

Molecular Partners reports key financials for H1 18 and corporate highlights for the second quarter 2018: Promising MP0250 clinical data in oncology and positive abicipar phase 3 efficacy data presented

August 30, 2018

- Promising initial data from MP0250 combination with bortezomib (Velcade®) in phase 2 study in multiple myeloma:
   Five of eight evaluable patients achieved an objective response with median time of treatment for responding
   patients of 22.5 weeks. MP0250 combination with osimertinib (Tagrisso®) in EGFR-mutated non-small cell lung
   cancer supported by AstraZeneca with free drug supply.
- Immuno-oncology: DARPin® I/O toolbox established and preclinical data presented at AACR 2018, including MP0310, a FAPx4-1BB multi-DARPin® product candidate.
- Abicipar: In July 2018, Allergan presented positive phase 3 topline data on abicipar, demonstrating its
  non-inferiority in a 12-week fixed dosing regimen with less than half the injections vs. Lucentis<sup>®</sup>; Allergan plans
  FDA filing in H1 2019 and launch in 2020, while in parallel testing an optimized formulation to reduce
  inflammation.
- Oncology expertise further strengthened with Bill Burns elected as Chairman and Pamela A. Trail joining as Chief Scientific Officer.
- Company well capitalized to capture key value inflection points into 2020 with CHF 122.4 million in cash and short-term deposits as of June 30, 2018.
- Net cash used in operating activities of CHF 19.4 million in H1 2018, reflecting ongoing build-out of R&D and clinical pipeline.

**Zurich-Schlieren, August 30, 2018.** Molecular Partners AG (SIX: MOLN), a clinical-stage biopharmaceutical company pioneering the use of DARPin<sup>®</sup> therapeutics to treat serious diseases, today announced its unaudited financial results for the first half-year 2018. In the course of the semester, the company reported promising updated data on the phase 2 trial of its lead oncology asset MP0250. Moreover, on July 19, the company's strategic partner Allergan announced positive phase 3 topline data for abicipar showing non-inferior efficacy results compared to Lucentis<sup>®</sup>, utilizing a fixed quarterly dosing regimen compared with every four weeks dosing for Lucentis<sup>®</sup>.

"We are very pleased with our company's clinical and business progress during the first half of 2018," said Patrick Amstutz, Chief Executive Officer of Molecular Partners. "We are focusing on our DARPin<sup>®</sup> candidates in oncology, while our partner, Allergan, is moving forward with abicipar and has exercised all three options from our discovery alliance agreement, underscoring our mutual conviction regarding the promising potential of DARPin<sup>®</sup> therapeutics in ophthalmology."

"We presented promising updates on clinical data for our lead oncology asset, MP0250, in multiple myeloma. Moreover, we have entered into a collaboration with AstraZeneca ensuring the free supply of Tagrisso® for our second phase 2 study of MP0250 in EGFR-mutated non-small cell lung cancer, and we have dosed the first patients," added Andreas Harstrick, Chief Medical Officer of the company.

## Updated data confirm promising progress of phase 2 study of MP0250 in multiple myeloma

In April, at the European Myeloma Network (EMN) Conference in Turin, as well as in June, at the 23rd Annual Congress of the European Hematology Association (EHA) in Stockholm, Molecular Partners presented updated preliminary results from the ongoing phase 2 study of its lead proprietary oncology candidate, MP0250. The ongoing, open-label phase 2 clinical study is examining the safety and efficacy of MP0250 in combination with bortezomib (Velcade<sup>®</sup>) and dexamethasone in patients with relapsed/refractory multiple myeloma (RRMM). All patients had been pretreated with at least two lines of therapy, including an IMiD and bortezomib, and 50% were considered proteasome refractory. The study is being performed at nine centers in Germany, Poland and Italy.

At the data cutoff on May 21, 2018, five of eight evaluable patients achieved an objective response (4 patients with PR/partial response; 1 patient with VGPR/very good partial response). Responses were durable, with median time on treatment for responding patients of 22.5 weeks and the longest response then still ongoing at 41 weeks. Main adverse events were consistent with the known side effect profile of VEGF-targeting agents and of Velcade<sup>®</sup>, respectively.

Overall, a total of at least 40 patients are planned to be treated in this phase 2 study. The company anticipates additional safety data and initial efficacy data to be disclosed before year-end 2018.

