

Kinarus Therapeutics Announces Discontinuation of the Phase 2 KINETIC Study of KIN001 in Hospitalized COVID-19 Patients Following a Prespecified Interim Analysis of Efficacy and Safety

- **KINETIC, a Phase 2 clinical study of KIN001, an oral drug combination, to be discontinued following recommendation of the DSMB**
- **KIN001 was shown to be safe and well tolerated**
- **Enrollment in the Phase 2 KINFAST study in ambulatory COVID-19 patients continues**
- **Data have no impact on plans to develop KIN001 for wet AMD, IPF or other indications**

Basel, Switzerland, 30.09.2022 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 independent Data and Safety Monitoring Board ("DSMB") has completed its prespecified data review for the Phase 2 KINETIC study in hospitalized COVID-19 patients, and has recommended discontinuation of the study.

The DSMB concluded that there is low probability to show statistically significant benefit with a reasonable number of hospitalized COVID-19 patients, in light of the lower than anticipated incidence of the primary endpoint due to evolution of the current treatment landscape. It therefore recommends that the KINETIC study be discontinued.

Safety data from KINETIC study indicate a favorable profile, with a balanced incidence of treatment-emergent adverse events (TEAEs) between study groups.

"While it is disappointing that KIN001 has not shown sufficient signs of efficacy in the KINETIC study, it is important to remember that hospitalized COVID-19 patients have severe disease with highly complicated pathophysiology. As many of our peers have learned since the beginning of the pandemic, it has become challenging to show the impact of therapeutic intervention at the current pandemic stage, given the disease characteristics in COVID-19 patients with severe disease. Moreover, there are also now relatively smaller numbers of patients that meet enrolment criteria, since fewer patients require hospitalization, in contrast to the situation earlier in the pandemic," said Dr Thierry Fumeaux, Chief Medical Officer of Kinarus.

"For these reasons, we are continuing to study KIN001 as planned in KINFAST, a second Phase 2 study in ambulatory COVID-19 patients who are not hospitalized" remarked Dr Fumeaux. "The goal of KINFAST is to reduce the time to recovery, as well as the severity of disease in mild to moderate symptomatic SARS-CoV-2 positive individuals. Currently, the course of COVID-19 in the majority of patients does not require hospitalization, with consequences for the single patient but also for society. This substantially increases the treatable population and, therefore, the potential for a significant benefit on this clinically and pharmaco-economically relevant outcome."

"The underlying scientific rationale for KIN001 remains intact as p38 MAP kinase, its key biological target, is well characterized and implicated in other indications via biological mechanisms that lead to a variety of chronic inflammatory diseases, including wet age-related macular degeneration (wAMD) and idiopathic pulmonary fibrosis (IPF). The DSMB recommendation has no impact on our plans to develop KIN001 for treatment of wAMD and IPF or other indications. Nevertheless, we are gratified by the safety of KIN001 in the KINETIC study, which bodes well for our development plans in other disease areas" said Dr Alexander Bausch, CEO of Kinarus.

KIN001 is a patented combination of pamapimod, a highly selective clinical stage small molecule inhibitor of the p38 MAPK signaling pathway, and pioglitazone, a marketed drug for the treatment of type 2 diabetes. Kinarus has discovered that combining pamapimod with pioglitazone results in synergistic efficacy and increased durability of response in preclinical models representing several disease indications. In SARS-CoV-2 infected cells, inhibition of p38 by KIN001 significantly reduces viral replication demonstrating synergistic activity vs. the single drugs. KIN001 also has the potential to blunt

the overactive inflammatory response in ambulatory patients with COVID-19, with potential to reduce disease duration, incidence of “long Covid”, hospitalization and long-term morbidity.

KIN001 enjoys broad patent protection in the US, EU, China, and other countries through at least 2037. Kinarus Therapeutics plans to study the potential of KIN001 as a treatment for wet Age-Related Macular Degeneration and Idiopathic Pulmonary Fibrosis.

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.

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