Interim Management Statement Q3 2021 of Molecular Partners: Advancement of COVID-19 Clinical Program and Continued Immuno-Oncology Momentum

October 28, 2021

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Oct. 28, 2021 (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 September 30, 2021.

“COVID-19 continues to be a major concern globally, and a main focus of our efforts at Molecular Partners. As new variants emerge and novel therapeutic modalities are being developed to fight the disease alongside vaccines, the need to develop efficacious and robust therapeutics is clearer than ever. Our COVID-19 program has significantly advanced in the last quarter. Having now enrolled over 700 patients across two global late stage studies, we have accomplished much and are approaching two significant milestones. In the coming weeks and months we are preparing for futility assessment in the NIH-sponsored hospitalized study and data from our phase 2b-3 EMPATHY study in outpatients,” said Patrick Amstutz, Ph.D., Molecular Partners’ CEO. “In addition, we have maintained momentum across our two immuno-oncology clinical programs, and advanced our preclinical AML program, a truly differentiated CD3 engaging molecule with a unique mechanism of action which is beyond the feasibility of most traditional therapies.”

Research & development highlights:

- **Ensovibep COVID-19 antiviral program: Two global studies ongoing**
  - In October 2021, the Phase 2b portion of the EMPATHY (ambulatory) study reached its target recruitment of 400 patients; Topline data from Phase 2b are expected in early 2022
  - Also in October 2021, the ACTIV-3 (hospitalized) study reached its initial target recruitment of 300 patients. A futility analysis of the study will be conducted at the next data and safety monitoring board (DSMB) assembly, in the coming weeks. Should ensovibep pass the futility analysis, the study will advance to full enrollment. Topline data are expected in 2022
  - Assessment of a subcutaneous formulation of ensovibep is ongoing in healthy volunteers and will provide the rationale to initiate patient studies in the coming months
  - Ensovibep continues to maintain full potency *in vitro* against all known variants of concern, including Delta variants

- **AMG 506 / MP0310 (FAP x 4-1BB)**
  - Ongoing Phase 1 trials with weekly dosing
  - Expecting data late in 2021 or early 2022, for Amgen and Molecular Partners' evaluation

- **MP0317 (FAP x CD40):**
  - The second immuno-oncology DARPin candidate is expected to enter the clinic in Q4 2021
  - Strong preclinical data supports 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)**
  - Molecular Partners’ lead AML targeting candidate selected, formally termed MP0533
  - Preclinical data to be presented at the ASH conference, December 2021
  - Expected to enter clinical trials in 2022

- **Abicipar:**
  - Molecular Partners regained global rights to abicipar, the Company’s registrational-stage ophthalmology therapeutic candidate for the treatment of neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME)
  - Molecular Partners is evaluating the program and will determine the appropriate next steps

Operational and financial highlights:

- Strong financial position with CHF 154.3 million in cash (incl. short term deposits) as of September 30, 2021

- Operating loss of CHF 47.6 million and net loss of CHF 45.9 million for the 9 months ended September 30, 2021
- Company funded into H2 2023, excluding any potential payments from R&D partnerships
- The Q3 2021 Financial Statements are available on the company's website

COVID-19 program rapidly advancing in two global registrational trials with Novartis and the NIH

Molecular Partners' lead infectious disease therapeutic candidate, ensovibep, is currently being evaluated in EMPATHY, a global Phase 2b-3 study designed to explore the use of ensovibep for the treatment of COVID-19 in patients who are in the early stages of infection to prevent worsening symptoms and hospitalization. Molecular Partners' collaboration partner, Novartis, is conducting the clinical trial for ensovibep, with Molecular Partners as a sponsor. The phase 2b portion of EMPATHY enrolled patients across six countries. Topline data for the first 400 patients are expected in early 2022, allowing for potential EUA submission and full data in 2022.

