



## **Interim Management Statement Q3 2020 of Molecular Partners: Emergence of New Opportunities and Strong Platform Validation of DARPin® Therapeutics**

October 29, 2020

**Zurich-Schlieren, Switzerland, October 29, 2020.** Molecular Partners AG (SIX: MOLN), a clinical-stage biotech company that is developing a new class of custom-built protein drugs known as DARPin® therapeutics, announced today its interim management statement for the period ending September 30, 2020.

“Responding to the global COVID-19 pandemic requires an unprecedented effort on the part of therapeutics innovators like Molecular Partners. We have used our pioneering knowledge of the unique DARPin® class to rapidly deliver what could be the first multi-specific treatment options for patients, which have formed the basis for a pivotal collaboration with Novartis. Its global development, regulatory & commercial capabilities will help rapidly bring the program forward with the potential to change the face of the pandemic,” said Patrick Amstutz, Ph.D., Chief Executive Officer of Molecular Partners. “Our work to date along with this highly validating partnership encourage our pursuit of other new initiatives in virology, in addition to our innovative oncology programs. We believe this pipeline evolution is a continued demonstration of the strength of our DARPin® leadership that has opened new avenues for delivering therapeutics that can achieve clinical outcomes other modalities cannot.”

### **Research & Development Highlights**

#### **Virology:**

- ○ Collaboration with Novartis for co-development of MP0420 and MP0423, including options for global commercialization; leveraging innovative protein drug development expertise of Molecular Partners with Novartis' expertise in global development and commercialization
- Terms of the Novartis agreement include total cash considerations of CHF 210 million (\$230 million USD), comprised of an upfront payment, equity purchase, and milestones, as well as a 22% royalty on sales in commercial territories
- Receipt of reservation fee from Swiss Government, securing a minimum of 200,000 doses of MP0420 with provisions for up to an additional 3,000,000 doses
- First-in-human studies of MP0420 expected to begin in November 2020

#### **Oncology:**

- ○ Continued AMG 506 (MP0310) (FAP x 4-1BB) phase 1 dose escalation study. Presentation of initial data describing dosing, safety and proof of mechanism anticipated by the end of 2020, with potential initiation of combination studies by Amgen in H2 2021
- MP0274 (HER2+) phase 1 study to conclude after dose escalation with no additional studies planned. In total, 22 patients were treated with MP0274, the drug was found to be safe and well tolerated with a PR as best response.
- MP0317 (FAP x CD40) on track for Clinical Trial Application filing expected before the end of 2020 with First-in-human study start expected to begin in H1 2021

#### **Financial highlights:**

- ○ Gross proceeds of CHF 80.2 million from share capital increase received in July 2020, providing anticipated financing into 2022
- Cash and short-term deposits of CHF 133.8 million as of September 30, 2020
- Net cash used in operating activities of CHF 31.3 million in first nine months of 2020
- Operating loss of CHF 38.3 million and net loss of CHF 41.2 million in first nine months of 2020
- On December 17, 2020 the Company plans to host an Investor & Analyst Day, highlighting recent accomplishments in both clinical development and research. This event will be held virtually, and will include commentary from senior management and Key Opinion Leaders.

## **Antiviral program: Ongoing prioritized development of two highly differentiated anti-COVID-19 multi-DARPin® candidates with unique advantages**

In the first half of 2020, the Company began leveraging its rapid discovery and candidate design capabilities to deliver multi-target binding DARPin® proteins that neutralized the SARS-CoV-2 virus in vitro. These two candidates, identified as **MP0420** and **MP0423**, exhibit among the highest potency in inhibiting SARS-CoV-2 live virus reported to-date, and in the third quarter 2020 the Company disclosed strong preliminary in vivo findings for both candidates.

The DARPin® technology offer a differentiated approach to treating COVID-19 through a single molecule that can engage with the spike protein of the SAR-CoV-2 virus with three DARPin® modules simultaneously to neutralize the virus. This offers potentially broader efficacy – across both therapeutic and prophylactic settings – and reduced potential for the development of viral drug resistance which can result from mutations that change any single molecular target. DARPin® candidates are also produced through rapid, high-yield microbial fermentation for potential speed, cost and scaling advantages over more complex mammalian cell production typically employed for antibody production.

