

## **INTERIM STATEMENT BY MANAGEMENT - Q1 2019**

**Positive MAPLE data for abicipar, promising research data for Molecular Partners' innovative oncology DARPin® candidates presented; Recruitment hold in MP0250 NSCLC trial; Ongoing focus on multiple myeloma for MP0250 clinical development**

### **Research & Development:**

- **MP0250 (VEGF x HGF) in MM: Additional patient data from ongoing Phase 2 study of MP0250 in combination with Velcade® (PI) support previously observed response rates and duration of treatment**
- **MP0250 in combination with osimertinib in EGFR-mutated Non-Small Cell Lung Cancer (EGFR mut NSCLC): Enrollment of new patients on hold due to adverse events; Strategic implications under review**
- **MP0274 (Her2) progressing in dose-escalation study in Her2-positive cancer patients**
- **Immuno-oncology: USD 50 million upfront payment collected in Q1 2019 from Amgen; MP0310 (FAP x 4-1BB) is on track to move into Phase 1 clinical trials in H2 2019**
- **Molecular Partners continues to explore DARPin® molecules targeting peptide-MHC complexes in collaboration with Gilead**
- **Preclinical data on FAP x CD40 multi-DARPin® molecule and on DARPin® drug conjugates (DDCs) presented at AACR 2019**
- **Preclinical data for CD3 DARPin® platform presented at PEGS Boston in April 2019**
- **Abicipar (VEGF): MAPLE trial with improved manufacturing process demonstrated decreased intraocular inflammation; abicipar is the first anti-VEGF therapy to maintain initial vision gains on a true fixed 12-week dosing interval; Allergan expects to file BLA to FDA for H1 2019**

### **Team:**

- **Talent base with 123 full-time employees (+9% year-on-year), reflecting ongoing build-out of research and clinical development expertise**

### **Financial highlights:**

- **Strong financial position with CHF 136.5 million in cash and short-term deposits as of March 31, 2019**
- **Net cash from operating activities of CHF 37.5 million in Q1 2019, mainly reflecting collection of USD 50 million Amgen receivable**
- **FY 2019 expense guidance reduced to CHF 60-70 million mainly due to suspended enrollment into NSCLC trial and reduced investments in manufacturing scale-up for MP0250**



**Zurich-Schlieren, May 9, 2019.** Molecular Partners AG (SIX: MOLN), a clinical-stage biotech company that is developing a new class of drugs known as DARPin® therapies\*, announced today its Interim Management Statement for the period ending March 31, 2019.

“Our team is focused on delivering on our strategic priorities by advancing clinical candidates MP0250 and MP0274 and by bringing our first immuno-oncology compound MP0310 to patients with our partner Amgen,” said Dr. Patrick Amstutz, CEO of Molecular Partners. “Additionally, our pioneering early-stage pipeline — including a tumor-localized CD40 activator (FAP x CD40), pMHC-complex targeting with DARPin® molecules, DARPin® CD3 platform and DARPin® drug conjugates — promises to break new ground in their therapeutic space and to further augment our robust DARPin® platform.”

### **Oncology: Update of MP0250 in multiple myeloma**

MP0250, Molecular Partners’ lead oncology asset, is a multi-DARPin® candidate that targets hepatocyte growth factor (HGF) and vascular endothelial growth factor (VEGF), two prominent tumor escape pathways, and has the potential to reverse resistance to standard of care cancer therapies.

The phase 2 study for MP0250 in combination with proteasome inhibitors (PIs) is being conducted at centers in Germany, Poland and Italy and continues to progress well. This study is evaluating MP0250 in combination with bortezomib (Velcade®) and dexamethasone in patients with multiple myeloma who have failed standard therapies. Additional patient data from the ongoing phase 2 study of MP0250 in combination with Velcade® (PI) support previously observed response rates and duration of treatment.

Pending progress of the discussions with the FDA regarding the adverse events identified in the NSCLC study, the company is planning the initiation of a phase 2 study for MP0250 in combination with IMiDs in refractory multiple myeloma in the US with the goal to open recruitment in 2019.

