Interim Management Statement Q1 2022 of Molecular Partners: Cash Runway into 2026 and Portfolio Progress Highlight Strategic Momentum

May 12, 2022

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., May 12, 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 quarter ending March 31, 2022.

"Following a significant capital inflow in January, resulting from Novartis exercising its right to in-license global rights to ensovibep, we are leveraging our strong cash position to follow our strategy; to prioritize candidates where DARPins have an innate advantage over other approaches. Programs like ensovibep, the breakthrough design of MP0533 and our new research in radioligand therapies, showcase the success of our evolved strategy, which emphasizes highly differentiated molecules that can rapidly demonstrate clear activity and benefit for patients," said Patrick Amstutz, Molecular Partners' CEO. "We continue to support Novartis on next steps for ensovibep's global strategy as we advance our internal portfolio, building on the strong clinical performance our DARPins candidates have continually demonstrated."

Research & development highlights:

- **Ensovibep COVID-19 antiviral program: Positive Phase 2 results, Option exercised by Novartis**
  - Part A of the EMPATHY global clinical trial met its primary endpoint with a statistically significant reduction in viral load over eight days in the ensovibep arms compared to placebo
  - Secondary EMPATHY endpoint of hospitalization and/or emergency room (ER) visits related to COVID-19, or death showed an overall 78% reduction in relative risk of events across all ensovibep arms compared to placebo
  - In April, the results of the EMPATHY Part A study were presented as a late breaker at the 2022 European Congress of Clinical Microbiology and Infectious Diseases (ECCMID)
  - Novartis exercised the option to license all rights to ensovibep, triggering a CHF 150 million payment to Molecular Partners
  - Novartis requested Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for ensovibep. As previously reported by Novartis, the EUA remains under review, and the FDA has indicated that Phase 3 data will be required prior to authorization. Novartis is currently engaged in developing a Phase 3 protocol for alignment with the FDA's recommendations
- **MP0310 (FAP x 4-1BB)**
  - Amgen returned global rights for MP0310 following a strategic pipeline review. The ongoing Phase 1 study is expected to continue as planned, with data expected later in 2022 that will inform further business development activity
- **MP0317 (FAP x CD40):**
  - The Phase 1 open-label dose escalation study, initiated in Q4 2021, continues in patients with solid tumors known to express FAP. Initial data from this study is expected in the second half of 2022
  - In March 2022, preclinical data were published in the research journal *Cancer Immunology Research*[1] supporting MP0317's potential to deliver tumor-localized immune activation while avoiding systemic toxicity seen with other CD40-targeting agents
- **MP0533 (CD33 x CD70 x CD123 x CD3)**
  - Following continued promising preclinical data supporting the unique design and mechanism of this candidate, a lead molecule was selected and named MP0533. It is expected to enter clinical development in 2022
  - New *in vivo* data from the MP0533 program will be presented at the European Hematology Association Congress (EHA2022) which will be held in Vienna, Austria from June 9 to 12

Q1 2022 operational and financial highlights:

- Strong financial position with CHF 296.2 million in cash (including short term deposits) as of March 31, 2022
- Revenue of CHF 172.8 million primarily due to payment received from Novartis upon exercise of option to in-license global rights to ensovibep
- Net cash from operating activities of CHF 163.6 million in Q1 2022
- Operating profit of CHF 152.6 million and net profit of CHF 153.1 million in Q1 2022
- Company expected to be funded into 2026, excluding any potential payments from R&D partnerships

- The Q1 2022 Financial Statements are available on the company's website

Ensovibep for COVID-19: In partnership with Novartis

Ensovibep is a first-in-class, multi-specific pan-variant DARPin therapeutic candidate, designed to bind three different epitopes on the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein simultaneously.

Part A of the EMPATHY clinical trial – a randomized, placebo-controlled study which enrolled 407 symptomatic patients infected with SARS-CoV-2 – met its primary endpoint with a statistically significant reduction in viral load over eight days in the ensovibep arms compared to placebo. The secondary endpoint of hospitalization and/or emergency room (ER) visits related to COVID-19, or death showed an overall 78% reduction in relative risk of events across all ensovibep arms compared to placebo.

Pursuant to the Option and Equity Rights Agreement executed in October 2020 with Novartis and following positive Phase 2 (Part A) results, Novartis exercised its option for ensovibep in January 2022, triggering a milestone payment of CHF 150 million to Molecular Partners. Novartis is now responsible for further development, manufacturing, distribution and commercialization activities.