First patients dosed in second phase 2 study of MP0250, evaluating MP0250 and osimertinib (Tagrisso®) in non-small cell lung cancer (NSCLC)

In April, Molecular Partners announced a collaboration with AstraZeneca (LON: AZN) to conduct a phase 1b/2 clinical study of MP0250 in combination

with osimertinib (Tagrisso®) in patients with EGFR-mutated non-small cell lung cancer (NSCLC) who were pre-treated with osimertinib. Under the collaboration agreement, AstraZeneca supplies osimertinib for the clinical study. The study is planned to enroll approximately 40 patients and will take place in the United States. The first patients in this phase 2 study were dosed and recruitment is ongoing. Initial safety data are expected by the end of 2018 with initial efficacy data to be disclosed in 2019.

### MP0274 in HER2-positive solid tumors: Enrollment for phase 1 study ongoing

Molecular Partners has amended the protocol of the phase 1 study of MP0274, a multi- DARPin<sup>®</sup> product candidate being developed for the treatment of HER2-positive solid tumors, to allow the enrollment of more patients at lower doses. In preclinical studies MP0274 induces a profound inhibition of specific downstream signaling pathways, and directly kills HER2-addicted tumor cells through the induction of apoptosis. This represents a new and differentiated mode of action as compared to current standard of care antibodies.

Enrollment and patient dosing of the phase 1 study is ongoing and the company continues to expect initial safety data in Q4 2018, with the first efficacy data expected in 2019.

# Immuno-oncology: Preclinical data on the company's DARPin® "toolbox" and on MP0310

At the 2018 annual meeting of the American Association of Cancer Research (AACR) in Chicago, Molecular Partners presented new preclinical data on MP0310 as well as its DARPin<sup>®</sup> "toolbox". MP0310 binds to 4-1BB and FAP and is the first immuno-oncology DARPin <sup>®</sup> candidate in development.

Preclinical data indicate that MP0310 can activate immune cells in the tumor microenvironment and not in the general circulation. This may translate into a better efficacy/safety profile than that seen with anti-4-1BB monoclonal antibodies.

Abicipar: Positive topline data announced for two pivotal phase 3 trials for patients with neovascular AMD, demonstrating the efficacy of an abicipar 12-week fixed dosing regimen with 50% fewer injections than Lucentis®

On July 19, 2018, Allergan and Molecular Partners announced positive phase 3 topline data from two clinical trials of abicipar. Those trials, called SEQUOIA and CEDAR, demonstrated that both the 8-week and 12-week treatment regimens of abicipar met the pre-specified primary endpoint of non-inferiority to ranibizumab (Lucentis<sup>®</sup>). SEQUOIA and CEDAR are identical global phase 3 studies designed to assess the efficacy and safety of abicipar compared with ranibizumab in treatment-naive patients with neovascular age-related macular degeneration (nAMD). The primary endpoint measured the proportion of treated patients with stable vision at week 52.

In the first year of both studies abicipar demonstrated similar efficacy, after 6 or 8 injections, to a regimen of 13 ranibizumab injections. The overall adverse events were similar among the three treatment arms. The incidence of intraocular inflammation was approximately 15% in the abicipar arms, higher than the rate seen in ranibizumab-treated patients, which was below 1% in both trials. To minimize inflammation, Allergan has further optimized the formulation of abicipar and is currently testing this formulation (MAPLE trial). The trial is currently recruiting patients, with a goal of 100 patients enrolled.

"We are very excited to see that the most advanced DARPin<sup>®</sup> molecule, abicipar, has reached its primary endpoint in phase 3. This is a very important milestone for Molecular Partners and the DARPin<sup>®</sup> technology in general," said Patrick Amstutz, CEO of Molecular Partners. "We are very pleased to see that abicipar can indeed help patients in need with less frequent dosing which was the key point when we generated abicipar in the first place," added Michael T. Stumpp, COO of Molecular Partners.

The SEQUOIA and CEDAR phase 3 clinical trials continue on a masked basis, now in their second year. Full data details of the primary endpoints and the secondary endpoints will be presented at an upcoming scientific conference. Allergan plans to file abicipar in the first half of 2019. Allergan will be requesting a meeting with the Food and Drug Administration (FDA) to discuss the corresponding BLA submission. The market launch of abicipar is foreseen for 2020.

