



**Molecular Partners reports key financials for H1 19 and corporate highlights: EMA has validated the marketing authorization application for abicipar; Focus of MP0250 on multiple myeloma with expected initiation of ph2 IMiD trial in Q4 19; MP0310 ph1 start on track for H2 19**

August 27, 2019

**Research & Development:**

- **MP0250 (VEGF x HGF) in MM: PI Trial (in combination with Velcade®) – Encouraging responses observed in first patient cohorts triggered decision for further investment;**  
**IMiD Trial (in combination with Pomalyst®) – Start of phase 2 trial expected in Q4 19, having received FDA approval**
- **MP0250 in EGFR-mutated Non-Small Cell Lung Cancer (EGFR-mut NSCLC) in combination with Tagrisso®: Following lift of partial clinical hold by FDA, strategic decision to discontinue phase 2 trial and focus resources on MM trials**
- **MP0274 (Her2): Phase 1 dose escalation trial in Her2-positive cancer patients progressing; first patients dosed at level of 4mg/kg**
- **MP0310 (FAP x 4-1BB): Novel Therapeutic Design for tumor-localized immune-modulator on track to dose the first patient in the phase 1 trial in H2 19 (co-development with Amgen)**
- **Research portfolio is focused on DARPin® candidates with innovative therapeutic designs, including tumor-localized FAP x CD40, peptide-MHC DARPin® binders and DARPin® T cell-engager candidates, and continues to progress according to plan**
- **Abicipar (VEGF): EMA has validated marketing authorization application for abicipar; EMA decision may be received in H2 20; US launch, following FDA filing and review, expected mid-2020; abicipar expected to be the first anti-VEGF therapy to sustain initial vision gains on true fixed 12-week dosing interval**

**Team:**

- **Molecular Partners appointed Nicolas Leupin, M.D., MBA, as Chief Medical Officer**
- **Daniel Steiner, Ph.D., promoted to lead the company's research department**
- **14% year-on-year increase of talent base to 128 full-time employees, reflecting ongoing build-out of research and clinical development expertise**

**Financial highlights:**

- **Ongoing strong financial position with CHF 123.3 million in cash and short-term deposits as of June 30, 2019, ensuring financing into 2021, beyond the expected market launch of abicipar mid-2020**
- **Net cash inflow from operating activities of CHF 27.0 million in H1 2019, positively reflecting the collection of the USD 50 million Amgen receivable in January 2019**
- **FY 2019 expense guidance reiterated at CHF 60-70 million**

**Zurich-Schlieren, Switzerland, August 27, 2019.** Molecular Partners AG (SIX: MOLN), a clinical-stage biotech company that is developing a new class of drugs known as DARPin® therapies\*, today announced

its unaudited financial results for the first half-year 2019 and further corporate highlights. Over the course of recent months, the company has reported the EMA acceptance of the MAA filing for abicipar and an improved safety profile for the drug as shown in the MAPLE trial. Further encouraging data for MP0250 in multiple myeloma (MM) and substantial progress of the company's research pipeline were reported.

"Molecular Partners today is highly focused on advancing DARPin® candidates with innovative therapeutic designs to move the needle of medicine. As a result of the strategic decision to discontinue MP0250 in NSCLC following the observation of adverse events in this study, our focus for MP0250 is on MM, including a phase 2 trial to be started in combination with Pomalyst®. Further, we are on track to dose the first patient with MP0310. In our research pipeline, we are excited about the tangible progress advancing innovative therapeutic designs – specifically in the areas of tumor-localized immune-modulation, DARPin® T cell-engagers, and DARPin® candidates targeting peptide MHC complexes," said Patrick Amstutz, Ph.D., Chief Executive Officer of Molecular Partners.

## **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 adaptive resistance to standard of care cancer therapies. The first phase 2 study is evaluating MP0250 in combination with bortezomib (Velcade®), a proteasome inhibitors (PIs), and dexamethasone in patients with multiple myeloma who have failed standard therapies. Additional patient data presented in H1 2019 for this ongoing phase 2 study support previously observed response rates and duration of treatment.

Following the review by the FDA, the initiation of an additional phase 2 study for MP0250 in combination with Pomalidomide (Pomalyst®) in refractory multiple myeloma is on track to open recruitment in US and Europe in Q4 2019.

