



## Molecular Partners Interim Management Statement Q3 2023: Continued Validation Seen Across the DARPin Portfolio

October 26, 2023

- *MP0317 Phase 1 dose escalation recruitment completed in patients with advanced solid tumors; updated clinical results to be presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2023*
- *MP0533 Phase 1/2a recruitment in r/r AML patients proceeding as planned with initial data expected at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2023*
- *Radio-DARPin Therapy (RDT) platform continues to progress, supporting the expansion of target universe accessible by radiotherapy; recent advances presented at the European Association of Nuclear Medicine (EANM) Annual Meeting in September 2023*
- *Funded well into 2026, with cash and cash equivalents of CHF 207 million as of September 30, 2023*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Oct. 26, 2023 (GLOBE NEWSWIRE) -- **Ad hoc announcement pursuant to Art. 53 LR: [Molecular Partners AG](#)** (SIX: MOLN; NASDAQ: MOLN), a clinical-stage biopharmaceutical company developing a class of custom-built protein drugs known as DARPin therapeutics ("Molecular Partners" or the "Company"), today announced corporate highlights and unaudited financial results for the third quarter of 2023.

"DARPin differentiation remains core to our strategy and we continue to develop programs where we see a distinct advantage to using our technology over others. In the second half of this year, we are making great progress towards our goal of showcasing DARPins' potential to provide sophisticated solutions for patients living with cancers, by presenting updated results from MP0317 and initial data from our ongoing Phase 1 trial of MP0533 in relapsed/refractory AML later this year," said Patrick Amstutz, Ph.D., Molecular Partners' Chief Executive Officer. "As our ongoing clinical trials remain on track, we are rapidly applying learnings from the positive data we have generated thus far from our Radio-DARPin Therapy platform to study new oncology targets in radiotherapy. The differentiated programs we are pursuing across our portfolio, in addition to our robust cash position, will serve as our springboard as we continue to execute on our clinical strategy in 2024."

### Research & Development Highlights

#### Oncology

##### *MP0533 (CD33 x CD123 x CD70 x CD3)*

Recruitment in the MP0533 Phase 1/2a trial in patients with relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome/AML (MDS/AML) is on track, with patients presently being treated at dose regimen five. Initial safety and activity data from this ongoing clinical trial will be presented at the American Society of Hematology (ASH) Annual Meeting and Exposition in December 2023. Additional data are expected to be presented in H1 2024.

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 tetraspecific 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.

##### *MP0317 (FAP x CD40)*

The Company has completed patient recruitment of the ongoing MP0317 dose escalation portion of the Phase 1 trial in patients with advanced solid tumors at the highest planned doses and will present latest results from this ongoing trial at the Society for Immunotherapy of Cancer (SITC) Annual Meetings on November 3, 2023:

**Abstract 721:** *Ongoing Phase 1 study of MP0317, a FAP-CD40 DARPin, shows a favorable safety profile and early evidence of tumor-localized CD40 activation in patients with advanced solid tumors*

MP0317, a localized CD40 agonist, is designed to activate immune cells specifically within the tumor microenvironment by anchoring to fibroblast activation protein (FAP), which is highly expressed within tumors. This design is intended to reduce systemic toxicities seen historically with CD40 agonists by selectively directing CD40's proven immuno-stimulatory properties to tumor tissues.

The data to be presented at SITC build on the findings from the MP0317 Phase 1 trial previously presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2023, including data confirming tumor localized CD40 activation and indicating a favorable safety profile for MP0317. These data support planning of future combination studies of MP0317 with potential partners. Final data of this Phase 1 study are anticipated in H1 2024.

## *Radio-DARPin Therapy (RDT) platform*

Molecular Partners' RDT platform is being developed to provide a unique and innovative delivery system for radioactive payloads. Thanks to their small size as well as their high specificity and affinity, DARPins represent ideal vectors for efficient delivery of therapeutic radionuclides to solid tumors, while overcoming some historic limitations of radioligand therapy approaches.

The Company presented positive preclinical data from its RDT platform in September 2023 at the European Association of Nuclear Medicine (EANM) Annual Meeting, showing that DARPins can be engineered to increase tumor uptake as well as reduce accumulation in kidneys. Additional work is ongoing to demonstrate the ability of RDT to efficiently deliver high amounts of radioactivity for effective tumor eradication. Importantly, it was shown that many of the learnings for RDT are likely to be applicable across the platform, not merely to individual targets. More details on these efforts will be presented in 2024.

Molecular Partners continues to progress its RDT platform and portfolio of projects, both in-house and in partnership with Novartis, to translate and apply learnings across programs and targets. As previously announced, the tumor-associated protein Delta-like ligand 3 (DLL3) has been selected as one of the first targets of Molecular Partners' proprietary RDT program.

## **Corporate and Management Highlights**

Philippe Legenne, M.D., MBA, MHS, SVP Medical Strategy and Development, has assumed the role of acting Chief Medical Officer effective as of August 25, 2023, as previously announced. Dr. Legenne joined Molecular Partners in early 2020. During his tenure, he has led the clinical development strategy and execution across the Molecular Partners portfolio. Prior to joining Molecular Partners, Philippe held positions of increasing responsibility at Johnson & Johnson, GSK, and Novartis, both in the United States and Europe. In his most recent role prior to Molecular Partners, Philippe led the EU medical organization for the oncology portfolio at Amgen. He received his medical degree from the Université de Lille (France), an MBA from ESSEC Business School (Paris), and a Master's degree in health economics from Université Paris Dauphine-PSL.

## **ESG**

In its commitment to corporate sustainability, the Company is continuously refining its ESG strategy to align with the expansion of the pipeline, the future growth of the company and the values and principles of its employees and shareholders. Priority areas for the Company include corporate sustainability; human capital management and Diversity, Equity and Inclusion (DE&I); product service and safety; access to medicine; and business ethics. Elsewhere, Molecular Partners offers generous benefits spanning from health to retirement planning to its employees and fosters diversity and inclusion as a key element of its recruitment process.

## **Financial and Business Outlook**

For the full year 2023, at constant exchange rates, the Company expects total expenses of CHF 65-70 million, of which approximately CHF 8 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 207 million in cash and short-term time deposits and no debt as of September 30, 2023, the Company expects to be funded well into 2026, excluding any potential receipts from R&D partners.

## **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, Molecular Partners' most advanced DARPin drug candidate. 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 (designed ankyrin repeat protein) 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 X - [@MolecularPrtnrs](https://twitter.com/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](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.