Molecular Partners reports financial results and highlights recent clinical pipeline progress for H1 2025

August 25, 2025

- *MP0533 data presented at European Hematology Association (EHA) highlights improved response rates and antitumor activity in low disease burden patients; additional data under amended dosing scheme expected in Q4 2025*
- *IND filing on first radio-DARPin program MP0712 and initiation of Phase 1 trial expected by end 2025; update on early imaging work planned in Q4 2025; expanded strategic radiotherapy partnership with Orano Med*
- *Appointed Martin Steegmaier, Ph.D. as CSO and member of Executive Committee*
- *Cash and cash equivalents and short-term time deposits total of CHF 114 million as of June 30, 2025, extending runway into 2028.*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Aug. 25, 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 half of 2025.

"Molecular Partners continues to make good progress towards key development milestones, notably in our two clinical programs. Following the expansion of our strategic radiotherapy partnership with Orano Med in January, we are advancing our lead program MP0712 towards its first-in-human trial. With the data package complete, we anticipate the IND filing and Phase 1 initiation in 2025, and initial clinical data in H1 2026. Our multispecific T cell engager MP0533 is making progress in its Phase 1/2a trial for acute myeloid leukemia. Recently presented data show both increased response rates and greater depth of responses and we look forward to presenting the first data under the amended study protocol in Q4 2025. We also strengthened our leadership with the appointment of Martin Steegmaier, Ph.D., as CSO, further underlining our commitment to delivering improved treatment options for patients and significant value for our stakeholders. Our finances remain robust with funding projected into 2028," said **Patrick Amstutz, Ph.D., CEO of Molecular Partners**.

Research & Development Highlights

MP0533 (Multispecific T Cell Engager; CD33 x CD123 x CD70 x CD3)

MP0533 is currently being evaluated in a Phase 1/2a clinical trial for relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS)/AML (ClinicalTrials.gov: NCT05673057). Molecular Partners presented updated data from the study at the 30th Annual European Hematology Association (EHA) Congress in June, outlining the impact of accelerated step-up dosing regimen of MP0533 on exposure and clinical responses in cohort 8, providing the rationale for further optimization to the dosing regimen implemented in the ongoing cohort 9.

Initial data from cohort 8 show promising antitumor activity: 3 of 8 (>30%) evaluable patients with relapsed/refractory disease achieved a clinical response after the first cycle, with one complete response and two complete responses with partial hematologic recovery. Notably, two patients maintained their responses for over three months, including one patient still responding after more than six months at data cutoff (14 April 2025) and still on treatment today. This cohort benefited from a higher starting dose and a faster step-up dosing schedule, leading to prolonged exposure within the predicted therapeutic range and notable blast reduction in most patients, with an acceptable safety profile after dose adjustments in cohort 8.

Encouraged by these results, Molecular Partners amended the study protocol for cohorts 9 and 10 by further accelerating the step-up dosing, increasing the dosing frequency and introducing anti-CD20 premedication for greater cumulative exposure. These changes aim to enhance both the depth and duration of patient responses. Cohort 9 is exploring a lower target dose than cohort 8 to assess the safety of up to daily dosing for the first 14 days of treatment, leading to significantly denser dosing; cohort 10 aims at reaching the same target dose as cohort 8 while exposing patients to more drug over time. Initiation of cohort 10 is anticipated to start in the coming weeks, pending appropriate approvals. Cohort 9 is now fully recruited, with initial data expected to be presented in Q4 2025.

MP0533 continues to show broad activity, with initial blast reductions in a majority of patients treated. The data continue to indicate that the patients more likely to see durable responses will be those who initiate therapy with a lower level of blasts at baseline. Looking forward, Molecular Partners plans to explore future cohorts of MP0533 in combination settings, both in relapsed/refractory as well as in front-line patients, should favorable antitumor activity continue to be observed. The company is engaging with regulators such as the U.S. Food and Drug Administration (FDA) to discuss next steps.