## **Clinical hold for MP0250 in Non-Small Cell Lung Cancer (NSCLC) lifted; strategic decision to discontinue the phase 2 trial**

In May 2019, Molecular Partners 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 the observation of a higher frequency of adverse events (nephrotic syndrome) in the kidney in this study leading to a partial clinical hold. Similar adverse events have also been observed for other anti-VEGF agents. In August 2019, the FDA has lifted the hold. However, the company has decided to prioritize multiple myeloma, where early clinical results have demonstrated the potential for MP0250 to play an important role for patients. As a result of this development, the company is redirecting its planned investment away from the NSCLC program.

## **MP0274 in HER2-positive solid tumors: Dose level of 4mg/kg reached**

MP0274 is a multi-DARPin® product candidate in phase 1 evaluation for the treatment of HER2-positive solid tumors. Recruitment in the dose escalation phase continues and in July 2019 the first patients in the new dose cohort of 4mg/kg were dosed. Further updates on the safety profile of MP0274 are expected in H2 2019.

## **Immuno-oncology: MP0310 on-track to dose first patient in H2 2019**

MP0310 is a DARPin® candidate testing a novel therapeutic design that locally activates 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) clustering. In December 2018, Molecular Partners entered into a collaboration and license agreement with Amgen for the clinical development and commercialization of MP0310.

Having received all required regulatory approvals in Q2 2019, Molecular Partners is on-track to dose the first patient in H2 2019.

## **Research pipeline: Portfolio continues to make sustained progress with novel therapeutic designs, including localized FAP x CD40, peptide-MHC binders and DARPin® T cell-engager candidates**

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 a means 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.

Molecular Partners further 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. 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.

Moreover, the company presented the first preclinical data on its novel CD3 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.

## **Abicipar: EMA validated the marketing authorization application for abicipar; FDA feedback on acceptance of BLA filing pending**

In August 2019, the European Medicines Agency (EMA) publicly announced that it has validated the marketing authorization application (MAA) for abicipar, Allergan and Molecular Partners' novel DARPin® therapy for the treatment of neovascular age-related macular degeneration. An EMA decision on the market approval may be received in the second half of 2020. The US launch, following FDA filing and review, is expected mid-2020. If approved, abicipar is expected to be the first anti-VEGF therapy to sustain vision gains on a true fixed 12-week dosing interval.

On April 2, 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. That reduction of the inflammation data shown in MAPLE is an important complement to the encouraging 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 2, 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®.

#### Nicolas Leupin, M.D., MBA, appointed new Chief Medical Officer

In August 2019, Molecular Partners appointed medical oncologist Nicolas Leupin, M.D., MBA, to the role of Chief Medical Officer and member of the Management Board effective September 1, 2019. Dr. Leupin succeeds Chief Medical Officer Andreas Harstrick, M.D. Following the transition in the coming months, it is expected that Andreas Harstrick continues to support the company's medical strategy as an external consultant as required.

Dr. Leupin is a medical oncologist with a proven track record in drug development, most recently as Chief Medical Officer at argenx, a clinical-stage biotechnology company developing antibody-based therapies for the treatment of severe autoimmune diseases and cancer.

#### Daniel Steiner, Ph.D., promoted to lead the company's research department

In June 2019, Molecular Partners announced a scientific leadership transition after a successful transformation of its research organization around a defined set of therapeutic strategies in oncology.

The company's Senior Vice President of Research Daniel Steiner, Ph.D., was promoted to assume the leadership of the research department of the company, and Pamela A. Trail, Ph.D., departed from her role as Chief Scientific Officer effective July 1, 2019. Daniel Steiner joined Molecular Partners more than ten years ago and has held different roles within the company with increasing responsibilities.

#### Financial highlights: Positive operating cashflow reflects upfront payment collected from Amgen

In the first half of 2019, Molecular Partners recognized total revenues of CHF 13.6 million (H1 2018: CHF 9.4 million) and incurred operating expenses of CHF 26.0 million (H1 2018: CHF 22.1 million). This led to an operating loss of CHF 12.4 million for the first half-year 2019 which was broadly on par with the previous year's level (H1 2018: operating loss of CHF 12.7 million). The company recognized a net financing loss of CHF 0.3 million (H1 2018: CHF 1.0 million income), mainly driven by FX effects on the USD, EUR and GBP cash positions. This resulted in a net loss of CHF 12.7 million for the first half-year 2019 (H1 2018: CHF 11.7 million).

