Molecular Partners Announces First Patient Dosed in a Phase 2 Clinical Trial of Ensovibep in COVID-19 Patients

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- **First study of ensovibep in patients with symptomatic COVID-19 disease**
- **Designed to evaluate dynamics of viral clearance, pharmacokinetics and tolerability of ensovibep**
- **Ensovibep is additionally planned to be tested in two global, placebo controlled, double blinded trials: A Phase 2-3 trial in an ambulatory patient setting (named EMPATHY), and a Phase 3 trial in a hospitalized patient setting sponsored by the NIH (ACTIV-3)**

Zurich-Schlieren, Switzerland, April 06, 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, today announced that the first patient has been dosed in a Phase 2a clinical trial of ensovibep, a DARPin® therapeutic candidate designed to bind to the SARS-CoV-2 spike protein at three distinct locations to prevent viral entry into cells. The single arm study will enroll patients with symptomatic COVID-19, and is designed to evaluate dynamics of viral clearance, pharmacokinetics and tolerability of ensovibep. The study, recruiting in the Netherlands, is designed to enroll up to 40 patients in two dose cohorts.

"In this first trial of ensovibep in patients, we hope to gain an early look at the viral clearance and the pharmacodynamic behavior of our lead COVID-19 candidate in the presence of the virus. Our preclinical trials with ensovibep have shown that it was able to bind and neutralize SARS-CoV-2 viruses both *in vitro* and *in vivo*, including against all currently known mutations of concern," said Patrick Amstutz, Ph.D., chief executive officer of Molecular Partners. "As part of our development program, we aim to see if these results mechanistically translate into clinical efficacy in patients, with the current trial focused on examining viral presence in treated patients and the potential of the remaining virus to infect cells."

In a Phase 1, randomized, double-blind, placebo-controlled single ascending dose study for safety, tolerability, and pharmacokinetics of intravenously administered ensovibep, run by Molecular Partners, initial data indicate that ensovibep is well tolerated with a half-life in the range of 2-3 weeks.

In partnership with Novartis, Molecular Partners aims to initiate additional clinical studies of ensovibep throughout the first half of 2021 with the goal of achieving clinical proof-of-concept and potential submission for emergency use authorization within 2021. The intended clinical program includes participation in the NIH's ACTIV-3 clinical trial, as recently announced, as well as a global Phase 2-3 study (EMPATHY), which will seek to enroll over 2,100 patients in the ambulatory setting to evaluate the ability of ensovibep to prevent disease worsening, hospitalizations and death.

About Molecular Partners' anti-COVID-19 program

Molecular Partners' two antiviral DARPin® candidates, ensovibep 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 COVID-19 prophylaxis and treatment. 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 DARPin® domain that binds to human serum albumin (HSA) to support a longer half-life and hence longer activity. All DARPin® candidates are constructed to benefit from high-yield and cost-effective manufacturing. Molecular Partners is investigating whether the high thermal stability of DARPin® molecules can be used to overcome cold-chain requirements.

In March 2021, the Company announced positive initial data from its Phase 1 study of ensovibep in healthy volunteers, which showed that ensovibep was safe and well-tolerated with a half-life of 2-3 weeks. In October 2020, Molecular Partners entered into a collaboration with Novartis AG in the form of an option agreement to develop, manufacture and commercialize Molecular Partners' anti-COVID -19 DARPin® candidates. Per the terms of the agreement, Molecular Partners will conduct Phase 1 clinical trials for ensovibep and perform all remaining preclinical work for MP0423; Novartis will conduct Phase 2 and Phase 3 clinical trials, with Molecular Partners as sponsor of those 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 ensovibep, 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.

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