Ensovibep is additionally being evaluated in ACTIV-3 for the treatment of hospitalized COVID-19 patients as part of the National Institutes of Health's (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) program, which is evaluating multiple therapies for COVID-19 in hospital setting. The Phase 3 study is presently enrolling hospitalized patients globally. The study has surpassed the target enrollment of approximately 300 patients required for the pre-planned interim futility analysis.The futility analysis will be conducted in November 2021 by the Data and Safety Monitoring Board (DSMB) to determine if enrollment in the ensovibep arm of ACTIV-3 may continue to its full enrollment. Topline data are expected in 2022.

In addition to its clinical development, ensovibep continues to be regularly tested in the laboratory for its inhibition of infectivity in newly discovered variants of the virus. As presented at the ISIRV-WHO conference in October 2021, all *in vitro* data to-date show that ensovibep retains full potency and viral inhibition against all known SARS-CoV-2 variants of concern, including the key Delta variants.

Immuno-oncology: Phase 1 trial of MP0317 (FAP x CD40); ongoing studies of AMG 506 (MP0310); Progress in AML program

MP0317 trial enrollment is expected to take place in the Netherlands and France. Up to 30 patients are expected to be enrolled 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 will gather a wide variety of biomarker data to support the establishment of combination therapies with MP0317 in specific indications.

Clinical studies of AMG 506 (MP0310) as a treatment for solid tumors are ongoing in collaboration with Amgen with weekly administration to identify a dosing regimen to obtain sustained 4-1BB activation.

MP0533, Molecular Partners' novel AML candidate, is a DARPin designed to engage CD3 on T cells and target AML cells by the tumor associated antigens CD33, CD70 and CD123, with an addition for half-life extension. The candidate binds to cells by an avidity dependent mechanism, preferentially targeting AML cells, which express two or more of these antigens. These malignant cells are then marked for termination by CD3 T-cell activation. Additional data from MP0533 will be presented at the Company's R&D day in December 2021 and presenters will include leading AML researchers from the University of Bern. Preclinical data from the new candidate will be presented at the ASH conference in December 2021, with clinical development expected to be initiated in 2022.

Balance sheet: Strong cash and equity positions as of September 2021

- In June 2021, Molecular Partners successfully completed an initial public offering of American Depositary Shares ("ADSs") on the Nasdaq, raising $63.8 million (CHF 58.8 million) in gross proceeds.
- Ongoing strong financial position with CHF 154.3 million in cash and short-term deposits as of September 30, 2021
- Net cash outflow from operating activities of CHF 71.6 million in the first nine months of 2021

Financial outlook 2021

For the full year 2021, at constant exchange rates, the Company expects total expenses of CHF 70 - 75 million, of which approximately CHF 7 million will be non-cash effective costs.

In terms of cash outflow, the Company expects a gross cash utilization of approximately CHF 90 million for the full year 2021, which includes a total of CHF 20 million payable to Novartis for the manufacturing of commercial supply (of which CHF 14.5 million occurred in the first nine months of 2021). This cash flow guidance does not include any potential receipts from R&D partnerships.

With CHF 154.3 million cash and short-term time deposits and no debt as of September 30, 2021, the Company expects to be funded into H2 2023, excluding any potential receipts from R&D partners.

Financial Calendar

December 15, 2021	R&D Day
March 15, 2022	Expected Publication of FY 2021 Annual report and audited 2021 results
April 13, 2022	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 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 2021 and that its current cash resources will be sufficient to fund its operations and capital expenditure requirements into H2 2023. 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 our expectations include our plans to develop and potentially commercialize our product candidates; our reliance on third party partners and collaborators over which we may not always have full control; our ongoing and planned clinical trials and preclinical studies for our 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 our ability to obtain and maintain regulatory approvals for our product candidates; the extent of clinical trials potentially required for our product candidates; the clinical utility and ability to achieve market acceptance of our product candidates; the potential impact of the COVID-19 pandemic on our operations or clinical trials; our plans and development of any new indications for our product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position; our 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' Registration Statement on Form F-1 filed with Securities and Exchange Commission (SEC) on June 14, 2021 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.

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