



## Interim Management Statement Q1 2023 of Molecular Partners: Well Capitalized to Pursue Highly Differentiated DARPin Portfolio Strategy

May 11, 2023

**MP0533:** Phase 1 trial of MP0533 for AML ongoing; initial recruitment is progressing well, and site expansion is ongoing; initial clinical results on track for Q4 2023

**MP0317:** Highest dose cohort (Q3W, 10mg/kg) now enrolling; clinical update at ASCO

**Radio DARPin Therapy (RDT):** Presented preclinical data supporting the RDT platform at TAT 12 and AACR

**Outlook:** Funded into 2026 with cash of CHF 232.4 million; total operating expenses of CHF 70 - 80 million expected for 2023

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., May 11, 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 announced its interim management statement for the quarter ending March 31, 2023.

"This quarter we made advances across our portfolio, including two clinical-stage oncology programs, MP0317 for solid tumors and MP0533 for AML. MP0317 is now recruiting patients at the top doses planned. We anticipate analyzing these data and working with potential partners to determine the best combinations and indications for the program. MP0533 recruitment has commenced, dose escalation is ongoing and progressing seamlessly. We look forward to the progress in this study and sharing initial data from the trial later this year," said Patrick Amstutz, Ph.D., Molecular Partners' Chief Executive Officer. "We are also progressing well with our Radio-DARPin platform, comprising both in-house and Novartis-partnered programs, presenting at two leading scientific conferences, documenting the growing data in support of our thesis that RDTs have the potential to overcome many of the current limitations in the radiotherapy field."

### Financial and Business Outlook

For the full year 2023, at constant exchange rates, the Company expects total expenses of CHF 70 - 80 million, of which approximately CHF 9 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciation. This guidance does not include any potential receipts from R&D partnerships.

With CHF 232.4 million in cash and short-term time deposits and no debt as of March 31, 2023, the Company expects to be funded into 2026, excluding any potential receipts from R&D partners.

### Research & Development Highlights:

#### MP0317

In November 2022, Molecular Partners presented early results from the ongoing Phase 1 trial of MP0317, the Company's DARPin candidate targeting fibroblast activation protein (FAP) and CD40, for the treatment of solid tumors at the Society for Immunotherapy of Cancer (SITC) annual meeting. These data demonstrated the first clinical observation of tumor localized CD40 activation provided by MP0317. The candidate was also seen to be safe and well tolerated. MP0317 is designed to resolve the historical limitations of systemic CD40 agonists by activating immune cells within the tumor microenvironment through the simultaneous binding of the immune stimulator CD40 and FAP, a protein highly expressed within tumors. The dose escalation of the Phase 1 study remains on track.

Additionally, a clinical update will be provided at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago in early June:

**Abstract Title:** Phase I study of MP0317, a FAP-dependent DARPin, for tumor-localized CD40 activation in patients with advanced solid tumors.

**Session Title:** Developmental Therapeutics—Immunotherapy

**Abstract Number for Publication:** 2584

**Session Date and Time:** 6/3/2023, 8:00 AM-11:00 AM

#### MP0533

In January 2023, the first patient was dosed and recruiting and dose escalation is going according to plan in the Phase 1 study of MP0533, a novel trispecific T-cell engager for the treatment of Acute Myeloid Leukemia (AML). The first clinical results from this trial are expected by the fourth quarter of 2023. MP0533 engages CD3 on T-cells while binding up to three tumor-associated antigens (TAAs) CD33, CD70, and CD123 on AML cells. By modulating the affinity to each TAA, Molecular Partners designed MP0533 to induce T-cell-mediated killing preferentially when the cancer cells express two or three of the TAAs. This avidity-driven T-cell activation ensures preferential killing of AML cells, which consistently express two or three of the target antigens. At the same time, it is designed to reduce the damage to healthy cells (which tend to express only one of the target antigens), a recurrent issue with other T-cell engagers in AML.

In an oral presentation at the American Society of Hematology (ASH) annual meeting in December 2022, Molecular Partners presented preclinical results showing MP0533 can induce preferential killing of cells expressing two or three tumor-associated antigens (TAAs) compared to cells expressing a single TAA. MP0533 was demonstrated to activate T-cells and destroy AML cells in samples from newly diagnosed and previously treated AML patients with different TAA expressions. Humanized mouse models confirmed MP0533's ability to activate intra-tumoral T-cells and control tumor growth. The research also showed that MP0533 was able to directly target and kill leukemic stem cells (LSCs), while sparing a variety of healthy cells including hematopoietic stem cells. The unique preclinical safety profile of MP0533 was further supported by several other parameters including a lower level of cytokine release relative to benchmark mono-targeted T-cell engagers, both in vitro in a whole blood assay and in vivo in the

humanized mouse AML models.

### **Radio DARPIn Therapy Platform**

Molecular Partners has continued to progress its Radio DARPIn Therapy (RDT) platform by reducing the kidney uptake of DARPIn radio conjugates to overcome nephrotoxicity (toxicity in the kidney), the key limitation of small protein-based radiotherapies. In 2023, the Company presented positive preclinical data from its RDT platform at the American Association for Cancer Research (AACR) annual meeting and the 12th International Symposium on Targeted Alpha Therapy (TAT 12) supporting its potential to significantly reduce accumulation in the kidney, a common challenge with small protein-based delivery vectors. In preclinical models, the surface engineering did not affect tumor uptake or uptake in other healthy organs and in combination with another kidney reduction strategy provided a cumulative benefit.

The Company also selected tumor-associated protein Delta-like ligand 3 (DLL3) as the first target of its proprietary RDT programs. Expression of DLL3 is low in healthy tissue but significantly increased in certain tumor types, providing an opportunity for selective targeting through the high affinity and specificity offered by DARPIns. These attributes, along with their small size, suggest that DARPIns represent ideal delivery vectors for therapeutic radionuclides to efficiently target cancer cells with minimal systemic side effects. Molecular Partners is developing RDT candidates as part of its proprietary pipeline as well as in its collaboration with Novartis in the radioligand area.

### **Virology**

Molecular Partners and Novartis signed a non-binding letter of intent to negotiate a Research Framework Agreement with a primary focus on emerging infectious global health threats.

### **Ophthalmology**

In November 2021, Molecular Partners regained global development and commercial rights to abicipar for the treatment of neovascular age-related macular degeneration (nAMD) and Diabetic Macular Edema (DME). Abicipar completed two positive Phase 3 studies, CEDAR and SEQUOIA, which supported the non-inferior efficacy of its quarterly dosing regimen compared to monthly ranibizumab.

The Company continues to evaluate potential business opportunities for abicipar outside of internal development at Molecular Partners.

### **Financial Calendar**

24 August 2023 - Publication of Half-year Results 2023 (unaudited)

26 October 2023 - Interim Management Statement Q3 2023

### **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 virology and has compounds in various stages of clinical and preclinical development across multiple therapeutic areas. [www.molecularpartners.com](http://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 2023 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; 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](http://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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