



Molecular Partners Presents Positive Data From Completed Phase 1 Trial Of MP0317 (FAP X CD40 DARPin) Monotherapy In Patients With Advanced Solid Tumors At ASCO 2024

June 1, 2024

- Mechanism of action supported by observed MP0317 localization and immune cell activation in the tumor microenvironment
- Favorable and manageable safety profile observed at all tested dose levels
- Weekly and three-weekly dosing schedules established, supported by pharmacokinetics and pharmacodynamics
- Data support further clinical evaluation of MP0317 in combination settings

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., June 01, 2024 (GLOBE NEWSWIRE) -- **Ad hoc announcement pursuant to Art. 53 LR Molecular Partners** AG (SIX: MOLN; NASDAQ: MOLN), a clinical-stage biotech company pioneering the design and development of a new class of custom-built protein drugs known as DARPin therapeutics, today announced it had presented the final data from its Phase 1 dose-escalation study of MP0317 at the American Society of Clinical Oncology (ASCO) Annual Meeting 2024, held in Chicago, IL, USA. MP0317 is a CD40 agonist designed to activate immune cells specifically within the tumor microenvironment (TME) by anchoring to fibroblast activation protein (FAP) which is expressed in high amounts around tumors. This tumor-localized approach has the potential to deliver greater efficacy with fewer side effects compared to systemic CD40-targeting therapies.

“The Phase 1 data for MP0317 demonstrate the ability of the FAP x CD40 DARPin to avoid the systemic toxicities of CD40 agonists while showcasing truly promising modulation of the tumor microenvironment,” said Philippe Legenne, MD, MBA, Molecular Partners’ acting Chief Medical Officer. “This further deepens the clinical evidence supporting DARPins’ ability to deliver multi-specific candidates with enhanced capabilities in oncology including localized activation of powerful immunostimulatory molecules. We will continue discussions with potential partners towards clinical evaluation of MP0317 in combination with complementary approaches.”

Mechanistic data & clinical response

The final analysis of this phase 1 dose-escalation study included 46 patients with advanced solid tumors and confirms earlier reported interim analysis findings. MP0317 treatment resulted in target occupancy in tumor biopsies with evidence of TME remodeling as characterized by increases in dendritic cells (DC), T follicular helper cells and plasma cells, as well as IFN γ downstream activation and DC maturation gene signature score increases. These findings were further supported by observed elevation of serum levels of CXCL10, a pro-inflammatory downstream effector of the IFN γ signaling.

In terms of clinical response, one patient achieved an unconfirmed partial response and stable disease was observed in 14 additional patients. The data support further clinical evaluation of MP0317 in combination with complementary anticancer therapies. Dose-response analyses of the final trial data propose MP0317 at dosages of 1.5mg/kg or above as providing an optimal benefit-risk profile, with adjustable dosing frequency to match a combination dosing scheme.

Safety & tolerability

MP0317 displayed a favorable and manageable safety profile across all nine planned dosing cohorts (0.03–10 mg/kg administered intravenously weekly (Q1W) or every 3 weeks (Q3W)). The most frequently observed adverse reactions were fatigue and lower grade infusion-related reactions (grade 1–2). Dose-limiting toxicity was reported in one patient (transient asymptomatic grade 3 elevation of liver enzymes) at the highest planned dose of 10 mg/kg administered Q3W.

Details of the poster presenting the final results from the MP0317 Phase 1 study at the 2024 ASCO Annual Meeting can be found below. The poster will be made available on Molecular Partners’ [website](#) after the presentation.

Title: Effect of MP0317, a FAP x CD40 DARPin, on safety profile and tumor-localized CD40 activation in a phase 1 study in patients with advanced solid tumors

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Timing: 1 June 2024; 9:00 am – 12:00 pm PST

About Molecular Partners AG

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

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