

# Interim Management Statement Q1 2021: Major Advances in COVID-19 Program, Continued Progress in Oncology Pipeline

May 4, 2021

**Zurich-Schlieren, Switzerland, May 04, 2021.** Molecular Partners AG (SIX: MOLN), a clinical-stage biotech company developing a new class of custom-built protein drugs known as DARPin® therapeutics, announced today its interim management statement for the period ending March 31, 2021

"Molecular Partners continues to grow and expand the reach of our DARPin® therapeutics platform, with the COVID-19 pandemic forming a meaningful change agent for us," said Patrick Amstutz, Ph.D., chief executive officer of Molecular Partners. "Twelve months ago, we were only at the initiating stages of our COVID-19 program, while this year we are approaching Phase 3 clinical trials with our partners at Novartis. I am extremely proud of our team and partners for not only bringing us to this stage of development in our new antiviral program, but also for continuing to advance our targeted oncology pipeline."

# Research & Development Highlights

# • COVID-19 antiviral programs:

- Completed Phase 1 dosing of ensovibep (MP0420) across three dose cohorts, and announced initial positive results
- Published data showing that ensovibep is effective in vitro against all variants of concern analyzed
- o Initiated single-arm Phase 2 study of ensovibep in COVID-19 positive patients, in the ambulatory setting
- o A global Phase 2 3 study in ambulatory patients in collaboration with Novartis initiating enrollment in May 2021

#### • AMG 506 (MP0310) in solid tumors:

- Proof of mechanism of action achieved, showing dose-dependent tumor accumulation and local activation of immune cells, as demonstrated after the first dose
- o Clinical studies ongoing to establish optimal dose regimen and activity with weekly dosing

#### • MP0317 (FAP X CD40):

- o Investigational New Drug Application (IND)-enabling work near completion
- o Expected to enter the clinic in the second half of 2021
- Four scientific posters published recently at the 2021 American Academy for Cancer Research (AACR) Annual Meeting, virtually from April 10-15:
  - Initial results highlighting the Company's new AML focused multi-specific T-cell engager program
  - o Additional data presented for MP0317, CD3 T cell engagers, and peptide-MHC DARPin® programs

# Operational and financial highlights:

- Election of two new members to the Company's Board of Directors: Agnete Fredriksen, Ph.D., and Dominik Höchli, M.D.
- Strong financial position with CHF 145.6 million in cash (incl. short term deposits) as of March 31, 2021
- Net cash used in operating activities of CHF 29.9 million in Q1 2021
- Operating loss of CHF 18.5 million and net loss of CHF 16.6 million in Q1 2021
- Company funded into 2023, excluding any potential payments from R&D partnerships

# **Clinical Updates:**

## COVID-19 program advancing in the clinic

Molecular Partners' lead anti-COVID-19 therapeutic candidate, ensovibep (MP0420), has been administered to healthy subjects in the Company's Phase 1 trial, with initial results showing it to be safe and well-tolerated, with a half-life in the range of 2-3 weeks. Additionally, a single-arm Phase 2 trial with ensovibep in COVID-19 ambulatory patients was initiated in March 2021 at a single center in the Netherlands. The initial Phase 1 results have informed the decision to move forward with the EMPATHY clinical trial program in April 2021, which is being conducted by our partner Novartis, with Molecular Partners as sponsor. The EMPATHY trial is a global, multi-center Phase 2 and 3 study that will seek to enroll 2,100 patients with COVID-19

in the ambulatory setting, to evaluate the safety and efficacy of ensovibep in preventing worsening symptoms and hospitalizations. In parallel, ensovibep will also be tested in hospitalized COVID-19 patients, in a new sub-trial of the National Institutes of Health's (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV-3) Program Phase 3 clinical trial.

In addition to the clinical development, ensovibep continues to be tested in vitro for its inhibition of infectivity in newly discovered variants of the virus. To date, ensovibep has been shown to be effective in inhibiting viral infectivity in all variants and point mutations of concern.