### **Update of MP0250 in Non-Small Cell Lung Cancer (NSCLC)**

Molecular Partners has suspended enrollment of new patients into the Phase 1b/2 clinical study of MP0250 in combination with osimertinib (Tagrisso®) in patients with EGFR-mutated Non-Small Cell Lung Cancer (NSCLC) following observation of adverse events in the kidney in this study leading to a partial clinical hold. Patient safety is of paramount importance to Molecular Partners. The company is working with the FDA to lift the hold by examining the relationship between the dose and duration of exposure to MP0250 and risk of renal injury. These side effects are not considered by investigators to be causally related to osimertinib. Strategic implications are under review.



### **MP0274 in HER2-positive solid tumors**

MP0274 is a multi-DARPin® product candidate in Phase 1 trial for the treatment of HER2-positive solid tumors. Recruitment in the dose escalation phase continues. Further updates on the safety profile of MP0274 are expected in H2 2019.

### **Immuno-oncology: MP0310 on track to move into clinic in H2 2019**

On December 19, 2018, the company announced a collaboration and license agreement with Amgen for the clinical development and commercialization of MP0310 (FAP x 4-1BB). MP0310 is a preclinical molecule designed to locally activate immune cells in the tumor by binding to Fibroblast Activating Protein (FAP) on tumor stromal cells (localizer) and co-stimulating T cells via 4-1BB (immune modulator).

Under the terms of the agreement, Amgen obtains exclusive global development and commercial rights for MP0310. The parties will jointly evaluate MP0310 in combination with Amgen's oncology pipeline products, including its investigational BiTE® (bispecific T cell engager) molecules. Under the agreement, Molecular Partners retains certain rights to develop and commercialize its proprietary DARPin® pipeline products in combination with MP0310.

In January 2019, Molecular Partners collected an upfront payment of USD 50 million. The company is further eligible to receive up to USD 497 million in development, regulatory and commercial milestone payments, as well as double-digit, tiered royalties up to the high teens. The parties agreed to share the clinical development costs in defined percentages for the first three indications subject to certain conditions. For all additional clinical trials, Amgen is responsible for all development costs. Molecular Partners and Amgen continue to expect to enter into clinical phase 1 trials for MP0310 in H2 2019, in line with previously communicated plans.

### **Immuno-oncology: Molecular Partners and Gilead join forces in targeting peptide-MHC complexes**

In March 2019, Molecular Partners and Gilead announced a collaboration exploring the potential of DARPin® molecules to selectively bind to peptide-MHC complexes. Peptide-MHC complexes provide entry to access the vast intracellular target space. However, to date, peptide-MHC complexes have been notoriously difficult to target with antibody-based therapeutics. Molecular Partners is evaluating whether DARPin® molecules provide a platform to selectively access this new therapeutic space in oncology.



### **Immuno-oncology: Preclinical data on FAP x CD40 multi-DARPin® molecule presented**

Molecular Partners presented additional preclinical data on the company's immuno-oncology platform at the 2019 annual meeting of the American Association for Cancer Research (AACR) in Atlanta. Using Molecular Partners' modular immuno-oncology toolbox, the company has designed a targeted approach to activate CD40 selectively in the tumor microenvironment. This approach is based on a multi-specific DARPin® molecule that incorporates a DARPin® directed to fibroblast activation protein (FAP) to localize an agonistic CD40 DARPin® selectively in solid tumors with the goal of increasing efficacy while reducing systemic toxicity. Preclinical data demonstrated that the company's multi-specific FAP x CD40 DARPin® molecule induced FAP-dependent activation of B cells, dendritic cells and macrophages.

### **Immuno-oncology: Novel T-cell engager platform presented at PEGS Boston**

On April 10, 2019, the company presented the first preclinical data on its novel T cell engager platform based on DARPin® molecules. Initial data suggest that the company's T cell engaging DARPin® molecule matches antibody-based reference molecules in critical functional dimensions, has excellent biophysical properties and can be formatted with albumin binders for half-life extension.

