



Molecular Partners Announces First Patient Dosed with CD40 Therapeutic Candidate MP0317 in Phase 1 Clinical Trial

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- Second immuno-oncology DARPin candidate to enter the clinic; combines immune stimulation with validated tumor-localizing technology
- Preclinical data support potential to deliver tumor-localized immune activation while avoiding systemic toxicity seen with other CD40-targeting agents

ZÜRICH-SCHLIEREN, Switzerland and CONCORD, Mass., Nov. 04, 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 dose administration for the first patient in a Phase 1 first-in-human study evaluating the safety and tolerability of MP0317, which targets both the fibroblast activation protein (FAP) and the immunostimulatory protein CD40 to enable tumor-localized immune activation. MP0317 is the second DARPin therapeutic candidate in the company's immuno-oncology pipeline to enter clinical trials. Through this mechanism of action, MP0317 is designed to activate immune cells specifically within the tumor microenvironment, potentially delivering greater efficacy with fewer side effects compared to other CD40-targeting agents.

"The multispecificity afforded by DARPin technology allows us to design novel immuno-oncology candidates with additional control mechanisms for greater specificity and reduced systemic toxicity compared to monoclonal antibodies and other approaches," said Nicolas Leupin, M.D., Ph.D., Chief Medical Officer of Molecular Partners. "Having previously demonstrated the ability of FAP-dependent tumor-localized immune engagement in our MP0310 program, we are excited to see how this mechanism translates to patient benefit in our second immuno-oncology program. MP0317 represents another step in the evolution of our DARPin platform to deliver increasingly sophisticated candidates that can potentially direct immune attack to the right cells, at the right place, and at the right time."

Preclinical data from MP0317 in human tumor samples show that it activates B-cells, dendritic cells and macrophages, and induces a broad range of pro-inflammatory activities, including macrophage repolarization and reversion of T-cell suppression. The multispecific design of MP0317 is expected to ensure that activation of CD40 will only occur in the presence of FAP, which is highly expressed in the connective tissue of a broad range of solid tumors. As previously presented¹, the anti-tumor effect induced by MP0317 was comparable to that achieved by an anti-CD40 antibody. The Company believes these data support MP0317's potential to deliver tumor-localized CD40-mediated immune cell activation while avoiding the systemic toxicity seen with other CD40-targeting agents.

The open-label dose escalation study announced today is designed to assess the safety and tolerability as well as pharmacokinetics and pharmacodynamics of MP0317 as a monotherapy in patients with solid tumors known to express FAP and CD40. Enrollment will take place in the Netherlands and France. Up to 30 patients are expected to be enrolled across six dosing cohorts and up to 15 patients dosed in a dose expansion cohort. Patients will be dosed every three weeks. In addition to evaluating monotherapy dynamics, the study will gather a wide variety of biomarker data to support the establishment of combination therapies with MP0317 in specific indications.

About Molecular Partners' Immuno-oncology Product Candidates

Molecular Partners is developing several candidates designed to activate the immune system to fight cancer while reducing damage to healthy cells. These candidates use multiple novel DARPin technologies potentially applicable against a wide range of tumor types, including DARPin candidates with the ability to restrict immune activation to the tumor microenvironment, the ability to target intracellular disease-associated proteins, and multiple novel control mechanisms for immune activation designed to direct immune attack to the right cells, at the right place, and at the right time. These capabilities can be combined during candidate design through the inherent modularity of the DARPin platform, to provide precise control over immune activation and potentially enable more effective cancer immunotherapies.

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 infectious disease, oncology and ophthalmology, and has compounds in various stages of clinical and preclinical development across multiple therapeutic areas. www.molecularpntrns.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, 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.

1. [AACR 2021. Poster 1733](#) - MP0317, a CD40x4FAP targeting multi-specific DARPin[®] therapeutic, drives immune activation and reverts myeloid-mediated T-cell suppression in vitro and ex vivo

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