## Financial highlights: Increased clinical activities and build-out of organization

In the first half of 2018, Molecular Partners recognized total revenues of CHF 9.4 million (H1 2017: CHF 6.0 million) and incurred operating expenses of CHF 22.1 million (H1 2017: CHF 22.7 million) in line with expectations. This led to an operating loss of CHF 12.7 million for the first half-year (H1 2017: operating loss of CHF 16.7 million). The company recognized a net financing income of CHF 1.0 million (H1 2017: CHF -2.7 million), mainly driven by positive FX effects on the USD and EUR cash positions. This resulted in a net loss of CHF 11.7 million for the first half-year 2018 (H1 2017: CHF 19.4 million).

# Key figures as of June 30, 2018

Key H1 H1change **Financials** (unaudited) 2018 2017 (CHF million, except per share, FTE data) Total 9.4 6.0 3.4 revenues R&D -17.7 -18.9 1.2 expenses

G&A expenses	-4.4 -3.8	-0.6
Operating result	-12.7 -16.7	4.0
Net result	-11.7 -19.4	7.7
Basic net result per share (in CHF) Net cash from (used in) operating activities	-0.56 -0.93 -19.4 -20.5	0.37
balance (incl. time		
deposits) as of June 30 Total	122.4156.9	-34.5
of June 30		<b>-34.5</b> -2.0
of June 30 Total shareholders' equity as of June 30 Number of total FTE as of June 30	,	
of June 30 Total shareholders equity as of June 30 Number of total FTE as	116.3118.3	-2.0

The net cash used from operating activities during the first half of 2018 was CHF 19.4 million (H1 2017: net cash used of CHF 20.5 million). Including time deposits, the cash and cash equivalents position decreased by CHF 8.9 million vs. year-end 2017 to CHF 122.4 million as of June 30, 2018 (December 31, 2017: CHF 131.3 million). The total shareholders' equity, at CHF 116.3 million as of June 30, 2018, remained broadly unchanged (December 31, 2017: CHF 116.7 million).

As a result of the adoption of IFRS 15, deferred revenues as of December 31, 2017 of CHF 18.4 million were partly reclassified to equity (CHF 8.9 million) to reflect the accumulated past effect of the adoption as of January 1, 2018. The remaining portion of CHF 9.4 million was recognized as revenues in H1 2018.

As of June 30, 2018, the company employed 112 FTE, up 8% year-over-year as well as compared to year-end 2017. About 90% of the employees are employed in R&D-related functions.

"During the first half of 2018, Molecular Partners' financial position continued to develop in line with our expectations. Our strong cash position provides us with financial flexibility to achieve multiple value-creating inflection points into 2020," said Andreas Emmenegger, Chief Financial Officer of Molecular Partners.

### Pamela A. Trail appointed Chief Scientific Officer and member of the Executive Management

On June 21, 2018, Pamela A. Trail, Ph.D, was appointed Chief Scientific Officer of Molecular Partners and a new member of the Executive Management Team of the company. Dr. Trail served most recently as Vice President of Oncology Strategy and Program Direction at Regeneron Pharmaceuticals. She has over 30 years of experience in directing cancer drug discovery efforts at leading pharmaceutical companies worldwide. Dr. Trail holds a Ph.D. in Immunology and Virology from the University of Connecticut. With her addition the company significantly strengthens its leading research capabilities applying the DARPin<sup>®</sup> platform to oncology drug development.

# Michael T. Stumpp appointed Chief Operating Officer

On June 21, 2018, Michael T. Stumpp, Ph.D., a co-founder of Molecular Partners and formerly Chief Scientific Officer of the company, was appointed Chief Operating Officer of Molecular Partners. Dr. Stumpp was part of the research team at the University of Zurich that invented the DARPin<sup>®</sup> technology. Since Molecular Partners' inception, he has overseen the DARPin <sup>®</sup> pipeline.

# **Business outlook and priorities**

As pertains to the company's proprietary **oncology pipeline**, Molecular Partners expects to report additional safety data and initial efficacy data from the phase 2 study of MP0250 in patients with multiple myeloma (MM) in 2018. The company also expects initial safety data from the phase 1b/2 study of MP0250 in NSCLC in 2018, having dosed the first patients. For MP0274, the proprietary, single-pathway DARPin<sup>®</sup> drug candidate for the treatment of HER2-positive cancer, Molecular Partners expects initial safety data in Q4 2018 and first efficacy data in 2019.