### **Oncology: DARPin® drug conjugates (DDCs) highlighted at AACR 2019**

The versatility of DARPin® molecules renders them an attractive alternative to antibodies for the development of drug conjugates. Molecular Partners has developed DARPin® drug conjugates (DDCs) in collaboration with ImmunoGen using a model EGFR multi-specific DARPin® molecule. The DDCs displayed antigen-specific activity across a panel of cell lines expressing EGFR with selectivity and potency similar to that observed with antibody-drug conjugates.

### **Abicipar: MAPLE results underline further progress of abicipar on its way towards market launch expected by Allergan in 2020**

On April 2, 2019, Allergan and Molecular Partners announced topline safety results from MAPLE, a 28-week open-label study which enrolled 123 patients and evaluated the safety of abicipar produced via a modified manufacturing process. As a result of the improvements in the manufacturing process, the incidence of intraocular inflammation (IOI) in the MAPLE study was lower than the rate observed in prior Phase 3 studies. Most IOI events were assessed as mild to moderate in severity. The incidence of severe IOI was more than halved to 1.6 percent, with one reported case of iritis and one reported case of uveitis. There were no reported cases of endophthalmitis or retinal vasculitis in this study.



The reduction of the inflammation data shown in MAPLE reinforces the positive efficacy data from previously reported Phase 3 trials. In those CEDAR and SEQUOIA trials, abicipar demonstrated its potential to transform the way physicians manage neovascular AMD with an anti-VEGF therapy. Clinical trial evidence has shown that fixed-interval dosing of anti-VEGF therapies administered either every month or every eight weeks results in better visual outcomes compared to real-world clinical outcomes. Abicipar could be the first fixed 12-week anti-VEGF treatment that improves visual outcomes in a real-world setting for a large number of AMD patients. A fixed-interval 12-week therapy would greatly reduce the treatment burden for patients with nAMD.

Additional data presented at the ARVO Conference in Vancouver on May 02, 2019 highlighted abicipar's higher cumulative probability of achieving clearance of sub-retinal fluid, an absence of intra-retinal thickening, as well as an absence of all fluids compared to Lucentis®.

Allergan expects to file the abicipar Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in the first half of 2019. Allergan plans to present additional data from the MAPLE study at a scientific conference later in 2019.

#### **Balance Sheet: Strong cash and equity positions as of March 31, 2019**

Molecular Partners' financial performance for the first quarter 2019 reflects the cash collection of the USD 50 million upfront payment from Amgen for the MP0310 collaboration. Cash and short-term deposits increased by CHF 37.5 million compared to year-end 2018 to CHF 136.5 million as of March 31, 2019.

Also as a consequence of the upfront payment collected from Amgen, the net cash flow from operating activities increased by CHF 29.0 million to CHF 37.5 million for the first quarter 2019 compared to the same period 2018.

As of March 31, 2019, the company employed 123 FTEs (+9% year-over-year), with approximately 85% of employees serving in R&D functions. This continued increase reflects the ongoing build-out of Molecular Partners' research activities as well as internal clinical development competencies and resources.

"We were able to reinforce our solid cash position with the collected USD 50 million upfront payment from our strategic collaboration with Amgen. This further increases our financial flexibility to capture multiple value-creating inflection points into H2 2020, beyond Allergan's expected market launch of abicipar and the related expected steady income stream from there on," said Andreas Emmenegger, Chief Financial Officer of Molecular Partners.



## **Business outlook and priorities**

In 2019, Molecular Partners will continue to advance its DARPin® candidates within its **immuno-oncology pipeline** and will present further research and preclinical data for additional therapeutic candidates resulting from the company's immuno-oncology toolbox. For the company's most advanced IO candidate, MP0310, Molecular Partners and its strategic collaboration partner Amgen expect to enter into a clinical phase 1 monotherapy trial in H2 2019.

In **oncology**, the company will present additional data from its ongoing phase 2 trial of MP0250 in patients with multiple myeloma (MM) in combination with Velcade® (PI). The company also expects to start the phase 2 trial of MP0250 in combination with Pomalidomide® (IMiD) for the same indication, pending outcomes of the discussion with the FDA. Molecular Partners also expects initial data for MP0274, the proprietary DARPin® candidate for the treatment of HER2-positive cancer, in 2019.

