Molecular Partners to Present Initial Data from Ongoing Phase 1/2a Trial of MP0533 for Patients with Relapsed/Refractory AML and AML/MDS at the 65th ASH Annual Meeting and Exposition

November 2, 2023

- *MP0533 shows acceptable safety profile in first three dose cohorts (5 patients total, data cut-off July 20); reported adverse reactions are of Grade 1/2 and no dose-limiting toxicity observed to date*
- *Emerging evidence of antitumor activity observed in dose cohort three, with one responder noted*
- *Data from ASH abstract released today support clinical proof of concept of MP0533 as a novel tetra-specific T cell engager*
- *Expanded data from the first three cohorts and data from fourth cohort will be presented at the ASH Annual Meeting and Exposition*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Nov. 02, 2023 (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, will present preliminary data from its ongoing Phase 1/2a trial of MP0533, a novel tetra-specific T cell engager at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition being held from December 9–12 in San Diego, California. MP0533 is in development for the treatment of patients with relapsed/refractory acute myeloid leukemia (r/r AML) and myelodysplastic syndrome (AML/MDS).

As of data cut-off (20 July 2023) of the abstract published today, five patients across three dosing regimens had been treated. The preliminary data reported indicate an acceptable safety profile, with no dose-limiting toxicity or Grade ≥3 adverse reactions. Grade 1/2 events considered related to MP0533 included infusion-related reactions and cytokine release syndromes. One of the two patients evaluable for MP0533 antitumor activity in the third treatment cohort achieved a response. The study is currently enrolling its fifth cohort with up to seven dose-escalating cohorts planned and a total enrollment of up to 45 patients. The Company anticipates to present data including from the fourth dose cohort at the ASH Annual Meeting and Exposition in December this year.

“The data from the ASH abstract represent the beginning of an exciting and encouraging clinical journey for the MP0533 program. We are now able to show initial clinical activity of the first tetra-specific, non-antibody-based T cell engager, MP0533, in patients with r/r AML and MDS/AML,” said Patrick Amstutz, Ph.D., Molecular Partners’ CEO. “We see both an acceptable tolerability profile at initial doses, as well as the emergence of single-agent anti-tumor activity at relatively low dose levels and we look forward to presenting additional data on MP0533’s potential to treat this particularly intractable blood cancer at the ASH Annual Meeting in December.”

The clonal heterogeneity and lack of single AML-specific target antigens represent major challenges for the development of targeted immune therapies for AML. To overcome these hurdles, Molecular Partners designed MP0533, a novel tetra-specific T cell-engaging, half-life extended DARPin, which simultaneously targets CD33, CD123 and CD70, as well as CD3 on T cells. This unique mode of action is designed to enable avidity-driven, T cell-mediated killing of leukemic stem cells and malignant blast cells, which commonly co-express at least two of the three target antigens, while preserving a therapeutic window that minimizes damage to healthy cells.

The ongoing single-arm, open-label, multicenter Phase 1/2a study of MP0533 is designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics, as well as assess preliminary antileukemic activity of MP0533 as a monotherapy for patients with r/r AML and AML/MDS.

The presentation details are as follows:

Session Name: 616. Acute Myeloid Leukemias: Investigational Therapies, Excluding Transplantation and Cellular Immunotherapies: Poster 2
Publication Number: 2921
Title: MP0533, a CD3-Engaging DARPin Targeting CD33, CD123, and CD70 in Patients with Relapsed/Refractory AML or MDS/AML: Preliminary Results of a Phase 1/2a Study
Session Location & Date: San Diego Convention Center, Halls G-H; Sunday, December 10, 2023
Presentation Time: 6:00–8:00 pm PT

The abstract will become available today on the ASH website at 9:00 am ET.

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 ophthalmologic 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 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 infectious disease 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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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 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.