Molecular Partners Presents Updated Positive Data from Ongoing Phase 1 Trial of MP0317 (FAP X CD40) Monotherapy in Patients with Advanced Solid Tumors at the 2023 SITC Annual Meeting

November 3, 2023

- *MP0317 continues to demonstrate tumor-localized CD40 activation, leading to elevated immune activity in the tumor microenvironment*
- *MP0317 monotherapy shows a favorable safety profile up to the highest planned doses*
- *Patient recruitment of the study's dose-escalation portion is complete, with final study results expected in H1 2024*
- *Data support continued clinical evaluation of MP0317, including in combination studies*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Nov. 03, 2023 (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, will present additional positive data from its Phase 1 study of MP0317 in patients with advanced solid tumors at the 2023 Annual Meeting of the Society for Immunotherapy of Cancer (SITC), being held November 1–5 in San Diego, California. MP0317 is a CD40 agonist designed to activate immune cells specifically within the tumor microenvironment (TME) by anchoring to fibroblast activation protein (FAP).

"MP0317 continues to demonstrate its potential to overcome the limitations of existing CD40 agonists through its unique DARPin design that allows to activate immune cells directly within the TME, while avoiding eliciting systemic toxicities," said Philippe Legenne M.D, acting CMO of Molecular Partners. "The encouraging results presented at SITC provide clinical evidence of MP0317-induced, tumor-targeted CD40 activation. The observed remodeling of the TME and MP0317's favorable safety profile across all dosing cohorts, including the highest planned doses, support further investigation of MP0317 in later-stage clinical studies including combination trials."

Details of the poster presenting updated results from the ongoing MP0317 Phase 1 study at the SITC 2023 Annual Meeting can be found below. The poster will be made available on Molecular Partners' website after the presentation.

Title: Ongoing Phase 1 study of MP0317, a FAP-CD40 DARPin, shows a favorable safety profile and early evidence of tumor-localized CD40 activation in patients with advanced solid tumors
Poster number: 721
Location & Timing: Exhibit Hall B, Friday November 3, 2023, 9am – 7pm ET

This update, based on data from 46 patients, corroborates earlier reported findings of MP0317-induced CD40 activation and related remodeling of the TME. The detection of MP0317 in tumor biopsies is associated with an increase in CD40-mediated re-programming of immune cells illustrated by IFNg production and dendritic cell (DC) maturation within the TME. Elevation of serum levels of CXCL10, an effector chemokine downstream of IFNg signaling, and changes in soluble biomarkers (sFAP & sCD40) post-MP0317 treatment support these findings. To date, one patient achieved a partial response and stable disease was observed in eight additional patients.

MP0317 continues to display a favorable safety profile across all dosing cohorts (0.03–10 mg/kg, Q3W & Q1W), with limited systemic inflammation-related adverse reactions compared to other CD40 agonists. Dose-limiting toxicity was reported in only one patient to date (transient asymptomatic Grade 3 elevation of liver enzymes), at the highest planned MP0317 dose of 10 mg/kg administered Q3W.

The positive results of this fully enrolled Phase 1 study in patients with refractory/relapsed tumors support continued clinical evaluation of MP0317 and potential investigation in combination studies. The Company expects to share final results of this study in 2024. For further information please see clinicaltrials.gov (NCT05098405).

This ongoing first-in-human Phase 1, open-label, dose-escalation study assesses the safety and tolerability as well as pharmacokinetics/pharmacodynamics and preliminary antitumor activity of MP0317 monotherapy in patients with advanced solid tumors known to express FAP and CD40 (NCT05098405). Recruitment for the dose-escalation portion of the study is complete, with 46 patients enrolled in the Netherlands and France across nine dosing cohorts. Patients received MP0317 at doses of 0.03–10 mg/kg in every-3-weeks (Q3W) or weekly (Q1W) schedules (data cut-off 10 October 2023).

About MP0317
MP0317 targets both the FAP and the immunostimulatory protein CD40 to enable tumor-localized immune activation. Through this proposed 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 systemic CD40-targeting therapies.

About DARPin Therapeutics

DARPin therapeutics are a new class of custom-built protein therapeutics based on natural binding proteins that open a new dimension of multi-functionality and multi-target specificity in drug design. A single DARPin candidate can engage more than five targets, and its flexible architecture and small size offer benefits over other currently available protein therapeutics. DARPin therapeutics have been clinically validated through to registration via the development of abicipar, a DARPin drug candidate for ophthalmological indications. The DARPin platform is a fast and cost-effective drug discovery engine, producing drug candidates with optimized properties for development and very high production yields.

About Molecular Partners AG
Molecular Partners AG is a clinical-stage biotech company developing DARPin (designed ankyrin repeat protein) 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 oncology and virology and has compounds in various stages of clinical and preclinical development across multiple therapeutic areas. www.molecularpartners.com. Find us on LinkedIn and X: @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, expectations regarding timing for reporting data from ongoing clinical trials or the initiation of future clinical trials, the potential therapeutic and clinical benefits of Molecular Partners' product candidates, the selection and development of future antiviral or other programs, and Molecular Partners' expected business and financial outlook, including expenses and cash utilization for 2023 and its expectation of its current cash runway. 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' 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 its plans to develop and potentially commercialize its product candidates; Molecular Partners' reliance on third party partners and collaborators over which it may not always have full control; 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 timing of and Molecular Partners' ability to obtain and maintain regulatory approvals for its product candidates; the extent of clinical trials potentially required for Molecular Partners' product candidates; the clinical utility and ability to achieve market acceptance of Molecular Partners' product candidates; the impact of any health pandemic, macroeconomic factors and other global events on Molecular Partners' preclinical studies, clinical trials or operations, or the operations of third parties on which it relies; Molecular Partners' plans and development of any new indications for its product candidates; Molecular Partners' commercialization, marketing and manufacturing capabilities and strategy; Molecular Partners' intellectual property position; Molecular Partners' 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' Annual Report on Form 20-F for the fiscal year ended December 31, 2022, filed with Securities and Exchange Commission (SEC) on March 9, 2023 and other filings Molecular Partners makes with the SEC. These documents are available on the Investors page of Molecular Partners' website at 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.