In **ophthalmology**, following the encouraging improvement of IOI levels as reported in the MAPLE trials, complementing the differentiating phase 3 efficacy data of abicipar in patients with neovascular AMD, Allergan plans to file abicipar with the FDA in H1 2019. Molecular Partners will continue to support Allergan in advancing abicipar through the phase 3 trials and in further optimizing the abicipar formulation. Allergan indicated at its Q1 2019 earnings call its intention to launch the phase 3 study for abicipar in DME in 2020.

## **Financial outlook 2019**

For the full year 2019, at constant exchange rates, the company expects total expenses of CHF 60-70 million, of which around CHF 6 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciations. This reduced guidance reflects the suspension of the enrollment into the NSCLC trial for MP0250 as well as the reduced investment in manufacturing scale-up for phase 3 material trials for MP0250. Capital expenditures in FY 2019 are expected to be approximately CHF 2 million.

This guidance is subject to the progress of the pipeline, mainly driven by the speed of enrollment of patients in clinical trials, manufacturing costs, and data from research and development projects. No guidance can be provided with regard to net cash flow projections. Timelines and potential milestone payments for existing and potentially new partnerships are not disclosed.



## Financial Calendar

August 27, 2019	Publication of Half-year Results 2019 (unaudited)
October 31, 2019	Interim Management Statement Q3 2019

<http://investors.molecularpartners.com/financial-calendar-and-events/>

## About the DARPin® Difference

DARPin® therapeutics are a new class of protein therapeutics opening an extra dimension of multi-specificity and multi-functionality. DARPin® candidates can engage more than five targets, offering potential benefits over those offered by conventional monoclonal antibodies or other currently available protein therapeutics. The DARPin® technology is a fast and cost-effective drug discovery engine, producing drug candidates with ideal properties for development and very high production yields.

With their low immunogenicity and long half-life in the bloodstream and the eye, DARPin® therapeutics have the potential to advance modern medicine and significantly improve the treatment of serious diseases, including cancer and sight-threatening disorders. Molecular Partners is partnering with Allergan to advance clinical programs in ophthalmology and is advancing a proprietary pipeline of DARPin® drug candidates in oncology and immuno-oncology. The most advanced global product candidate is abicipar, a molecule currently in phase 3, in partnership with Allergan. Several DARPin® molecules for various ophthalmic indications are also in preclinical development. The most advanced DARPin® therapeutic candidate wholly owned by Molecular Partners, MP0250, is in phase 2 clinical development for the treatment of solid and hematological tumors. MP0274, the second-most advanced DARPin® candidate owned by Molecular Partners, binds to Her2 and inhibits downstream signaling, which leads to induction of apoptosis. MP0274 is currently in phase 1. The company's lead immuno-oncology product candidate MP0310 is a FAP x 4-1BB multi-DARPin® therapeutic candidate designed to locally activate immune cells in the tumor by binding to FAP on tumor stromal cells (localizer) and co-stimulating T cells via 4-1BB (immune modulator). Molecular Partners has closed a collaboration agreement with Amgen for the exclusive clinical development and commercialization of MP0310. MP0310 is expected to enter into the clinic in H2 2019. Molecular Partners is also advancing a growing preclinical and research pipeline in immuno-oncology that features its "I/O toolbox" and additional development programs. DARPin® is a registered trademark owned by Molecular Partners AG.

## About Molecular Partners AG

Molecular Partners AG is a clinical-stage biotech company that is developing a new class of therapies known as DARPin® therapeutics. The company continues to attract talented individuals who share the passion to develop breakthrough medicines for serious diseases. Molecular Partners has compounds in various stages of clinical and preclinical development and several more in the research stage, with a current focus on oncology and immuno-oncology. The company establishes research and development partnerships with leading pharmaceutical companies and is backed by established biotech investors.

For more information regarding Molecular Partners AG, go to: [www.molecularpartners.com](http://www.molecularpartners.com).



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