

# Interim Management Statement Q3 2022: Continued Progress Across Oncology Programs with First Clinical Data Expected from Phase 1 Trial of MP0317 and Initiation of Phase 1 Trial of MP0533 Anticipated by Year-End

October 27, 2022

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Oct. 27, 2022 (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, today announced its interim management statement for the guarter ending September 30, 2022.

"We have made notable progress this quarter across our oncology programs including MP0317, MP0533, as well as our DARPin-radioligand therapy programs. We look forward to presenting the first clinical data from the MP0317 program for patients with solid tumors at SITC. At ASH, we are excited to share the latest preclinical data from our tetra-specific AML candidate, MP0533, in an oral presentation, which remains on track to enter clinical development by year-end," said Patrick Amstutz, Molecular Partners' CEO.

## Research & Development Highlights

#### MP0317 (FAP x CD40)

• Initial clinical data from Phase 1 clinical study of MP0317 to be presented at the 37<sup>th</sup> Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2022

## MP0533 (CD33 x CD70 x CD123 x CD3)

- On track to initiate Phase 1 clinical study of MP0533 by year-end 2022
- Preclinical data supporting the unique design and mechanism of MP0533 to be presented in an oral presentation at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2022
- Molecular Partners to host event for ASH attendees detailing MP0533 on the evening of December 10th in New Orleans

# **DARPin-Radioligand Therapies**

- Both proprietary, and Novartis-partnered, DARPin-radioligand programs advancing through research and discovery phases
- On track to designate the first proprietary DARPin-radioligand target in H1 2023

# **Ensovibep COVID-19 Antiviral Program**

· Novartis remains engaged in dialogue with regulatory agencies about a potential Phase 3 protocol for ensovibep

## MP0310 (FAP x 4-1BB)

 Phase 1 study data currently being collected and reviewed. No additional internal investment in the development of the program is currently planned

# Abicipar for wet age-related macular degeneration

• Evaluation of business development opportunities for pivotal-stage asset continues, informed by correspondence with the FDA and discussions with potential partners

## **Corporate and Leadership Highlights**

- Established ESG working group of key Company stakeholders to advance the Company's ESG goals, reporting to the Company's Board of Directors
- Expanded ESG initiatives with the publication of the Company's ESG priorities and progress, accessible on the investors section of Molecular Partners' website
- Michael Pitzner appointed General Counsel and Senior Vice President, Legal effective November 1, 2022, transitioning the role from Julien Gander
- Anne Goubier, D.V.M, Ph.D., was promoted to Senior Vice President of Biology

#### Q3 2022 Operational and Financial Highlights

- Strong financial position with CHF 267 million in cash (including short term deposits) as of September 30, 2022
- Operating profit of CHF 132 million and net profit of CHF 135 million for the nine months ended September 30, 2022
- Company continues to expect to be funded into 2026, excluding any potential payments from R&D partnerships

Oncology: Phase 1 clinical data from MP0317 expected later this year; MP0533 on track for Phase 1 initiation by year-end; DARPinradioligand programs progressing

MP0317 binds both the fibroblast activation protein (FAP) and the immunostimulatory protein CD40 and is designed to enable tumor-localized immune activation without the systemic immune activation produced by other CD40-targeting agents. The ongoing Phase 1 trial of MP0317 is expected to enroll up to 30 patients, dosed once every 3 weeks, across six dosing cohorts and up to 15 patients are then expected to be enrolled in a dose expansion cohort. Further, the Company has recently initiated a weekly dosing regimen to provide potential options for future combinations with either immunotherapy, radiation, or chemotherapy. In addition to evaluating safety, tolerability, and pharmacokinetics of a monotherapy, the study plans to gather a variety of biomarker data to support the establishment of combination therapies with MP0317 in specific indications. Initial Phase 1 data are planned to be presented at SITC in November 2022.