In July 2020, the Company announced a partnership with AGC Biologics, a global biopharmaceutical contract development and manufacturing organization, to secure initial clinical and commercial-scale manufacturing capacity for the COVID-19 program. In August 2020, the Company announced the reservation by the Swiss Federal Office of Public Health: Bundesamt für Gesundheit (FOPH-BAG) of up to 3.2 million doses of MP0420, if the candidate is approved in Switzerland. Under the terms of the agreement, the Company immediately received a reservation fee in the mid to high single-digit millions of Swiss Francs.

In September, Molecular Partners completed the initial Good Manufacturing Practice (GMP) manufacturing runs of MP0420. More than 1 kg of DARPin® material was produced in each of the 100 liter *E.coli*-based bacterial fermenter runs.

In October, the Company announced further supportive preclinical data from in vivo assessments of its two DARPin® candidates targeting SARS-CoV-2. These candidates show robust activity in an aggressive viral challenge hamster model, supporting potential efficacy as therapeutic options in patients with late-stage disease. In a highly susceptible COVID-19 challenge model developed by expert virologists at Freie Universität Berlin, hamsters were first infected with SARS-CoV-2 and then administered either select doses of the two anti-COVID-19 DARPin® candidates or placebo, at either 0, 6, or 24 hours. In the five-day experiment, all animals treated with DARPin® molecules recovered and survived, while 83% of animals in the placebo group had to be euthanized due to severe disease progression.

Further, on October 27, the Company signed a collaboration with Novartis (SWX symbol: NOVN) for the co-development of MP0420 and MP0423 as well as options for global commercialization. This collaboration combines the innovative protein drug development expertise of Molecular Partners with Novartis' expertise in clinical development, manufacturing, regulatory affairs & commercialization to accelerate global development of both candidates.

Under the terms of the collaboration agreement, Molecular Partners received a cash payment of CHF 20 million (~\$22 million USD). As part of the transaction, Novartis also agreed to acquire CHF 40 million (~\$44 million USD) worth of ordinary shares at a price of CHF 23 (~\$25 USD) per share. As a result, Novartis now holds approximately 6% of the outstanding shares of Molecular Partners. Molecular Partners is eligible to receive a future milestone payment of CHF 150 million (~\$165 million USD), upon Novartis exercising the option to both therapeutic candidates, and 22% royalty on sales. Molecular Partners has agreed to forgo royalties in lower income countries, and is aligned with Novartis' plans to ensure affordability based on countries' needs and capabilities.

Multiple characteristics of DARPin® therapeutics make them ideally suited for antiviral therapies, particularly at time of global need. Offering logistical solutions that other potential therapeutics in development may not possess, including (i) sub-picomolar potency, allowing investigation of subcutaneous administration as both early intervention and potential prophylaxis; (ii) highly scalable microbial manufacturing, allowing for up to 4 production runs on the same fermenter, per month; and (iii) high temperature stability of DARPin® drugs (>80°C) which may allow for avoidance of cumbersome cold chain storage. Molecular Partners is actively exploring opportunities to develop DARPin® therapeutics against other infectious diseases.

## **Immuno-oncology programs: Recruitment for AMG 506 (MP0310) continues in higher dose cohorts**

Molecular Partners continued recruitment of patients with solid tumors in the ongoing phase 1 dose escalation study of **AMG 506** (MP0310) (FAP x 4-1BB), in partnership with Amgen. AMG 506 (MP0310) is a tumor-localized immune agonist being evaluated in this phase 1 trial as a single agent in patients with advanced solid tumors. MP0310 includes localizer (FAP) and stimulator (4-1BB) DARPin® domains, which respectively provide tumor-specificity and immune activation. Initial presentation of data from the dose escalation cohorts are expected by year-end 2020 and will help inform potential phase 1b combination studies with Amgen assets which are anticipated to be conducted by Amgen.

