazone, a marketed drug for the treatment of type 2 diabetes. Several p38 MAPK inhibitors were studied by the pharmaceutical industry and largely abandoned after promising but only transient efficacy was observed. Kinarus

discovered through its own research that the combination of pamapimod with pioglitazone (i.e., KIN001) produced synergistic efficacy and increased the durability of pamapimod's effects in preclinical models representing several disease indications. KIN001 enjoys broad patent protection in the US, EU, China, and other countries through at least 2037.

Kinarus Therapeutics Holding AG (www.kinarus.com) was founded in 2017 by experienced pharmaceutical executives in Basel, Switzerland. The Kinarus team utilizes its knowledge and drug development competencies to in-license and develop mid-stage clinical assets in which they have identified an increased probability of clinical and regulatory success and a rapid path to market. Kinarus possesses the exclusive worldwide license to pamapimod, covering all indications, and has patented KIN001, its novel mechanism in combination with pioglitazone.

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