Molecular Partners Presents Results from a Phase 2a Trial of Ensovibep in 12 COVID-19 Patients at ESWI 2021

December 6, 2021

- *First presentation of data from patients treated with ensovibep demonstrate the candidate to be safe and well-tolerated*
- *All patients exhibited reductions in viral load and complete COVID-19 clinical symptom recovery*
- *Additional data presented includes review of the supportive Phase 1 study of ensovibep in healthy volunteers*
- *Global Phase 2-3 EMPATHY clinical study for ambulatory COVID-19 patients ongoing with topline data available in early 2022*

ZURICH-SCHLIEREN, Switzerland and CONCORD Mass., Dec. 06, 2021 (GLOBE NEWSWIRE) -- 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 announced the presentation of results from the Phase 2a study of ensovibep for COVID-19 patients as well as additional data from the Phase 1 study in healthy volunteers at the virtual European Scientific Working Group on Influenza (ESWI) Conference.

The single arm Phase 2a study enrolled 12 patients, all of whom were confirmed as positive for COVID-19 with mild to moderate symptoms. The single center study was designed to evaluate dynamics of viral clearance, pharmacokinetics and tolerability of ensovibep. The results were presented by study investigator Dr. Johan van der Plas from the Centre for Human Drug Research (CHDR), Leiden, the Netherlands;

- First ensovibep data from COVID-19 infected patients: 225 mg and 600 mg doses were seen to be safe and well tolerated
  - No disease enhancement, infusion related reactions, or dose limiting toxicities observed
- Viral load data (qPCR) showed a comparable decline for both dose levels
- Infectivity of virus extracted through nasopharyngeal swabs was reduced to zero within 3-5 days post treatment in patients with positive titers at baseline.
- Favorable PK profile in patients consistent with the profile observed in healthy volunteers: Confirmation of half-life and prolonged therapeutic exposure >2 weeks in all dosed patients
- Complete COVID-19 clinical symptom recovery in the study population

These findings support large-scale controlled evaluation of ensovibep as a treatment for mild-to-moderate COVID-19.

“As global COVID-19 cases continue to rise, with many countries under-vaccinated and new variants such as Delta and Omicron spreading quickly and affecting millions of lives, it is imperative that we find therapeutics designed to combat this virus as well as its future mutations,” said Dr Lutz Hegemann, Group Head of Corporate Affairs and Global Health for Novartis, Molecular Partners’ COVID-19 collaboration partner. “These data further support ensovibep’s potential as a valuable treatment option for COVID-19 patients and we look forward to reviewing the results from the ongoing, global Phase 2-3 trial, EMPATHY.”

Molecular Partners also presented additional data from the Phase 1, randomized, double-blind, placebo-controlled single ascending dose study for safety, tolerability, and pharmacokinetics of intravenously administered ensovibep, which indicated that it was well tolerated with a half-life in the range of 2-3 weeks.

“These data characterize the safety and pharmacodynamic profile of ensovibep in ambulatory COVID-19 patients and provide an early insight into the antiviral activity of ensovibep, as we await a major data read-out from our global EMPATHY study in early 2022,” said Patrick Amstutz, CEO of Molecular Partners. “We remain confident that ensovibep’s unique tri-specific mechanism, designed to maintain potency against viral mutations and its potential for a one-time simple administration make it a differentiated therapeutic candidate that could help combat this ongoing threat.”

Presentation details:

Phase 1 Poster:
Title: Ensovibep, a potential antiviral COVID-19 treatment, is safe and well tolerated in healthy volunteers: preliminary safety and PK results from a phase 1, multi-part, ascending, single-dose study
Presenter: Marianne Soergel, Molecular Partners AG, Schlieren, Switzerland
Date and time: Monday 6 December, 12:00 - 13:45 CET

Phase 2 Oral Presentation
Title: Safety, tolerability and pharmacokinetics of ensovibep in patients with mild to moderate COVID-19 - preliminary report of a phase 2a, open-label, single dose escalation study.
Presenter: J.L. van der Plas, Centre for Human Drug Research (CHDR), Leiden, The Netherlands; Department of Infectious Diseases, Leiden University Medical Center (LUMC), Leiden, The Netherlands
Date and time: Monday 6 December, 18:00 - 19:45 CET

Ensovibep is currently being evaluated in EMPATHY, a global Phase 2-3 study designed to explore the use of ensovibep for the treatment of COVID-19 in patients who are in the early stages of infection to prevent worsening symptoms and hospitalization. Molecular Partners’ collaboration

partner, Novartis, is conducting the clinical trial for ensovibep, with Molecular Partners as a sponsor. The Phase 2b portion of EMPATHY enrolled patients across six countries. Topline data for the first 400 patients are expected in early 2022.

Based on continued evaluation of ensovibep, it maintains full potency *in vitro* against the individual positions of relevance to ensovibep that are mutated in the Omicron variant. Testing has been initiated in order to confirm the potency of ensovibep against a full Omicron pseudotype virus that includes all mutations simultaneously. In previous studies, ensovibep has maintained activity *in vitro* against all variants of concern detected, including the Delta strain.

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; Find us on Twitter - @MolecularPrtnrs

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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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