

## INTERIM MANAGEMENT STATEMENT – Q3 2019

### Encouraging Additional Phase 3 Data Presented for Abicipar, and Start of Phase 1 Trial for MP0310, the First Immuno-oncology DARPin® with a Novel Therapeutic Design

#### Research & Development:

- **MP0310 (FAP x 4-1BB):** First patient dosed in phase 1 trial for this tumor-localized immune-modulator, representing a key milestone as the first novel therapeutic design of an immuno-oncology DARPin® candidate in clinical development (in co-development with Amgen)
- **MP0250 (VEGF x HGF) in Multiple Myeloma:** Update on ongoing phase 2 PI trial (in combination with Velcade®) to be provided at ASH and company's R&D Day in December 2019
- **Abicipar (VEGF):**
  - FDA accepted Biologics License Application (BLA) and EMA validated Marketing Authorisation (MAA) in neovascular age-related macular degeneration (nAMD) in Q3 2019; U.S. launch, following FDA filing and review, expected mid-2020; EU approval expected in H2 2020
  - Encouraging two-year data from phase 3 studies in nAMD presented at AAO meeting in San Francisco; abicipar expected to be the first anti-VEGF therapy to sustain initial vision gains on a consistent 12-week dosing interval
- **Research:** R&D Day on December 12, 2019 in New York City will underline the company's continued progress and focus on novel therapeutic designs

#### Team:

- Talent base with 133 full-time employees (+17% year-on-year), reflecting ongoing strong build-out of the organization, in both R&D and SG&A areas
- Nicolas Leupin, M.D., MBA, started in his roles as Chief Medical Officer and Member of the Management Board effective September 1, 2019
- Seth D. Lewis to join the company in November 2019 as Senior Vice President Investor Relations & Corporate Communications - Strategy, based in the company's Boston-area office

#### Financial highlights:

- Strong financial position with CHF 112.3 million in cash and short-term deposits as of September 30, 2019
- FY 2019 expense guidance slightly reduced to CHF 55-60 million

**Zurich-Schlieren, October 31, 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 September 30, 2019.

“Abicipar represents the first DARPin® therapeutic to be accepted for review by FDA (U.S.) and EMA (EU), validating the potential of the DARPin® platform to yield candidates that fulfill all dimensions of development necessary for approval. We are convinced that the expected consistent 12-week dosing interval of Abicipar can bring benefit to patients,” said Patrick Amstutz, Ph.D., Chief Executive Officer of Molecular Partners. “Additionally, we are proud that MP0310, our first candidate from our suite of novel therapeutic design immuno-oncology molecules, has successfully entered the clinic. We are recruiting patients to evaluate MP0310’s ability to localize activation of the immune system to the tumor, potentially enabling higher anti-cancer activity without dose-limiting systemic side-effects.”

#### **Oncology: Update of MP0250 in multiple myeloma to be presented in Q4 19**

MP0250 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 adaptive resistance to standard of care cancer therapies.

The first phase 2 trial for MP0250 in combination with proteasome inhibitors (PIs) is evaluating MP0250 in combination with bortezomib (Velcade®) and dexamethasone in patients with multiple myeloma who have failed standard therapies. The company will provide an update on the phase 2 trial data at both the ASH conference in Orlando and at the company’s R&D Day in New York City.

#### **Immuno-oncology: Initiation of phase 1 trial of MP0310, a novel tumor-localized immunotherapy**

For MP0310, also referred to by Amgen as AMG 506, the first patient has been enrolled and dosed in the first-in-human study of MP0310 as a single agent in patients with advanced solid tumors. The trial will evaluate the optimal dose range of MP0310 in preparation for planned combination studies with Amgen’s oncology pipeline products.

MP0310 is the first product candidate in Molecular Partners’ DARPin® immuno-oncology pipeline. It is designed to activate immune cells specifically in the tumor and not in the rest of the body, potentially delivering greater efficacy with fewer side effects. Preclinical studies of MP0310 have demonstrated immune T cell activation restricted to solid tumor tissues, and strong CD8 T cell activation and expansion in vitro and in vivo. Additionally, preclinical data show MP0310 does not induce strong systemic activation of CD8 T cells and, therefore, has lower risk of the systemic side effects and toxicities.

The MP0310-CP101 trial intends to enroll up to 54 patients at three sites in France. The open-label, dose-escalation study will evaluate the safety, tolerability and pharmacokinetics of MP0310 in patients with locally advanced or metastatic solid tumors.

**Abicipar: Additional encouraging two-year data from phase 3 studies in nAMD presented at AAO**

Allergan and Molecular Partners announced the two-year data from the CEDAR and SEQUOIA clinical studies of abicipar in patients with neovascular (wet) age-related macular degeneration (nAMD) at the annual meeting of the American Academy of Ophthalmology (AAO) in San Francisco. In the second year of these studies, quarterly-dosed of abicipar resulted in the maintenance of visual gains comparable to monthly-dosed ranibizumab (Lucentis®).

