Interim Management Statement Q1 2024 of Molecular Partners: Pipeline Progressing with Two Additional Programs to Enter the Clinic in 2025, Update to MP0533 Program

May 16, 2024

- *MP0533: Phase 1 trial continues to demonstrate acceptable safety and antitumor activity up to cohort 6, dosing in cohort 7 ongoing, additional dose escalation cohorts being prepared*
- *Radio-DARPin Therapy (RDT): Lead DLL3 candidate advancing into IND-enabling studies with partner Orano Med, preclinical data to be presented at SNMMI 2024*
- *Switch-DARPin Platform: Initial data to be presented at EHA 2024; Preclinical proof-of-concept studies for c-KIT program planned for H2 2024*
- *MP0317: Final data from Phase 1 dose escalation to be presented at ASCO 2024*
- *Outlook: Funded into 2026 with cash and short-term deposits of CHF 174.1 million; total operating expenses of CHF 70-80 million expected for 2024*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., May 16, 2024 (GLOBE NEWSWIRE) -- **Ad hoc announcement pursuant to Art. 53 LR** Molecular Partners AG (SIX: MOLN; NASDAQ: MOLN), a clinical-stage biotech company pioneering the design and development of DARPin therapeutics for medical challenges that other drug modalities cannot readily address ("Molecular Partners" or the "Company"), today announced corporate highlights and unaudited financial results for the first quarter of 2024.

“This quarter we demonstrated continued progress across our clinical and preclinical pipeline with preparations underway for two new clinical candidates and first-in-human data for our Radio DARPin platform in 2025,” said Patrick Amstutz, Ph.D., Molecular Partners’ Chief Executive Officer. “Building on encouraging initial data and clinical activity, MP0533 dose escalation will expand and now explore higher potential doses, to see what the true clinical impact can be and which patient subpopulations can benefit most. We plan to share data from these higher dose clinical cohorts starting in the second half of this year. For our emerging pipeline, we plan to announce preclinical data from our Switch-DARPin Platform at EHA and anticipate translational efficacy data in the second half of 2024. Our lead Radio-DARPin candidate is advancing into IND-enabling studies in collaboration with our partner Orano Med, with initiation of clinical studies planned for 2025 and pre-clinical data to be presented at SNMMI in June 2024.”

Financial and Business Outlook

For the full year 2024, at constant exchange rates, the Company expects total operating expenses of CHF 70-80 million, remaining consistent with the prior year. Of this figure, approximately CHF 8 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciation.

With CHF 174.1 million in cash and short-term time deposits and no debt as of March 31, 2024, the Company expects to be funded well into 2026. This guidance does not include any potential receipts from R&D partnerships.

Research & Development Highlights

MP0533: Clinical update and planned dose escalation expansion
MP0533 (CD33 x CD123 x CD70 x CD3), a novel tetra-specific T cell-engaging DARPin, is currently being evaluated in a Phase 1/2a clinical trial for patients with relapsed/refractory acute myeloid leukemia (r/r AML) and myelodysplastic syndrome/AML (MDS/AML) (NCT05673057).

Results presented at the American Society of Hematology (ASH) Annual Meeting 2023 from the first 11 patients treated with MP0533 indicated a favorable safety profile across the first four dosing regimens (DRs), with no dose-limiting toxicities observed. The study is on track with DR 7 enrollment complete and dosing currently ongoing. Based on the current MP0533 safety data and discussion with treating physicians and key opinion leaders, a protocol amendment was filed on April 25, 2024 to expand enrollment to higher dose cohorts (DRs 8-11) for further characterization of the MP0533 dose-response. The company expects to enroll patients in higher cohorts seamlessly in the second half of 2024.

The mechanism of action of MP0533 is designed to preferentially kill AML cells (blasts and leukemic progenitor and stem cells) that express any combination of the cell surface antigens CD33, CD123, and CD70, while sparing healthy cells which tend to express only one or none of these targets. Updated data, with cut-off as of March 12, 2024, show that MP0533 continues to demonstrate clinical activity similar to what has been reported in earlier dose cohorts. In DRs 5 and 6, an additional 17 patients were treated with MP0533, and of these, 2 patients reached ELN criteria of Morphological Leukemia Free State (MLFS), with additional patients showing early blast reductions in the bone marrow. The drug safety profile remains acceptable with the majority of adverse events reported as infusion-related reactions and cytokine release syndrome. The current data supports expansion to higher dose cohorts to explore the activity of MP0533 in a highly heterogeneous r/r AML patient population. Diverse parameters (e.g., leukemic stem cells, clonal evolution, immune activation) are being examined to inform the next development steps including the potential of earlier lines of treatment, and combination settings. The Company anticipates providing a next clinical update from the study in the second half of 2024 at a scientific congress.

Radio-DARPin Therapy Platform
Molecular Partners continues to advance its RDT platform and programs. At the J.P. Morgan Healthcare Conference in January 2024, the company presented data demonstrating successful increase of tumor uptake and reduction of kidney absorption by applying novel engineering approaches to modify the DARPin backbone (Stealth-DARPins) and its half-life. This enabled further internal progress of the RDT platform and pipeline expansion.