For **MP0317** (FAP x CD40), the Company's second tumor-localized immune agonist, IND-enabling work continues to advance and Molecular Partners envisages a Clinical Trial Application (CTA) filing before the end 2020. A presentation at the World BiSpecific Forum in October 2020 underlined the mechanism of action and anti-tumor effects of this candidate.

For **MP0274** (HER2+), after the completion of recruitment for the phase 1 trial already in the first half 2020, this trial will be concluded in Q4 2020. MP0274 is a multi-specific DARPin® product candidate being developed for the treatment of solid tumors with strong expression of the highly validated target protein HER2. In total 22 patients have received treatment with MP0274, one patient still continues on study. To date, MP0274 has been reported to be safe and well tolerated, and with one patient observed to have a Partial Response (PR). Presently, the Company does not plan any additional studies for MP0274.

For the phase 2 study of **MP0250** (VEGF x HGF) in combination with the proteasome inhibitors (PIs) bortezomib (Velcade®) and dexamethasone in multiple myeloma, no new data were disclosed in the third quarter 2020 and no additional patients were enrolled into the study. The Company is evaluating potential clinical collaborations around MP0250, with updates anticipated before the end of 2020.

## **Abicipar**

In Q3 2020, AbbVie withdrew its filings for abicipar with both the European Medicines Agency and the Japanese Regulatory Agency and is committed to working with these agencies to determine appropriate next steps and requirements for potential resubmissions for abicipar. Molecular Partners is in

ongoing dialogue with AbbVie on the status of the program.

There is substantial need for better treatment options for nAMD and the Company remains confident in the totality of data supporting abicipar's clinical profile for this indication, and continues to support AbbVie as it determines next steps.

### **Balance sheet: Strong cash and equity positions as of September 2020**

Molecular Partners' financial performance for the first nine months of 2020 reflects an operating cash outflow of CHF 31.3 million. In July 2020 the Company was able to reinforce its solid cash position with a private placement financing, raising gross proceeds of CHF 80.2 million. This further increases the Company's financial flexibility to capture multiple value-creating inflection points into 2022. Moreover, in August 2020 Molecular Partners received a fee in the mid to high single digit millions of Swiss Francs from the Swiss Federal Office of Public Health: Bundesamt für Gesundheit (FOPH-BAG) as a purchase reservation fee for up to 3.2 million doses of MP0420.

As a consequence, cash and short-term deposits increased by CHF 69.4 million in Q3 2020 to CHF 133.8 million as of September 2020 (June 2020: CHF 64.4 million).

As of September 2020, the Company employed 143.4 FTEs, representing an 8% increase year-over-year, with approximately 85% of employees serving in R&D functions.

### **Business outlook and priorities**

For the remainder of 2020, Molecular Partners will focus on advancing its immuno-oncology and infectious disease programs. For the COVID-19 program, the Company anticipates to start first-in-human studies for MP0420 in November 2020.

For AMG 506 (MP0310), following the planned reporting of initial data from the phase 1 study in December 2020, these data will be used to inform potential phase 1b combination studies with Amgen assets to be conducted by Amgen. For MP0317, the Company plans to file appropriate regulatory applications around the end of 2020 and expects to initiate clinical studies in the first half of 2021.

### **Financial outlook 2020**

For the FY 2020, at constant exchange rates, the Company continues to expect total expenses in the range of CHF 65-75 million, of which approximately CHF 6.0 million will be non-cash effective costs. Capital expenditures in FY 2020 are expected to be approximately CHF 3.0 million.

### **Financial Calendar**

- December 17, 2020 R&D Day
- February 5, 2021 Publication of FY 2020 results (unaudited)
- March 26, 2021 Publication of FY 2020 Annual report

### **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 the registrational stage. 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 a new class of custom-built protein drugs known as DARPin® therapeutics, designed to address challenges current modalities cannot. The company has compounds in various stages of clinical and preclinical development with a focus on oncology. Molecular Partners has formed partnerships with leading pharmaceutical companies to advance DARPin® therapeutics across multiple therapeutic areas. For more information regarding Molecular Partners AG visit [www.molecularpartners.com](http://www.molecularpartners.com) or follow the company on Twitter @MolecularPrtnrs.

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