Through week 104, patients received 2 mg of abicipar every 8 weeks or every 12 weeks, or 0.5 mg of ranibizumab every 4 weeks. At week 104 in the pooled phase 3 data, the proportion of patients with stable vision was 93%, 90% and 94% in 8-week abicipar, 12-week abicipar and 4-week ranibizumab treatment regimens, respectively. This continuation of stable vision in the second year further reinforces the ability of abicipar to deliver effective outcomes with consistent quarterly dosing for the majority of patients.

Mean changes in best-corrected visual acuity (BCVA) seen in year two were similar when compared to year one across all treatment arms. Central retinal thickness (CRT) continued to decrease during year two when compared to year one. CRT for patients treated with abicipar dosed quarterly and every 8 weeks were similar to ranibizumab dosed every 4 weeks through week 104. Overall incidence rates of treatment-emergent adverse events at the end of year two were comparable between treatment groups. The pooled rate of new cases of intraocular inflammation in year two for patients who received abicipar in the 8- and 12-week arms was 1.9%, which is similar to the ranibizumab arm of 1%. The data shown at AAO therefore reinforce a sustained response at two years with less frequent dosing of abicipar compared to standard of care therapy.

**Abicipar: FDA accepted the BLA and EMA the MAA for patients with nAMD in Q3 2019, key milestones for the company and its DARPin® technology platform**

In the third quarter 2019, the U.S. Food and Drug Administration (FDA) accepted a Biologics License Application (BLA) and the European Medicines Agency (EMA) validated a Marketing Authorisation Application (MAA) for abicipar pegol, a novel, investigational DARPin® therapy, in patients with neovascular (wet) age-related macular degeneration (nAMD). The FDA is expected to take action on the BLA mid-2020. A decision from the European Commission is expected in the second half of 2020. The BLA and MAA filings are based on data from two phase 3 trials, CEDAR and SEQUOIA, which supported the non-inferior efficacy of the abicipar quarterly dosing regimen to maintain vision gains with more than 50 percent fewer injections versus ranibizumab (13 vs. 6) dosed monthly in the first year. The FDA filing acceptance marked an important milestone for the DARPin® technology as abicipar becomes our first DARPin® candidate to receive filing acceptance by the FDA.

## **Balance sheet: Strong cash and equity positions as of September 2019**

Molecular Partners' financial performance for the first nine months of 2019 reflects the cash collection in Q1 2019 of the USD 50 million upfront payment from Amgen for the MP0310 collaboration. Cash and short-term deposits increased by CHF 13.3 million over the first nine months of 2019 to CHF 112.3 million as of September 30, 2019 (June 30, 2019: CHF 123.3 million).

As of September 30, 2019, the company employed 133 FTEs, a 17% increase year-over-year, with approximately 85% of employees serving in R&D functions.

## **Business outlook and priorities**

For the remainder of 2019, Molecular Partners will continue to advance its DARPin<sup>®</sup> candidates within its immuno-oncology **research pipeline**, specifically the FAP x CD40 molecule, the CD3 DARPin<sup>®</sup> T cell-engager platform as well as the peptide-MHC programs, and expects to present an update at the company's R&D Day in New York City.

In **immuno-oncology**, recruitment of patients for the phase 1 trial of MP0310 (AMG 506) that is in collaboration with partner Amgen will continue in Q4 2019.

In **oncology**, the company expects to present additional data from its ongoing phase 2 trial of MP0250 in patients with multiple myeloma (MM) in combination with Velcade<sup>®</sup> in December 2019, both at the ASH conference as well as at the company's R&D Day. The company further plans to present initial safety data for MP0274, the company's proprietary DARPin<sup>®</sup> candidate for the treatment of HER2-positive cancer, in Q4 2019.

In **ophthalmology**, Molecular Partners continues to work closely with its partner Allergan in the preparation and education of the market for the expected market launch of abicipar in 2020. The FDA and EMA are currently reviewing the respective regulatory applications for abicipar in patients with nAMD. The FDA is expected to take action on the BLA in mid-2020. A decision from the European Commission is expected in the second half of 2020. Allergan further indicated 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 trimmed the guidance for expected total expenses to CHF 55-60 million, of which around CHF 5 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciations. This guidance reflects the discontinuation of 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

December 12, 2019	R&D Day in New York City
February 6, 2020	Publication of Full-year Results 2019 (unaudited)
April 29, 2020	Annual General Meeting

<http://investors.molecularparters.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 in partnership with Allergan is abicipar, a molecule for which phase 3 data have been filed to the respective regulators in both the US and in Europe,. 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 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. The molecule has entered in phase 1 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 such as novel therapeutic desigens to target peptide-MHC complexes. 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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