Molecular Partners publishes Phase 1 MP0317 data in Nature Cancer demonstrating tumor-localized CD40 activation and tumor microenvironment remodeling

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- *Positive Phase 1 data confirm MP0317's tumor-localized CD40 activation with a favorable safety profile in patients with advanced cancer types*
- *Pharmacokinetic profile of MP0317 well suited for combination treatment settings, including checkpoint inhibitors*
- *Randomized Phase 2 investigator-initiated trial of MP0317 in front-line cholangiocarcinoma open with patient dosing ongoing*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., May 01, 2026 (GLOBE NEWSWIRE) -- **Ad hoc announcement pursuant to Art. 53 LR** Molecular Partners AG (SIX: MOLN; NASDAQ: MOLN), a clinical-stage biotech company developing a novel class of custom-built protein drugs known as DARPin therapeutics ("Molecular Partners" or the "Company"), today announced the publication of Phase 1 clinical data in *Nature Cancer* demonstrating the potential of the tumor-localized CD40 agonist, MP0317, to modulate the tumor microenvironment (TME). MP0317 is designed to activate immune cells specifically within the TME by anchoring to fibroblast activation protein (FAP), which is expressed in high amounts in the stroma of various solid tumors. This tumor-localized approach has the potential to deliver greater efficacy with fewer side effects compared to systemic CD40-targeting therapies.

The peer-reviewed paper published by Steehgs et al., entitled "*Tumor-localized CD40 agonism with MP0317, a FAPxCD40 DARPin, reprograms the tumor microenvironment - results of a Phase 1 monotherapy study*", reports the positive results from the completed Phase 1 dose escalation study of MP0317 (NCT05098405). The comprehensive biomarker data confirm proof-of-mechanism for MP0317, including tumor-localized activation of the CD40 pathway and evidence of TME remodeling in patients with advanced solid tumors. MP0317 displayed a favorable safety profile up to the highest tested dose and serum pharmacokinetics confirmed suitability for dosing either weekly or every three weeks. Of the 46 patients in the study, one patient achieved an unconfirmed partial response and 14 patients stable disease in this heterogeneous population with advanced diseases. Data were presented at the 2024 Annual Meetings of the American Society of Clinical Oncology (ASCO) and of the Society for Immunotherapy of Cancer (SITC).

"The Phase 1 data published in *Nature Cancer* demonstrate the promising ability of MP0317 to turn cold tumors hot by locally modulating the tumor microenvironment, while avoiding systemic toxicities often seen with untargeted CD40 agonists. These data support further clinical evaluation of MP0317 in combination with other immunotherapy modalities, such as checkpoint inhibitors," said coordinating investigator Philippe Cassier, M.D., Ph.D., of the Centre Léon Bérard in Lyon, France. "We are currently enrolling patients with cholangiocarcinoma in an investigator-initiated Phase 2 study of MP0317 in combination with standard of care chemotherapy and anti-PDL1 therapy, led by Prof. Christophe Borg, and look forward to assessing its clinical benefit for patients."

An investigator-initiated, proof-of-concept Phase 2 study of MP0317 combined with standard-of-care (SoC) for the treatment of patients with advanced cholangiocarcinoma is now open with eight sites activated (NCT07036380) and patient dosing ongoing. The multicenter study aims to recruit 75 patients in France, randomized 2-to-1 with 50 patients in the experimental arm, and 25 in the control arm. The objective of the study is to assess the clinical benefit of MP0317 combined with SoC comprising the immunotherapy durvalumab, an anti-PD-L1 checkpoint inhibitor, plus gemcitabine-cisplatin-based chemotherapy, compared to SoC alone. The TME is known to play a crucial role in cholangiocarcinoma development and treatment resistance. MP0317 is hypothesized to lead to immune-mediated reshaping of the TME, thereby improving the 12-month progression-free survival rate of patients compared to those treated with SoC alone.

The publication in *Nature Cancer* is available online and accessible via the following URL: https://www.nature.com/articles/s43018-026-01150-1

About Molecular Partners AG
Molecular Partners AG (SIX: MOLN, NASDAQ: MOLN) is a clinical-stage biotech company pioneering a novel class of protein drugs known as DARPin therapeutics, for medical challenges other treatment modalities cannot readily address. Molecular Partners leverages the key properties of DARPins to design and develop differentiated therapeutics for cancer patients, including targeted radiopharmaceuticals and next-generation immune cell engagers. The Company has proprietary programs in various stages of pre-clinical and clinical development, as well as programs developed through partnerships with leading pharmaceutical companies and academic centers. Molecular Partners, founded in 2004, 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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This press release contains 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; the expected benefits of the strategic review; and Molecular Partners' expected business and financial outlook, including anticipated expenses and cash utilization for 2026 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, but are not limited to, those set forth in under the heading "Risk Factors" in Molecular Partners' Annual Report on Form 20-F for the year ended December 31, 2025 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.