Molecular Partners Reports Financial Results and Highlights from Q1 2025

May 15, 2025

- *Clinical programs on track, with two major milestones later this year, and cash position, CHF 131 million as of March 31, 2025, expected to provide funding well into 2027*
- *IND filing and initial clinical data on first targeted Radio-DARPin therapy program, MP0712, expected in 2025; strategic partnership with Orano Med expanded from four to ten programs*
- *Data from dosing cohort 8 in Phase 1/2a trial of MP0533 demonstrate increased rates and depth of responses; study protocol amendment now approved, and dosing cohort 9 enrollment initiated, additional data expected in 2025*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., May 15, 2025 (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 ("Molecular Partners" or the "Company"), today announced corporate highlights and unaudited financial results for the first quarter of 2025.

"Molecular Partners is on track to reach key clinical milestones in 2025. In January, we expanded our strategic radiotherapy partnership with Orano Med and are continuing to advance the lead program, MP0712, towards a first-in-human trial. With the data package of MP0712 complete, we anticipate both the IND filing and initial clinical data on MP0712 in 2025. The early images and dosimetry data will be a strong surrogate for the expected efficacy and safety in Phase 1. Our multispecific T cell engager MP0533 is progressing in its Phase 1/2a trial in acute myeloid leukemia. Initial data from cohort 8, with an additional dosing point in the step-up dosing, indicate increased rates and depth of responses, while the fully amended dosing scheme is being tested in cohort 9. Our focus remains firmly on delivering results that further validate our science and create meaningful value for patients and stakeholders alike, based on a solid financial position with funding in place well into 2027," said **Patrick Amstutz, Ph.D., CEO of Molecular Partners**.

Research & Development Highlights

MP0712, Radio-DARPin Pipeline and Global Partnership with Orano Med

In January 2025, Molecular Partners and Orano Med further expanded their agreement to co-develop up to ten ^{212}Pb-labeled radiotherapy programs. Molecular Partners holds commercialization rights to MP0712, a Radio-DARPin therapy (RDT) candidate targeting delta-like ligand 3 (DLL3) for the treatment of small cell lung cancer (SCLC), and to the second program, targeting mesothelin (MSLN). In addition to its world class expertise and capabilities in the development of targeted alpha therapy (TAT) with ^{212}Pb, Orano Med will ensure the production of the ^{212}Pb-based Radio-DARPins for clinical trials and commercialization.

Molecular Partners presented preclinical data in April at the American Association for Cancer Research (AACR) Annual Meeting 2025, showing high tumor uptake and a favorable toxicity profile for MP0712, with good efficacy and tumor reduction in mouse models matching clinically relevant DLL3 expression levels. With these data, the Investigational New Drug (IND)-enabling package is complete.

The IND application for MP0712 is planned for mid 2025 and dialogue with the U.S. Food and Drug Administration (FDA) is ongoing. Based upon discussion with the agency the Company has determined that a Phase 0 imaging study, which was previously planned, will not be necessary. MP0712 will proceed directly to a Phase 1 dose-escalation study utilizing ^{212}Pb, which includes an imaging step using ^{203}Pb. This study will initiate in the second half of 2025, pending IND submission and clearance.

In addition, Molecular Partners has received and accepted a request from Nuclear Medicine Research Infrastructure (NuMeRI) in South Africa to provide MP0712 for imaging use under the legal framework in South Africa for compassionate care (also referred to as Section 21 of the Medicines and Related Substances Act). This approach enables the generation of first images applying MP0712 labelled with ^{203}Pb in patients with SCLC. While the decision of where and how to share data from the image work under Section 21 remains at the discretion of NuMeRI, the Company anticipates providing an update on MP0712 in H2 2025.

The second RDT program co-developed with Orano Med targets MSLN, a tumor target overexpressed across several cancers with high unmet need, such as ovarian cancer. The development of therapeutics against MSLN has been hampered by high shedding of MSLN, leading to high levels of soluble MSLN. Leveraging the unique properties of DARPins, Molecular Partners has developed Radio-DARPins able to selectively bind to membrane-bound MSLN without being impacted by shed MSLN. First preclinical data from the MSLN program were presented at AACR 2025, with *in vivo* results showing a favorable biodistribution with strong tumor accumulation of the Radio-DARPin in a MSLN-overexpressing model in mice. Molecular Partners will present more preclinical data on the MSLN program in an oral presentation at the 2025 Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting in June.

MP0533 (Multispecific T Cell Engager)

MP0533 is currently being evaluated in a Phase 1/2a clinical trial for relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome/AML (ClinicalTrials.gov: NCT05673057). Dose escalation in cohorts 1–7 showed an acceptable safety profile and initial activity, yet with unsustained responses (four responders reported and encouraging blast reductions across additional patients).

