Molecular Partners Provides Update from ACTIV-3 Global Clinical Study of Ensovibep in Patients Hospitalized with COVID-19

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- Following the futility analysis, the independent Data and Safety Monitoring Board (DSMB) recommends that the recruitment of patients in the ensovibep arm of ACTIV-3 not continue in hospitalized patients
- The global phase 2-3 EMPATHY study in non-hospitalized patients is still ongoing with topline data from phase 2b expected in early 2022

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Nov. 16, 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 announced that a planned futility analysis of ensovibep in the ongoing ACTIV-3 clinical study (NCT04501978) has not met the thresholds required to continue enrollment of adults with COVID-19 in the hospitalized setting. This global Phase 3 ACTIV-3 platform study is being conducted by the National Institutes of Health (NIH) as part of its Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) program. ACTIV is evaluating multiple therapies for COVID-19 to see what, if any, benefit can be seen over current standard of care. At the time of the analysis, 470 patients had been randomized in the ensovibep arm of the study. Ensovibep was observed to be generally safe and well tolerated with reported side effects consistent with standard of care.

"Demonstrating efficacy in hospitalized patients with COVID-19 has proven particularly challenging for antiviral therapies, with most investigational agents tested so far in the ACTIV-3 study not passing futility criteria – potentially due to the multi-systemic inflammatory component of late-stage COVID-19 disease. We wish to thank our collaborators and patients for participating in this study. When available, we will share any potential learnings to better inform this population, which is still in great need for treatment options," said Patrick Amstutz, Ph.D., Molecular Partners' CEO. "We are encouraged that ensovibep's safety profile continues to be supported, and we are now focused on its performance for patients in earlier stages of the disease. Ensovibep's unique mechanism has the potential to meaningfully expand the medical toolkit in our collective fight against the ongoing pandemic, particularly in the face of global under-vaccination and the threat posed by continual new viral strains where we continue to retain potency."

Molecular Partners and Novartis are collaborating on the development of ensovibep and are evaluating it in another global late-stage study, EMPATHY, which is designed to assess ensovibep's ability to rapidly reduce viral load and prevent worsening of symptoms and hospitalization of patients who are in the early stages of disease. Novartis is conducting EMPATHY with Molecular Partners as sponsor, with topline interim data for the first 400 patients expected in early 2022.

Ensovibep is the lead therapeutic candidate in Molecular Partners' infectious disease pipeline. As a DARPin therapeutic candidate, it is designed to target SARS-CoV-2's spike protein at three sites to limit viral escape via mutation. In vitro data to-date demonstrate that ensovibep retains potency in inhibiting all known SARS-CoV-2 variants of concern, including the Delta variants. Molecular Partners has also initiated assessment of ensovibep when administered subcutaneously to complement the global registrational studies presently underway using administration via infusion.

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, as amended, including, without limitation, implied and express statements regarding the clinical development of Molecular Partners' current or future product candidates, including expectations regarding timing of ongoing clinical trials, including receipt of data for such trials, and the potential therapeutic and clinical benefits of Molecular Partners' product candidates. 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, including the timing of such trials and studies; the risk that the results of preclinical studies and clinical trials may not be predictive of future results in connection with future clinical trials; 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; the potential impact of the COVID-19 pandemic on our operations or clinical trials; 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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