Molecular Partners Presents Positive Interim Safety and Mechanistic Data From Ongoing Phase 1 Trial of MP0317 for Treatment of Solid Tumors

November 10, 2022

- First clinical observation of tumor localized CD40 activation provided by MP0317
- No systemic or dose-limiting toxicities observed, a key parameter for CD40 agents
- Dose escalation remains ongoing with study recruitment anticipated to complete in 1H 2023

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Nov. 10, 2022 (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 the presentation of positive interim results from the ongoing Phase 1 trial of the company's MP0317 (FAP X CD40) program for the treatment of solid tumors at the Society for the Immunotherapy of Cancer 37th Annual meeting.

While holding promise, the development of CD40 agonists for cancer therapy has faced challenges due to systemic CD40 activation leading to dose-limiting toxicity (DLT). MP0317 is designed to resolve these limitations by activating immune cells specifically within the tumor microenvironment through the simultaneous binding of the immune stimulator CD40 as well as a protein highly expressed within tumors named fibroblast activation protein, or FAP.

"This first clinical data supports the potential of MP0317 as a candidate able to achieve the goal of restricting CD40 activity to tumors. We are now progressing into dosages well above those that produced dose-limiting toxicities with non-DARPin CD40 agents, a significant achievement we hope to translate into observed clinical effect," said Nicolas Leupin, MD, Ph.D., CMO of Molecular Partners. "Our oncology programs continue displaying the potential of DARPin therapeutics to solve historical drug development challenges such as localizing potent immune activation to tumors in order to spare damage to healthy cells."

This Phase 1, first-in-human, multicenter, open label, dose escalation study enrolling patients with relapsed/refractory advanced solid tumors is intended to evaluate the safety of MP0317 and investigate a range of other biomarkers to better characterize the candidate's mechanism and activity. At the point of data cutoff, 4 cohorts had received an intravenous dose of MP0317 every 3 weeks until disease progression, unacceptable toxicity, or other discontinuation criteria were met.

Key reported data:

- MP0317 was seen to be safe and well tolerated with no dose limiting CD40-related systemic toxicities having been observed to date, and no signs of inflammatory cytokine release.
- The most frequent adverse events were grade 2 infusion related reactions (e.g., rapidly resolved infusion site inflammation) in 3/13 dosed patients at the time of data cutoff, with no DLT observed. This spans cohorts 1-4, with dosages ranging from 0.03 mg/kg to 1 mg/kg.
- Tumor biopsies from the earlier cohorts (1-3) already show evidence of MP0317 co-localization with both CD40 and FAP, in 3 of the 5 tumor biopsies available for analysis.
- In addition, early PD data show signs of CD40-mediated immune activation.
- These data support that MP0317's mechanism is working as intended.

These results will be presented at SITC 2022 in a poster, the details of which can be found below. The poster will be made available on Molecular Partners website, after the presentation on November 10.

Poster: "A phase 1 study to characterize the safety and tolerability of MP0317, a tumor targeting FAP dependent CD40 agonist DARPin, in patients with relapsed/refractory solid tumors"
Number: 1475
Timing: November 10, 2022
Presenter: Paul Baverel, PhD

The dose escalation of the Phase 1 remains ongoing and Molecular Partners expects the final data set to inform the therapeutic dose for evaluation in a potential Phase 2 trial. Subsequent to the data cutoff, current ongoing dosing levels include a 3 mg/kg cohort dosed every 3 weeks, as well as a 0.5 mg/kg weekly dosing cohort. A total of 19 patients have been enrolled in the Phase 1 study as of Nov. 1, 2022.

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, 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 expenses and cash utilization for 2022 and its expectation that its current cash resources will be sufficient to fund its operations and capital expenditure requirements into 2026. 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 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 potential impact of the COVID-19 pandemic 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, 2021 filed with Securities and Exchange Commission (SEC) on March 15, 2022 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.

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