In the ongoing cohort 8, an additional dosing timepoint was introduced to allow steeper step-up and more frequent dosing to reach the MP0533 target

dose faster. Data from this cohort indicate increased rates and depth of responses, with three out of eight evaluable patients demonstrating responses (data cutoff 16 December 2024). The Company will present additional data on Cohort 8 at the European Hematology Association (EHA) Congress in June 2025.

The study protocol has been amended to improve the exposure profile of MP0533 based on the learnings from the dose escalation cohorts, and has been approved by regulatory authorities in April 2025. It foresees further MP0533 dose densification and premedication to mitigate loss of exposure, with the objective to further increase the rate, depth and duration of responses observed in cohort 8. Enrollment has started and data on the amended dosing scheme are expected in 2025.

Switch-DARPin Platform (Next-generation Immune Cell Engagers)

By employing a multi-specific Switch-DARPin, Molecular Partners aims to increase the safety and potency of T cell engagers (TCEs). Preclinical proof-of-concept in a solid tumor model for a novel CD3 Switch-DARPin TCE was presented at AACR 2025.The CD3 Switch-DARPin activates T cells specifically in the presence of cells co-expressing MSLN and epithelial cell adhesion molecule (EpCAM), increasing tumor specificity. The data presented provide further validation of Switch-DARPins and show that conditional T-cell activation with potent CD2 co-stimulation in solid tumors, but not in healthy tissues, is feasible.

Molecular Partners' first Switch-DARPin program, MP0621, is designed to induce killing of hematopoietic stem cells (HSCs) as a next-generation conditioning regimen for HSC transplantation. The Company has presented pre-clinical proof-of-mechanism data on MP0621 in 2024. As its portfolio strategy prioritizes therapeutic candidates for oncology, MP0621 is being evaluated for partnering.

MP0317 (localized agonist)

Molecular Partners presented comprehensive biomarker analyses from the completed Phase 1 dose escalation trial of the localized CD40 agonist MP0317 in solid tumors at SITC in November 2024. MP0317 is designed to activate immune cells specifically within the tumor microenvironment by anchoring to fibroblast activation protein (FAP), which is expressed in high amounts in the stroma of various solid tumors. The Company believes this tumor-localized approach has the potential to deliver greater efficacy with fewer side effects compared to systemic CD40-targeting therapies.

Molecular Partners is in discussion with leading academic centers regarding potential investigator-initiated trials of MP0317 in 2025, in combination with immune checkpoint inhibitors and additional standard of care for patients with solid tumors.

Corporate Governance Highlights

All motions proposed by the Board of Directors at the Annual General Meeting, held in April 2025, were approved by the shareholders of the Company.

Financial and Business Outlook
For the full year 2025, at constant exchange rates, the Company expects total operating expenses of CHF 55-65 million of which around CHF 7 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciation.

The Company's cash and cash equivalents and short-term time deposits were CHF 131 million as of March 31, 2025 and based on current operating assumptions, will be sufficient to fund its operating expenses and capital expenditure requirements well into 2027.

About DARPin Therapeutics
DARPin (Designed Ankyrin Repeat Protein) therapeutics are a new class of custom-built protein drugs based on natural binding proteins that open new dimensions of multi-functionality and multi-target specificity in drug design. The flexible architecture, intrinsic potential for high affinity and specificity, small size and high stability of DARPins offer benefits to drug design over other currently available protein-based therapeutics. DARPin candidates can be radically simple, with a single DARPin unit acting as the delivery vector to a specific target; or multispecific, with the possibility of engaging more than five targets, and combining multiple and conditional functionalities in a unique DARPin drug candidate. The DARPin platform is designed to be a rapid and cost-effective drug discovery engine, producing drug candidates with optimized properties and high production yields. DARPin therapeutics have been clinically validated across several therapeutic areas and developed through to the registrational stage.

About Molecular Partners
Molecular Partners AG 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 2025 and its expectation of its current cash runway. These statements may be identified by words such as “aim”, "anticipate”, “expect”, “guidance”, “intend”, “outlook”, “plan”, “potential”, “will” 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 cause Molecular Partners’ actual results to differ from its financial and business projections and guidance; and other risks and uncertainties set forth in Molecular Partners’ Annual Report on Form 20-F for the year ended December 31, 2024 and other filings Molecular Partners makes with the SEC from time to time. These documents are available on the Investors page of Molecular Partners’ website at www.molecularpartners.com. In addition, this press release contains information relating to interim data as of the relevant data cutoff date, results of which may differ from topline results that may be obtained in the future. 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.