Molecular Partners' financial performance for the first half-year 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 24.3 million compared to year-end 2018 to CHF 123.3 million as of June 30, 2019. Total shareholders' equity, at CHF 78.1 million as of June 30, 2019, decreased by CHF 13.6 million (December 31, 2018: CHF 91.7 million).

As of June 30, 2019, the company employed 128 FTE, up 14% year-over-year. About 85% of the employees are employed in R&D-related functions.

#### Key figures as of June 30, 2019

Key Financials (unaudited)	H1 2019	H1 2018	Change
<i>(CHF million, except per share, FTE data)</i>			
<b>Total revenues</b>	<b>13.6</b>	<b>9.4</b>	<b>4.2</b>
R&D expenses	-19.0	-17.7	-1.3
G&A expenses	-7.0	-4.4	-2.6
<b>Operating result</b>	<b>-12.4</b>	<b>-12.7</b>	<b>0.3</b>
<b>Net result</b>	<b>-12.7</b>	<b>-11.7</b>	<b>-1.0</b>
Basic net result per share (in CHF)	-0.60	-0.56	-0.04
<b>Net cash from (used in) operating activities</b>	<b>27.0</b>	<b>-19.4</b>	<b>46.4</b>
<b>Cash balance (incl. time deposits) as of June 30</b>	<b>123.3</b>	<b>122.4</b>	<b>0.9</b>

<b>Total shareholders' equity</b>	<b>78.1</b>	<b>116.3</b>	<b>-38.2</b>
as of June 30			
<b>Number of total FTE</b>	<b>127.7</b>	<b>112.3</b>	<b>15.4</b>
as of June 30			
– thereof in R&D	106.7	100.4	6.3
– thereof in G&A	21.0	11.9	9.1

“Our ongoing strong cash position provides us a cash runway into 2021. This implies a solid financial flexibility to achieve multiple value-creating inflection events, including the expected market launch of abicipar in 2020 and the related expected income stream from there on,” said Andreas Emmenegger, Chief Financial Officer of Molecular Partners.

### Business outlook and priorities

In the second half of 2019, Molecular Partners will continue to advance its DARPin® candidates within its immuno-oncology **research pipeline**, specifically the FAP x CD40 molecule, the CD3 DARPin® T cell-engager platform as well as the peptide MHC program, and will present further research and preclinical data for additional therapeutic candidates resulting from the company's immuno-oncology toolbox.

In **immuno-oncology**, Molecular Partners expects to start the clinical phase 1 trial for MP0310 that is in a collaboration with partner Amgen in H2 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® (PI) in H2 2019. Molecular Partners also expects to start the phase 2 trial of MP0250 in combination with Pomalidomide® (IMiD) for the same indication. The company further plans to present initial safety data for MP0274, the company's proprietary DARPin® candidate for the treatment of HER2-positive cancer, in H2 2019.

In **ophthalmology**, following EMA's validation of the MAA filing for abicipar, a corresponding EMA decision may be received in the second half of 2020. The US launch, following FDA filing and review, is expected mid-2020. If approved, abicipar is expected to be the first anti-VEGF therapy to sustain vision gains on a true fixed 12-week dosing interval. Allergan is furthermore expected to present additional clinical data on the second year of the phase 3 trial in the second half of 2019.

### Financial outlook 2019

For the full year 2019, at constant exchange rates, the company continues to expect 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 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.

### Documentation

The [results presentation](#), the [press release](#) and the [half-year 2019 report](#) will be available on [www.molecularpartners.com](http://www.molecularpartners.com) from 7:00am (CET) on Tuesday, August 27, 2019.

### Financial Calendar

	Interim
October 31, 2019	Management Statement Q3 2019
December 12, 2019	R&D Day in New York
February 6, 2020	Publication of Full-year Results 2019 (unaudited)
April 29, 2020	Annual General Meeting

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

\*DARPin® is a registered trademark owned by Molecular Partners AG

### 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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