Molecular Partners presents positive data from ongoing Phase 1/2a trial of MP0533 in AML at EHA 2025

June 11, 2025

- *Three of eight evaluable patients with R/R AML responded after cycle 1 in ongoing cohort 8, including 1 patient with ongoing response beyond 6 months*
- *Acceptable safety profile across all cohorts, including in cohort 8 with steeper step-up dosing*
- *Data support further dose optimization to maximize therapeutic benefit of MP0533, with dosing in cohort 9 now ongoing*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., June 11, 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 a poster presentation with positive, updated data from a Phase 1/2a trial of the tetraspecific T-cell engager MP0533 in relapsed/refractory acute myeloid leukemia (AML), at the 30th EHA (European Hematology Association) Congress, taking place in Milan on June 12–15, 2025.

The poster, *Updated Results from the Ongoing Phase 1/2a Study of MP0533, a Tetra-Specific Designed Ankyrin Repeat Protein (DARPin; CD33 x CD123 x CD70 x CD3), in Patients with Relapsed/Refractory AML or MDS/AML*, outlines the impact of accelerated step-up dosing regimen (steeper and faster) 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.

Data from cohort 8 show that 3 of 8 evaluable patients (> 30%) achieved a clinical response after the first cycle, with one patient achieving a complete response and two patients a complete response with partial hematologic recovery as best overall response. Two patients maintained a response for more than 3 months and one patient remains on treatment, maintaining a response beyond 6 months at the time of data cutoff (14 April 2025). Cohort 8 implemented a higher starting dose than cohorts 1-7, and the inclusion of an additional day of dosing, reaching the target dose by day 12, as opposed to day 15 previously.

Cohort 8 data indicate that patients maintained exposure to MP0533 for a longer period of time within the predicted therapeutic range through the accelerated step-up dosing scheme, within the first cycle. Data show that patients reached over 4 days of relevant exposure, with 5 out of 8 patients displaying > 50% blast reduction. MP0533 shows an acceptable safety profile after adjustment of the target dose in cohort 8.

"I am encouraged by the number and level of responses observed in the most recent cohort and have started to include patients with the new 'dense administration' schedule aiming to establish the full potential of this product for our R/R AML patients," said **Pierre Bories, MD, PhD, Principal Investigator** at Institut Universitaire du Cancer Toulouse - Oncopole, France.

In cohorts 1-7, where step-up dosing reached target dose by day 15, exposure to predicted therapeutic doses was limited to roughly 2 days in the first cycle, most likely due to target-mediated-drug deposition. This prior treatment protocol, despite demonstrating initial blast reductions in ~30% of patients, resulted in limited responses.

Based on the encouraging antitumor activity observed in cohort 8, the amended protocol for cohort 9 and beyond includes further acceleration of the step-up dosing to reach therapeutically-relevant doses faster, increased frequency of dosing for higher cumulative MP0533 exposure, and the introduction of anti-CD20 premedication to mitigate loss of exposure, with the objective to further increase the depth and duration of responses in patients.

Cohort 9 is currently dosing patients and initial data from the amended dosing scheme are expected in H2 2025. Additionally, future study cohorts will evaluate the combination of azacitidine/venetoclax with MP0533.

Details of the presentation:

Updated Results from the Ongoing Phase 1/2a Study of MP0533, a Tetra-Specific Designed Ankyrin Repeat Protein (DARPin; CD33 x CD123 x CD70 x CD3), in Patients with Relapsed/Refractory AML or MDS/AML
Time: June 13, 18:30 - 19:30 CEST (Poster Session 1)

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 2025 and its expectation of its current cash runway and the expected use of proceeds from the October 2024 offering. 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.