



## **Molecular Partners Reports Continued Progress of Ensovibep Global Clinical Program; Positive in vitro Data Demonstrating Maintained Inhibition of Delta and All Other Known Variants of Concern of SARS-CoV-2**

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- **Ensovibep maintains potency in an in vitro assay and demonstrated full inhibition of all newly emerging known variants of concern, including the Delta variants of concern**
- **EMPATHY Phase 2/3 trial enrolling ambulatory patients in 5 countries with more countries to be added in the coming months, with interim data expected in H2 2021 and full topline data expected in early 2022**
- **ACTIV-3, a Phase 3 trial enrolling hospitalized patients across 4 countries with more countries expected to be added in the coming months, with topline data expected in 2022**
- **Subcutaneous formulation on track for initiation of clinical trials in H2 2021**

ZURICH-SCHLIEREN, Switzerland, July 08, 2021 (GLOBE NEWSWIRE) -- **Ad hoc announcement pursuant to Art. 53 LR**

[Molecular Partners AG](#) (SIX: MOLN; NASDAQ: MOLN), a clinical-stage biotech company developing a new class of custom-built protein drugs known as DARPin® therapeutics, today reported on the clinical progress of its novel antiviral candidate, ensovibep, as part of a presentation with its partner Novartis at the 1st Credit Suisse ESG Forum Switzerland virtual event. Ensovibep is designed to bind and inhibit SARS-CoV-2, the virus that causes COVID-19. Ensovibep is currently being studied in a Phase 2 single-arm pilot study in ambulatory patients in the Netherlands; a global Phase 2/3 study in ambulatory patients, conducted in collaboration with Novartis (EMPATHY); and a National Institutes of Health (NIH)-sponsored global Phase 3 study in hospitalized patients as part of the ACTIV-3 master protocol.

During today's presentation, management outlined initiation of a subcutaneous program to align with the global registrational studies presently underway using administration via infusion. Initiating this year, the studies will evaluate ensovibep delivered subcutaneously to healthy individuals and subsequently to COVID-19 patients. Subcutaneous administration may increase ease and speed of administration to complement ensovibep's simple, high yield manufacturing process, stability, and potential inhibition of all major viral variants to-date.

"The need for antiviral treatment that is active against all viral variants emerging globally continues to be critical, especially in a context of mixed vaccination rates," said Patrick Amstutz, Ph.D., chief executive officer of Molecular Partners. "We continue to be encouraged by the in vitro data seen for ensovibep against all known viral variants of concern. As we and Novartis continue to open additional clinical sites in multiple countries, data such as these suggest we can offer a truly differentiated solution to patients in need."

The EMPATHY study is presently enrolling across 5 countries, with continued expansion expected into additional territories as the evolving pandemic dictates. The ACTIV-3 study is presently enrolling patients in the hospitalized setting for assessment with ensovibep across more than 50 centers in 4 countries. The ACTIV-3 study protocol is open for recruitment in the hospitalized setting across 120 centers presently with more centers to open in the coming months. The program is aimed to be active in countries where the virus has high case numbers and to cover emerging variants on a global level.

Finally, and in parallel to the clinical progress updated today, ensovibep continues to be evaluated for its potency and inhibition against all emerging and established variants of concern. These evaluations are conducted across multiple laboratories, including the NIH. In vitro data to date show that ensovibep retains full potency and viral inhibition against all known SARS-CoV-2 variants in circulation, including the key Delta variants containing the T478K and K417N mutations, presently a particular concern as it may be associated with higher infectivity rates, even in individuals who are vaccinated.

### **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, 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. [www.molecularpartners.com](http://www.molecularpartners.com); Find us on Twitter - [@MolecularPrtnrs](https://twitter.com/MolecularPrtnrs)

## **Cautionary Note Regarding Forward-Looking Statements**

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe”, “expect”, “may”, “plan”, “potential”, “will”, “would” and similar expressions, and are based on Molecular Partners AG’s current beliefs and expectations. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Some of the key factors that could cause actual results to differ from our expectations include our plans to develop and potentially commercialize our product candidates; our reliance on third party partners and collaborators over which we may not always have full control; our ongoing and planned clinical trials and preclinical studies for our product candidates; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the extent of clinical trials potentially required for our product candidates; the clinical utility and ability to achieve market acceptance of our product candidates; our plans and development of any new indications for our product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position; our ability to identify and in-license additional product candidates; and other risks and uncertainties that are described in the Risk Factors section of Molecular Partners’ Registration Statement on Form F-1 filed with Securities and Exchange Commission (SEC) on June 14, 2021 and other filings Molecular Partners makes with the SEC. These documents are available on the Investors page of Molecular Partners’ website at <http://www.molecularpartners.com>. Any forward-looking statements speak only as of the date of this press release and are based on information available to Molecular Partners as of the date of this release, and Molecular Partners assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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