# Molecular Partners Presents Positive Initial Data from First Four Dosing Cohorts of Ongoing Phase 1/2a Trial of MP0533 for Patients with Relapsed/Refractory AML and AML/MDS at ASH Annual Meeting

December 10, 2023

- *Initial antitumor activity observed in early MP0533 dose-escalation cohorts, with a previously undisclosed complete response (CR) observed in dose range four, in addition to the previously reported responder in dose range three*
- *MP0533 monotherapy continues to demonstrate an acceptable safety profile across the first four dosing cohorts, with no dose-limiting toxicities observed*
- *Phase 1/2a trial remains ongoing with patients being enrolled in fifth of seven planned dose-escalation cohorts*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Dec. 10, 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, today presented positive initial clinical data from its ongoing Phase 1/2a trial of MP0533, a novel tetra-specific T cell engager, in a poster at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition. These data, which highlight encouraging initial safety and antitumor activity, expand upon those previously disclosed in the conference abstract.

"We are excited to share these initial data for MP0533, where we see antileukemic activity, already at these low doses, with a favorable safety profile. We look forward to the continuation of this study and evaluating the full potential of MP0533 for patients," said Patrick Amstutz, CEO of Molecular Partners. "For the first time ever, a non-antibody-based T-cell engager shows clinical activity, opening the door for next-generation DARPin drugs, such as tetra-specifics and logic-gated molecules."

As of the data cut-off (October 24, 2023), 11 patients had been enrolled in the first four dosing regimens (DR) of the ongoing Phase 1/2a trial of MP0533 monotherapy in patients with relapsed/refractory acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS/AML). The trial enrollment remains on track with patients currently being treated in the fifth of seven dose-escalation cohorts planned.

MP0533 continues to demonstrate an acceptable safety profile across all four DRs studied. No dose-limiting toxicities (DLTs) were observed as of data cut-off, and all patients were able to receive their full dose of MP0533. The most frequently reported MP0533-related adverse events were infusion-related reactions and cytokine release syndrome (all Grade 1-2).

Two responders have been observed to date, including a patient achieving complete response (CR) in DR 4 and another patient with morphological leukemia-free state (MLFS) in DR 3 (initially identified as CRi at the time of abstract submission, data cutoff July 2023). These responses are particularly notable for having occurred at dose levels below those predicted for therapeutically relevant activity.

Details of the poster presenting these results from the ongoing Phase 1/2a trial of MP0533 at the 65th ASH Annual Meeting and Exposition can be found below. The poster will be made available on Molecular Partners' website after the presentation. For more information on the trial, please visit clinicaltrials.gov (NCT05673057).

**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

**About MP0533**
MP0533 is a novel, avidity-driven, tetra-specific T cell-engaging, half-life extended, DARPin, which simultaneously targets the tumor-associated antigens CD33, CD123 and CD70 as well as the immune activator CD3 on T cells. MP0533's affinity to each tumor-associated antigen is tuned to preferentially kill AML cells which commonly co-express at least two of these three target antigens whereas most healthy blood cells only express one or none. MP0533's unique avidity-driven mode of action therefore enables targeted T cell-mediated killing of AML cells while preserving a therapeutic window that minimizes damage to healthy cells.

**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 in different indications, and through to registration with 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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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.