Also in January 2024, Molecular Partners entered a strategic collaboration with Orano Med to co-develop ^{212}Pb-based RDTs for patients with solid tumors. The collaboration combines the power of DARPins, as a highly differentiated modality for tumor-targeted delivery of radioisotopes, with Orano Med's leading capabilities in Targeted Alpha Therapy and supply, to further advance the RDT platform and expand Molecular Partners' RDT portfolio.

The tumor-associated protein Delta-like ligand 3 (DLL3) was selected as the target of the Company's lead RDT program to be advanced into IND-enabling studies in the first half of 2024. The initiation of clinical studies and first-in-human data for our RDT platform are expected in 2025 through co-development with Orano Med.

Molecular Partners will provide an update in an oral presentation at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting 2024 in Toronto on June 11.

Abstract Title: Lead-212 Radio-DARPin Therapeutic (RDT) targeting delta-like ligand 3 (DLL3) shows promising preclinical antitumor efficacy and tolerability in small cell lung cancer (SCLC)

Session Title: Integrated Session: Radionuclides (CMIIT/RPSC)
Presentation Timing: June 11, 2024; 8:00-9:15 am local time

Molecular Partners also expects to nominate additional targets and RDT candidates in 2024.

In addition, Molecular Partners continued to progress its RDT portfolio of projects in partnership with Novartis.

Switch-DARPin Platform

The Switch-DARPin platform provides a logic-gated "on/off" function (the "Switch") to multispecific DARPin candidates leading to target activation only in the presence of defined antigens. The objective is conditional activation of a targeted immune response. The first Switch-DARPin program (cKIT x CD16a x CD47) was introduced at the annual J.P. Morgan Healthcare Conference in January 2024. This approach is designed to induce exhaustive killing of hematopoietic stem cells as next-generation conditioning regimen to increase long-term disease control post hematopoietic stem cell transplant (HSCT) for AML patients, including those with a poor cytogenetic risk profile, and those currently not eligible for standard high-intensity conditioning. Our intent is to extend the access to potentially curative HSCT for more patients with AML as well as additional hematologic malignancies, and genetic diseases requiring HSC transplant.

The company will present initial preclinical data at the European Hematology Association (EHA) Congress 2024 in Madrid on June 14 and has planned preclinical proof-of-concept studies for the second half of 2024.

EHA 2024 Abstract Title: C-KIT X CD16a X CD47 Switch-DARPin with conditional blockade of CD47: a next-generation targeted conditioning for hematopoietic stem cell transplantation

Session Title: Stem Cell Transplantation – Experimental
Abstract Number for Publication: P1294
Poster Session Timing: June 14, 2024; 6-7 pm CET

MP0317: Final Phase 1 data at ASCO

MP0317 simultaneously targets CD40 and fibroblast activation protein (FAP) to enable tumor-localized immune activation. The phase 1 dose-escalation study of MP0317 in patients with advanced solid tumors (NCT05098405) was completed in January 2024. The final outcomes of the 46 treated patients will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting 2024 in Chicago, IL on June 1.

Abstract Title: Effect of MP0317, a FAP x CD40 DARPin, on safety profile and tumor-localized CD40 activation in a phase 1 study in patients with advanced solid tumors.

Session Title: Developmental Therapeutics - Immunotherapy
Abstract Number: 2573
Poster Session Timing: June 1, 2024 from 9:00 am CDT (Hall A)

Corporate and Management Highlights
On February 5, 2024 a putative class action complaint against the Company, its directors, and certain of its executive officers was dismissed without prejudice in the Company's favor, and the plaintiff filed a stipulation of dismissal with prejudice on February 23, 2024. The case was ordered closed on February 29, 2024. The original case was filed on July 12, 2022 in the U.S. District Court for the Southern District of New York.

At the Company's Annual General Meeting on April 17 2024, all motions proposed by the Board of Directors at the Annual General Meeting were approved by the shareholders of the Company.

Financial Calendar

August 26, 2024 – Publication of Half-year Results 2024 (unaudited)

October 31, 2024 – Interim Management Statement Q3 2024

About Molecular Partners AG

Molecular Partners AG (SIX: MOLN, NASDAQ: MOLN) is a clinical-stage biotech company pioneering the design and development of DARPin therapeutics for medical challenges other drug modalities cannot readily address. The Company has programs in various stages of pre-clinical and

clinical development, with oncology as its main focus. Molecular Partners leverages the advantages of DARPins to provide unique solutions to patients through its proprietary programs as well as through partnerships with leading pharmaceutical companies. Molecular Partners was founded in 2004 and has offices in both Zurich, Switzerland and Concord, MA, USA. For more information, visit www.molecularpartners.com and find us on LinkedIn and Twitter/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 and its RDT and Switch-DARPin platforms; the selection and development of future programs; Molecular Partners' collaboration with Orano Med including the benefits and results that may be achieved through the collaboration; and Molecular Partners' expected business and financial outlook, including anticipated expenses and cash utilization for 2024 and its expectation of its current cash runway. These statements may be identified by words such as "anticipate", "believe", "expect", "guidance", "intend", "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 potential that Molecular Partners' product candidates may exhibit serious adverse, undesirable or unacceptable side effects; 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; unanticipated factors in addition to the foregoing that may impact Molecular Partners' financial and business projections and guidance; 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, 2023, filed with Securities and Exchange Commission (SEC) on March 14, 2024 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.