Molecular Partners and Novartis Report Positive Initial Results from Phase 1 Study of its COVID-19 Antiviral Therapy, Ensovibep, in Healthy Volunteers

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- **Initial findings show ensovibep to be safe and well tolerated with no significant adverse events**
- **Predictable exposure seen post administration, confirming the expected half-life of 2-3 weeks**
- **Global phase 2/3 registrational study planned to initiate in Q2 2021**

Zurich-Schlieren, Switzerland, March 09, 2021. Molecular Partners AG (SIX: MOLN), a clinical-stage biotech company that is developing a new class of custom-built protein drugs known as DARPin® therapeutics, and its collaborator Novartis, today announced initial results from its ongoing phase 1 study of its first tri-specific COVID-19 antiviral treatment, ensovibep (MP0420), in healthy volunteers.

In the placebo-controlled phase 1 study, healthy volunteers were randomized 3:1 to receive an infusion of ensovibep, or placebo, respectively. Two dosing cohorts have been fully enrolled and received a single infusion of 3mg or 9mg per kilogram body weight, with 8 patients per dose cohort (16 total: 12 active, 4 placebo). In each of these cohorts, ensovibep was seen to be safe and well tolerated, with no significant adverse events reported. Preliminary results showed extended exposure of the DARPin® candidate in serum, with a half-life of 2-3 weeks, as was expected from preclinical experiments. These data confirm the systemic administration of a multi-specific DARPin® antiviral therapy to be safe and well tolerated, and support advanced plans for additional clinical work in positively diagnosed patients.

“We are excited to see the predictable exposure of ensovibep in this study. These data, coupled with the strong activity demonstrated preclinically against the major variants of SARS-CoV-2 in circulation, make it imperative that we move as quickly as possible to treating patients with our antiviral. These data now show that administration of a DARPin® candidate at these therapeutically relevant dose levels is possible with full consideration of safety and tolerability. We look forward to move rapidly to initiate our phase 2/3 global registration study with our partner Novartis, early in the second quarter of this year,” said Nicolas Leupin, M.D., CMO of Molecular Partners.

Per protocol, a third cohort in this phase 1 study, at a 20mg per kilogram dose level has been planned. As previously disclosed, this cohort has not been enrolled due to the “lock down” enforced in the UK due to the pandemic, starting at the end of 2020. It is possible this cohort can be enrolled in the coming weeks as restrictions lift, but Molecular Partners and Novartis have already identified the therapeutic dose levels which will be investigated in the upcoming clinical studies for infected patients, which are below the 20mg per kilogram dose level.

About Molecular Partners’ anti-COVID-19 program

Molecular Partners two antiviral DARPin® candidates, MP0420 and MP0423, are designed to target multiple different sites on the SARS-CoV-2 virus simultaneously for enhanced antiviral effects and potential use as both prophylactics and treatments. The benefits of this multi-specificity include cooperative binding, extremely high potencies and potential prevention of viral ‘escape’ via mutations. The candidates are formatted with a half-life extending DARPin® domain that binds to human serum albumin (HSA) to support long-acting activity. All DARPin® candidates are constructed to benefit from high-yield and low-cost microbial manufacturing. Molecular Partners is investigating whether the high thermal stability of DARPin® molecules can be used to overcome cold-chain requirements.

Following strong preclinical data supporting the anti-COVID-19 program candidates, in October 2020 the Company entered into a collaboration with Novartis in the form of an option and license agreement to develop, manufacture and commercialize Molecular Partners’ anti-COVID-19 DARPin® program. Per the terms of the agreement, Molecular Partners is conducting Phase 1 clinical trials for ensovibep and performing all remaining preclinical work for MP0423; Novartis will conduct Phase 2 and Phase 3 clinical trials, with Molecular Partners as sponsor of these trials. Upon option exercise, Novartis would be responsible for all further development and commercialization activities. Molecular Partners is also collaborating with AGC Biologics, Baccinex, and Ivers-Lee Clinical Supply Management (IL-CSM) to support development of its anti-COVID-19 program, and has reached an agreement with the Swiss Government regarding rights to purchase up to 3.2 million doses of MP0420, if it is approved in Switzerland.

About Molecular Partners AG

Molecular Partners AG is a clinical-stage biotech company developing DARPin® therapeutics, a new class of custom-built protein drugs designed to address challenges current modalities cannot. The Company has formed partnerships with leading pharmaceutical companies to advance DARPin® therapeutics in the areas of ophthalmology, oncology and infectious disease, and has compounds in various stages of clinical and preclinical development across multiple therapeutic areas.

For more information see www.molecularpartners.com and follow the Company on Twitter at @MolecularPrtnrs.

About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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