

# Emergency Use Authorization Request for Ensovibep Submitted to the US Food and Drug Administration for the Treatment of COVID-19

## February 10, 2022

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Feb. 10, 2022 (GLOBE NEWSWIRE) -- Ad hoc announcement pursuant to Art. 53 LR: <u>Molecular Partners AG</u> (SIX: MOLN; NASDAQ: MOLN), a clinical-stage biotech company developing a new class of custom-built protein drugs known as DARPin therapeutics, was informed by its partner Novartis that the company has requested Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for ensovibep, a DARPin antiviral therapeutic candidate to treat COVID-19.

This submission is based on the totality of the data from clinical and preclinical studies including the positive results of the Phase 2 portion of the EMPATHY study, a randomized, placebo-controlled study which enrolled 407 symptomatic patients infected with SARS-Cov-2.

### About ensovibep

Ensovibep is a DARPin therapeutic candidate, designed specifically to inhibit target cell entry of SARS-CoV-2, the virus that causes COVID-19. DARPins (Designed Ankyrin Repeat Proteins) are mono or multi-specific protein-based therapies, designed to specifically engage their targets for various effects. Ensovibep includes three covalently linked individual DARPin domains which bind to the spike protein of SARS-CoV-2. With these domains incorporated into a single molecule, ensovibep is designed to block the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein, even in the presence of some mutations of the spike protein. Several characteristics of DARPin therapeutics make them potentially suitable for COVID-19 treatment, including multi-specific binding, the rapid onset of action, and scalable bacterial production.

### 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

#### **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, as amended, including, without limitation, implied and express statements regarding the clinical development of Molecular Partners' current or future product candidates or product candidates of Molecular Partners' collaborators, including expectations regarding the potential therapeutic and clinical benefits of such product candidates or the timing or ability of Molecular Partners or its collaborators to obtain and maintain regulatory approvals for such 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 Molecular Partners' expectations include the timing of and ability to obtain and maintain regulatory approvals for its product candidates or product candidates of its collaborators, including Emergency Use Authorization for ensovibep; Molecular Partners' ongoing and planned clinical trials and preclinical studies for its 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 extent of clinical trials potentially required for its product candidates; Molecular Partners' reliance on third party partners and collaborators over which it may not always have full control; Molecular Partners' plans to develop and potentially commercialize its product candidates; the clinical utility and ability to achieve market acceptance of its product candidates; Molecular Partners' commercialization, marketing and manufacturing capabilities and strategy; Molecular Partners' ability to identify and in-license additional product candidates; Molecular Partners' intellectual property position; 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.

For further details, please contact: Seth Lewis seth.lewis@molecularpartners.com Tel: +1 781 420 2361 Shai Biran, Ph.D. shai.biran@molecularpartners.com Tel: +1 978 254 6286 Thomas Schneckenburger, European IR & Media thomas.schneckenburger@molecularpartners.com Tel: +41 79 407 9952