Novartis requested Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for ensovibep. As previously reported by Novartis, the application of the EUA remains under review and additional clinical data will be required to be authorized. While the current Omicron wave of SARS-Cov-2, and the lower incidence of hospitalization associated with it, has made clinical trials challenging to execute in this evolving environment, Novartis is continuing to supply additional documentation and data to the FDA in regards to the EUA review. The FDA has indicated that additional Phase 3 clinical data will be required to support EUA; Novartis is currently engaged in developing a Phase 3 study protocol in alignment with the FDA's recommendations.

If approved or authorized by relevant regulatory authorities, ensovibep would be the first approved multi-specific antiviral candidate for the treatment of COVID-19 and the first DARPin therapy approved or authorized by a regulatory agency. Based on the strong clinical performance of ensovibep, the Company is assessing further viral disease areas where DARPins can offer advantages over existing antivirals or where no effective treatments exist.

Oncology: Phase 1 trial of MP0317; Phase 1 trial of MP0310; Progress of AML candidate MP0533; Development of a DARPin-based radioligand program
The ongoing Phase 1 trial of MP0317 is expected to enroll up to 30 patients across six dosing cohorts and up to 15 patients are then expected to be enrolled in a dose expansion cohort. In addition to evaluating monotherapy dynamics, the study plans to gather a wide variety of biomarker data to support the establishment of combination therapies with MP0317 in specific indications. MP0317 targets both the fibroblast activation protein (FAP) and the immunostimulatory protein CD40. MP0317 is designed to enable tumor-localized immune activation and fewer side effects compared to other CD40-targeting agents.

MP0310 is also designed to deliver tumor-localized immune activation and activates the immunostimulatory 4-1BB protein. A Phase 1 study of this candidate as a treatment for solid tumors is ongoing, with a full dataset expected later in 2022. Following Amgen's strategic pipeline review and return of global rights to MP0310, the Phase 1 dataset will inform further business development activity.

MP0533, Molecular Partners' novel acute myeloid leukemia (AML) candidate, is a DARPin designed to engage CD3 on T-cells while binding up to three tumor-associated antigens (CD33, CD70 and CD123) on AML cells. Preclinical studies have shown the binding strength of MP0533 increasing significantly with the number of tumor-associated antigens present. This 'avidity-dependent' mechanism, enabled by the DARPin platform, leads 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 activated by MP0533. Clinical development is expected to begin in 2022.

Molecular Partners is also collaborating with Novartis to develop, manufacture and commercialize DARPin-conjugated radioligand therapies (DARPin-RLTs). The collaboration combines DARPins' unique properties, including small size and very high affinity and specificity, with the RLT capabilities and expertise of Novartis. DARPin-RLTs have the potential to deliver molecule-targeted radiation deeply into the tumor thereby harnessing the power of radioactive atoms for tumor-killing. Under the terms of the agreement, Molecular Partners will collaborate with Novartis to discover DARPin-RLTs that target specific tumor-associated antigens. Both parties will collaborate on the discovery and optimization of the therapeutic candidates for further development.

Balance sheet: Strong cash and equity positions as of March 2022

- Ongoing strong financial position with CHF 296.2 million in cash and short-term deposits as of March 31, 2022
- Net cash inflow from operating activities of CHF 163.6 million in the first three months of 2022

Financial outlook 2022

For the full year 2022, at constant exchange rates, the Company expects total expenses of CHF 75 - 85 million, of which approximately CHF 9 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciation. This cash flow guidance does not include any potential receipts from R&D partnerships.

With CHF 296.2 million in cash and short-term time deposits and no debt as of March 31, 2022, the Company expects to be funded into 2026, excluding any potential receipts from R&D partners.

Financial Calendar

25 August 2022 - Publication of Half-year Results 2022 (unaudited)

27 October 2022 - Interim Management Statement Q3 2022

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.

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, the potential therapeutic and clinical benefits of Molecular Partners' product candidates, the selection and development of future antiviral or other programs, 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 "believe", "expect", "may", "plan", "potential", "will", "would" and similar expressions, and are based on Molecular Partners AG's 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 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 http://www.molecularpartners.com. 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.

[1] Rigamonti, N. et al. (2022). A multispecific anti-CD40 DARPin construct induces tumor-selective CD40 activation and tumor regression. Cancer Immunology Research

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