# Phase 1 trial of AMG 506 (MP0310) (FAP X 4-1BB)

As presented in December 2020 at our R&D day, preliminary clinical data from the ongoing Phase 1 clinical trial of AMG 506 (MP0310) show that the molecule performs as intended. AMG 506 (MP0310) showed colocalization with FAP at low concentrations, and the FAP binding was observed to be dose dependent, with a saturation of the tumor-expressed FAP in high AMG 506 (MP0310) concentrations. Furthermore, by analyzing paired biopsies of patients, significant tumor-localized increases in immune activation were seen across multiple immune cell types after a single injection, while systemic inflammatory markers were unchanged, and no AMG 506 (MP0310) activity was seen in peripheral tissues.

Additional dosing work is ongoing in the current Phase 1 clinical trial to test dosing regimens, including the exploration of weekly dosing, aiming to identify the right dose to provide durable activity after several injections of our tumor localized 4-1BB agonist.

#### MP0317 (FAP x CD40) IND-enabling work complete, scheduled to enter the clinic in H2 2021

In April 2021, Molecular Partners presented data from the MP0317 program at the AACR conference, showing new mechanism of action (MOA) data on the tumor-localized immune agonist MP0317, the second DARPin® protein in the Company's immuno-oncology pipeline. As previously indicated, the company anticipates entering the clinic with MP0317 on the second half of 2021.

## First CD3 T cell engager program to focus on AML therapies

As recently presented at the AACR conference, Molecular Partners' first CD3 T cell engager will be focused on targeting AML tumor cells as well as T cells, to activate the immune cells against the tumor. Initial proof of concept data shows the Company was able to achieve a wide therapeutic window using a triple- tumor-antigen targeting CD3 DARPin® engager molecule.

## Balance sheet: Strong cash and equity positions as of March 2021

Molecular Partners' financial performance for the first three months of 2021 reflects an operating cash outflow of CHF 29.9 million. Cash and short-term deposits decreased by CHF 28.1 million in Q1 2021 to CHF 145.6 million as of March 31, 2021 (year-end 2020: CHF 173.7 million). The decrease in cash and short-term deposits was driven by a large prepayment of CHF 9.3 million for the manufacturing of commercial supply for ensovibep.

As of March 31, 2021, the company employed 151.6 FTEs, a 9% increase year-over-year, with approximately 82% of employees serving in R&D functions.

# Financial outlook 2021

For the FY 2021, at constant exchange rates, the company continues to expect total expenses of CHF 65-75 million, of which around CHF 6 million will be non-cash effective costs.

In terms of cash outflow the company expects a gross cash utilization of CHF 85-95 million for FY2021, which includes a total of CHF 20 million payable to Novartis for the manufacturing of commercial supply (of which CHF 9.3 million occurred during Q1 2021). This cash flow guidance does not include any potential receipts from R&D partnerships.

With CHF 145.6 million cash at hand and no debt as per March 31, 2021 the company expects to be funded into 2023, excluding any potential receipts from R&D partners.

#### **Financial Calendar**

26 August 2021 Publication of Half-year Results 2021 (unaudited)

28 October 2021 Interim Management Statement Q3 2021

# About DARPin® therapeutics

DARPin® therapeutics are a new class of custom-built protein therapeutics based on natural binding proteins that open a new dimension of multi-functionality and multi-target specificity in drug design. A single DARPin® candidate can engage more than five targets, and its flexible architecture and small size offer benefits over conventional monoclonal antibodies or other currently available protein therapeutics. DARPin® therapeutics have been clinically validated through to registration via the development of abicipar, Molecular Partners' most advanced DARPin® drug candidate. The DARPin® platform is a fast and cost-effective drug discovery engine, producing drug candidates with optimized properties for development and very high production yields. DARPin® is a registered trademark owned by Molecular Partners AG.

#### **About Molecular Partners AG**

Molecular Partners AG is a clinical-stage biotech company developing DARPin® therapeutics, a new class of custom-built protein drugs designed to address challenges current modalities cannot. The Company has formed partnerships with leading pharmaceutical companies to advance DARPin® therapeutics in the areas of ophthalmology, oncology and infectious disease, and has compounds in various stages of clinical and preclinical development across multiple therapeutic areas.

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