The company will continue to advance its **immuno-oncology pipeline** and will present further research and preclinical data for its DARPin<sup>®</sup> candidate MP0310 in 2018. In this promising field, Molecular Partners has reinforced its focus on activating agonists in a tumor-restricted way.

In **ophthalmology**, following the positive phase 3 topline results of abicipar announced by Allergan on July 19, 2018, Molecular Partners will continue to support Allergan in advancing abicipar through phase 3 studies in patients with neovascular AMD and in further optimizing the abicipar formulation in order to minimize inflammation. Molecular Partners will also continue to support Allergan in the launch of the phase 3 study for abicipar in DME with the improved abicipar formulation expected for 2019 as well as in advancing the three preclinical ophthalmology assets optioned-in from the existing research collaboration. Allergan anticipates a market launch for abicipar for the neovascular AMD indication in the year 2020.

#### Financial outlook 2018

As the first half of 2018 developed in line with management's expectations, Molecular Partners is able to add more precision to the financial outlook 2018 which was provided with the company's 2017 full-year results on February 8, 2018, as well as in the company's quarterly management statement on April 26, 2018.

For the full year 2018, at constant exchange rates, the company expects total expenses at the lower end of the CHF 50-60 million range indicated, of which around CHF 6 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciations. However, this guidance is subject to the progress of the pipeline, mainly driven by manufacturing costs, the speed of enrollment of patients in clinical studies and data from research and development projects.

No guidance can be provided with regard to net cash flow projections. Timelines and potential milestone payments from existing and potentially new partnerships are not disclosed.

## R&D day in New York on December 6, 2018

Molecular Partners will host its 2<sup>nd</sup> R&D Update in New York City on December 6, 2018. For details and to reserve a seat, please contact Susan Noonan at <a href="mailto:susan@sanoonan.com">susan@sanoonan.com</a>.

### Investor documentation of H1 2018 results

The H1 2018 results presentation, the H1 2018 press release as well as the <u>unaudited Financial Statements for H1 2018 and the company's H1 2018</u>
Report and additional information are available on the investors section of the company's website.

#### Conference call and audio webcast

Molecular Partners will conduct a conference call and audio webcast of the company's H1 2018 results on August 30, 2018, at 2:00pm CET (1:00pm GMT, 8:00am EST).

In order to register for the H1 2018 conference call, please dial the following numbers approximately 10 minutes before the start of the presentation:

(0)58 Switzerland310 / Europe 5000 +44 (0)207 107 UK 0613 +1 (1) 631 570 USA 5613

Participants will have the opportunity to ask questions after the presentation.

The <u>H1 2018 audio webcast</u> will be accessible, both live and as a replay, on the investors section of the company's website <u>www.molecularpartners.com</u>, along with the accompanying presentation slides.

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

# **Financial Calendar**

- November 1, 2018 Q3 2018 Management Statement
- December 6, 2018 R&D Day in New York
- February 7, 2019 Publication of Full-year Results 2018 (unaudited)
- March 15, 2019 Expected Publication of Annual Report 2018
- April 16, 2019 Annual General Meeting

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<sup>®</sup> candidates are potent, specific, safe and very versatile. They can engage more than 5 targets at once, 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 good safety profile, low immunogenicity and long half-life in the bloodstream and the eye, DARPin<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> molecules for various ophthalmic indications are also in development. The most advanced DARPin<sup>®</sup> therapeutic candidate wholly owned by Molecular Partners, MP0250, is in phase 2 clinical development for the treatment of solid tumors and hematological tumors. MP0274, the second-most advanced DARPin<sup>®</sup> drug candidate owned by Molecular Partners, has broad anti-HER activity; it inhibits HER1, HER2 and HER3-mediated downstream signaling via Her2, leading to induction of apoptosis. MP0274 is currently in phase 1. Molecular Partners is also advancing a growing preclinical pipeline that features several immuno-oncological development programs. DARPin<sup>®</sup> is a registered trademark owned by Molecular Partners AG.

#### **About Molecular Partners AG**

Molecular Partners AG is a clinical-stage biopharmaceutical company that is developing a new class of therapies known as DARPin<sup>®</sup> therapeutics. With a management team that includes many of the founding scientists, 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.

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