MP0712 (^{212}Pb x DLL3), Radio-DARPin Pipeline and Global Partnership with Orano Med

The Phase 1 Investigational New Drug (IND) application for MP0712, a ^{212}Pb-based Radio-DARPin therapy (RDT) candidate targeting the tumor-associated protein delta-like ligand 3 (DLL3), co-developed with Orano Med for the treatment of small cell lung cancer (SCLC), is in preparation. Molecular Partners presented preclinical data in April at the American Association for Cancer Research (AACR) Annual Meeting 2025, showing a high tumor uptake and a favorable safety profile for MP0712, with good efficacy in mouse models matching clinically relevant DLL3 expression levels. Dialogue with the FDA is ongoing and IND filing expected in Q3 2025. The first clinical sites in the U.S. are identified and, pending regulatory clearance, patient dosing is planned to initiate in 2025 with initial first-in-human clinical data expected in H1 2026.

In H1 2025, Molecular Partners 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 allows for the potential to generate initial images applying MP0712 labelled with ^{203}Pb in patients with SCLC and other DLL3-expressing neuroendocrine cancers. 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. ^{203}Pb and ^{212}Pb are an element-equivalent pair of lead (Pb) isotopes, with ^{203}Pb primarily used for imaging and ^{212}Pb for therapeutic applications (targeted alpha therapy, TAT). As a “matched pair”, pre-treatment imaging with ^{203}Pb will provide a prediction of treatment behavior with ^{212}Pb.

The second RDT program co-developed with Orano Med is MP0726, targeting mesothelin (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 levels of shed 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. The Company presented preclinical data on MP0726 at AACR 2025 in April and at the 2025 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) in June. Initial clinical data are expected in 2026.

In January 2025, Molecular Partners and Orano Med further expanded their agreement to co-develop up to ten radiotherapy programs. In addition to its world class expertise and capabilities in the development of TAT with ^{212}Pb, Orano Med will ensure the production of the ^{212}Pb-based Radio-DARPins for clinical trials and commercialization. Orano Med possesses virtually unlimited source material for ^{212}Pb production and has established robust and independent supply and manufacturing capabilities required for the seamless delivery of TAT to clinical sites internationally.

Switch-DARPins (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 with CD2 costimulation was presented at AACR in April 2025. The data show the feasibility of conditional T cell activation with potent co-stimulation in solid tumors, but not in healthy tissues. In addition, data showed that the CD3 Switch-DARPin activates T cells specifically in the presence of cells co-expressing the tumor targets MSLN and EpCAM, increasing tumor specificity. The Company will present an update on the CD3 Switch-DARPin program at the Annual Meeting of the Society for Immunotherapy of Cancer (SITC) in Q4 2025.

MP0317 (tumor-localized CD40 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 has committed to supporting an investigator-initiated trial of MP0317. The study is being designed for the treatment of patients with advanced cholangiocarcinoma in combination with standard-of-care. A study protocol has been submitted; pending regulatory approval, the study could be initiated in 2025.

Corporate Governance Highlights

As announced on August 21, 2025, Molecular Partners appointed Martin Steegmaier, Ph.D., as Chief Scientific Officer (CSO) and member of its Executive Committee, effective October 1, 2025. He brings a wealth of experience in oncology drug development, having previously contributed to the advancement of several innovative cancer therapies at major biotech and pharmaceutical companies.

In H1 2025, Molecular Partners undertook a strategic review of its operations and headcount, with the objectives of increased efficiency in the organization and to sharpen the focus on advancing its clinical assets. As a result of this review, the Company informed the Amt für Wirtschaft of Kanton Zürich (Office for Economic Affairs) in June 2025 of its intention to reduce its current workforce by no more than 40 positions, representing up to ~24% of all positions. All employees affected have been informed, and based upon these headcount reductions, the Company now anticipates its cash runway to extend into 2028, beyond its prior guidance of 2027.

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 by a wide majority.

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 114 million as of June 30, 2025 and based on current operating assumptions, will be sufficient to fund its operating expenses and capital expenditure requirements into 2028.

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 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 and Nuclear Medicine Research Infrastructure including the benefits and results that may be achieved through the collaborations; and Molecular Partners' expected business and financial outlook, including expected benefits of its H1 2025 headcount reduction, 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.