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Molecular Partners Announces First Patient Dosed in COVID-19 NIH-Sponsored ACTIV-3 Trial Evaluating Antiviral Candidate Ensovibep

- Global Phase 3 trial designed to investigate safety and efficacy of ensovibep in hospitalized adults with COVID-19
- Ensovibep receives U.S. FDA Fast Track Designation for the treatment of COVID-19 in both hospitalized and ambulatory settings

Zurich-Schlieren, Switzerland, June 13, 2021. Molecular Partners AG (SIX: MOLN), a clinical-stage biotech company developing a new class of custom-built protein drugs known as DARPin® therapeutics, today announced that the first patient has been dosed in a new Phase 3 sub-study evaluating ensovibep, as part of the National Institutes of Health's (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership designed to speed development of treatments and vaccine candidates for COVID-19. Molecular Partners also announced that the U.S. Food and Drug Administration (FDA) has granted ensovibep Fast Track designation, which is intended to expedite the development and review of new therapies to treat serious conditions and fill an unmet medical need.

As part of the ACTIV-3 international master protocol, the new Phase 3 sub-study is designed to evaluate the safety and efficacy of ensovibep for the treatment of COVID-19 positive adults in the hospitalized setting. Ensovibep is an anti-SARS-CoV-2 investigational DARPin® therapeutic candidate designed to bind the virus' spike protein on three distinct sites simultaneously to inhibit viral entry into cells and proliferation of the virus. In order to be selected for ACTIV-3, Molecular Partners provided the NIH with relevant data and in addition provided ensovibep for independent preclinical assessments by the NIH.

Initial results from a Phase 1 trial evaluating ensovibep in healthy volunteers were announced in March 2021, indicating that ensovibep was well tolerated with a half-life in the range of 2-3 weeks. These promising results have informed the decision to move forward with the EMPATHY clinical trial program, which initiated enrollment in May 2021, and is being conducted by Novartis, with Molecular Partners as sponsor. The EMPATHY trial is a Phase 2 and 3 study that will seek to enroll 2,100 patients with COVID-19 in the ambulatory setting, to evaluate the safety and efficacy of ensovibep in preventing worsening symptoms and hospitalizations.

ACTIV-3 Clinical Trial Design
As previously described, the ACTIV-3 trial arm evaluating ensovibep is planned to initially enroll 300 participants who have been hospitalized with mild to moderate COVID-19 with fewer than 13 days of symptoms, who will receive either ensovibep or placebo. Participants will also receive standard of care for COVID-19, including the FDA-approved antiviral remdesivir. Five days after dosing, participants' clinical status will be assessed, based on need for supplemental oxygen, mechanical ventilation, or other supportive care. The protocol includes an interim analysis for futility after the first 300 patients have been randomized and recruited. If the ensovibep treatment arm appears to have a positive benefit:risk profile, the trial will enroll an additional 700 participants. Trial participants will be followed for 90 days following enrollment to analyze their response to treatment. The primary efficacy endpoint is the time from randomization to participants' sustained recovery for 14 days after release from the hospital.

About ACTIV
On April 17, 2020 the National Institutes of Health (NIH) announced the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines.

Coordinated by the Foundation for the National Institutes of Health (FNIH), ACTIV brings NIH together with its sibling agencies in the Department of Health and Human Services, including the Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), and the U.S. Food and Drug Administration (FDA); other government agencies including the Department of Defense (DOD) and Department of Veterans Affairs (VA); The Operation (formerly known as Operation Warp Speed); the European Medicines Agency (EMA); and representatives from academia, philanthropic organizations, and numerous biopharmaceutical companies.

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 prophylactics and treatments. The potential benefits of this multi-specificity include cooperative binding, 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 October 2020, Molecular Partners entered into a collaboration with Novartis AG in the form of an option and license 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, if agreed by the parties, perform all remaining preclinical work for MP0423; Novartis is conducting Phase 2 and Phase 3 clinical trials, with Molecular Partners as sponsor of those trials. Upon exercise of its option to exclusively license global rights of ensovibep and MP0423, 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.

In March 2021, Molecular Partners announced positive initial data from its Phase 1 study of ensovibep in healthy volunteers, which demonstrated that ensovibep was well-tolerated with a half-life of 2-3 weeks. In March 2021 Molecular Partners initiated a single-arm Phase 2 study of ensovibep in COVID-19-positive patients in the ambulatory settings, at a single center in the Netherlands. In May 2021, Novartis and Molecular Partners initiated enrollment in EMPATHY, a Phase 2-3 study of ensovibep. The study will seek to enroll 2,100 patients with COVID-19 in the ambulatory settings, to evaluate the safety and efficacy of ensovibep in preventing worsening symptoms and hospitalizations.

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.

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This press release may contain certain forward-looking statements relating to the company and its business. These statements may include, without limitation, any statements preceded by, followed by, or including words such as “target,” “believe,” “expect,” “aim,” “intend,” “may,” “anticipate,” “estimate,” “plan,” “project,” “will,” “can have,” “likely,” “should,” “would,” “could”, and other words and terms of similar meaning or the negative thereof, and include, without limitation, statements regarding the design, timing and results of the ongoing ACTIV-3 and EMPATHY clinical trials for ensovibep, including patient enrollment expectations; and the potential of ensovibep to provide therapeutic benefit to COVID-19 patients. Although the company believes its expectations are based on reasonable assumptions, all statements other than statements of historical fact included in this press release about future events are subject to (i) change without notice and (ii) factors beyond the company’s control. Forward-looking statements involve certain risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of the company to be materially different from those expressed or implied by such statements, including, without limitation: the cost, timing and results of clinical trials; that many drug candidates do not become approved drugs on a timely or cost effective basis or at all; the ability to enroll patients in our clinical trials; possible safety and efficacy concerns; the inherent uncertainties associated with preclinical and clinical trial and product development activities and regulatory approval requirements; and risks that preliminary results from clinical trials are not necessarily predictive of future clinical trial results. Readers should therefore not place undue reliance on these statements, particularly not in connection with any contract or investment decision. Except as required by law, the company assumes no obligation to update any such forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.