**MP0533** engages CD3 on T cells while binding up to three tumor-associated antigens (CD33, CD70, and CD123) on AML cells. Preclinical studies have shown that MP0533 T cell activation and tumor killing increased significantly with the number of tumor-associated antigens present. This 'avidity-dependent' mechanism, enabled by the DARPin platform, can lead to preferential targeting of AML cells which, unlike healthy cells, generally express two or more of these antigens. Once bound, the AML cells are marked for termination by nearby T cells. MP0533 remains on track to initiate clinical development before the end of 2022.

**DARPin-based radioligand therapy (DARPin-RLT) candidates** are being developed both internally and in collaboration with Novartis. Thanks to their small size and their high specificity and affinity, DARPins represent ideal delivery vectors for therapeutic radionuclides to efficiently target cancer cells with minimal systemic side effects. Molecular Partners anticipates designating the first proprietary DARPin-radioligand target in H1 2023.

## Ophthalmology

In August 2021, Molecular Partners regained global development and commercial rights to abicipar for the treatment of neovascular age-related macular degeneration (nAMD) and Diabetic Macular Edema (DME). Abicipar went through two positive Phase 3 studies, CEDAR and SEQUOIA, which supported the non-inferior efficacy of its quarterly dosing regimen compared to monthly ranibizumab.

The Company is currently evaluating potential business development opportunities for abicipar. Based on correspondence with the FDA and discussions with potential partners, the options for resumed development may include the development and commercialization program by a partner, or the formation of a new company focused on abicipar with new investors and a dedicated management team.

# Leadership & Governance

Michael Pitzner appointed General Counsel and Senior Vice President of Legal effective November 1, 2022, transitioning the role from Julien Gander. Most recently Michael served as Head Legal Biologics, Cell & Gene and CMO (Global NTO) at Novartis.

Anne Goubier, D.V.M, Ph.D., was promoted to Senior Vice President of Biology. She joined Molecular Partners in 2020 and oversees the biology department, covering the path from target identification to clinical pharmacology, building on her more than two decades of biotechnology experience across drug discovery and development.

## **Financial and Business Outlook**

For the full year 2022, at constant exchange rates, the Company expects total expenses of CHF 70-75 million, of which approximately CHF 9 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciation. This guidance does not include any potential receipts from R&D partnerships.

With CHF 267 million in cash and short-term time deposits and no debt as of September 30, 2022, the Company expects to be funded into 2026, excluding any potential receipts from R&D partners.

#### **Documentation**

The Q3 2022 Financial Statement will be made available on the company's website after 10.00pm CET / 4.00pm ET on October 27, 2022.

## Financial calendar

March 9, 2023 Full-Year Results 2022 April 4, 2023 Annual General Meeting

# **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 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.

#### **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. www.molecularpartners.com; Find us on Twitter - @MolecularPrtnrs

#### 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, expectations regarding the timing of interactions with regulatory agencies and potential partners, the potential therapeutic and clinical benefits of Molecular Partners' product candidates, the selection and development, and timing thereof, of future antiviral, DARPin-radioligand or other programs, or any potential business development opportunities for product candidates, Molecular Partners' position of financial strength and ability to execute on the next phase of its strategy, and Molecular Partners' expected expenses and cash utilization for 2022 and its expectation that its current cash resources will be sufficient to fund its operations and capital expenditure requirements into 2026. These statements may be identified by words such as "anticipate", "believe", "expect", "may", "plan", "potential", "will", "would" 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 impact of the COVID-19 pandemic or other geopolitical 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; and other risks and uncertainties that are described in the Risk Factors section of Molecular Partners' Annual Report on Form 20-F for the fiscal year ended December 31, 2021 filed with Securities and Exchange Commission (SEC) on March 15, 2022 and other filings Molecular Partners makes with the SEC. These documents are available on the Investors page of Molecular Partners' website at <a href="https://www.molecularpartners.com">www.molecularpartners.com</a>. 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.

For further details, please contact: Seth Lewis @molecularpartners.com Tel: +1 781 420 2361 Thomas Schneckenburger, European IR & Media thomas.schneckenburger@molecularpartners.com Tel: +41 79 407 9952