Heidelberg Pharma AG: Interim Management Statement on the First Nine Months of 2020

- IND application to the FDA for the Phase I/IIa clinical trial of HDP-101 in preparation
- Private placement with gross proceeds of EUR 14.4 million and further financing commitment of EUR 15 million by majority shareholder dievini received
- Expansion of own ATAC pipeline leads to increased expenses and adjustment of forecast
- Milestone payment received from partner Magenta in September
- Encouraging first data from partner RedHill with upamostat in COVID-19

Ladenburg, Germany, 8 October 2020 – Heidelberg Pharma AG (FSE: HPHA) today reported on the first nine months of fiscal year 2020 (1 December 2019 – 31 August 2020) and the Group's financial figures.

Dr. Jan Schmidt-Brand, CEO and CFO of Heidelberg Pharma AG, commented: “We are very relieved that we have mastered the past months without major restrictions despite the difficult COVID-19 situation. Our own research and development work continued as planned. However, there were delays with partners, which affected expected milestone payments and the duration of early-stage research. The maintenance of personal contacts with scientific partners and investors was significantly limited by the pandemic measures and could largely only take place virtually.

The focus continues to be on our ATAC candidate HDP-101, but the expansion of our pipeline is also becoming increasingly important. Thanks to the financing commitment of our main shareholder dievini in July, we were able to intensify the development of further product candidates and initiate important work in recent weeks. As a result, our expenses have increased significantly, and we have already adjusted our forecast for 2020. This broadening of our own pipeline is an important step to further exploit the potential of our ATAC platform technology and increase the value of the company."

Important operational developments and achievements

- **HDP-101 (BCMA ATAC) development program:** The preclinical development of HDP-101, a BCMA Antibody Targeted Amanitin Conjugate for treating multiple myeloma, has now been completed. The first batch of the development candidate HDP-101 was tested in the final GLP toxicity study, and the preclinical study was recently successfully completed. The clinical team has finalized the study protocol of the Phase I/IIa study of the clinical development program for HDP-101 and is in contact with the U.S. Food and Drug Administration (FDA) to resolve any final questions. The company expects to be able to submit the IND application for the study to the FDA in the near future. Coordination with the German regulatory authority, the Paul Ehrlich Institute, will follow.
- **Execution of a capital increase and financing commitment by majority shareholder dievini:** In April 2020, Heidelberg Pharma AG carried out a private placement with gross proceeds of EUR 14.4 million. At an issue price of EUR 5.10, 2,820,961 new shares were issued from authorized capital, which corresponded to just under 10% of the share capital at that time. In July 2020, Heidelberg Pharma received a further financing commitment of up to EUR 15 million from its main shareholder dievini Hopp Biotech holding GmbH & Co. KG,

Walldorf, Germany, (dievini). This commitment enabled Heidelberg Pharma to advance further development candidates from its proprietary project portfolio and start the necessary work. The financing range until mid-2021 will thus be maintained despite the expanded pipeline.

- **Virtual Annual General Meeting and election of a new Supervisory Board:** The Annual General Meeting of Heidelberg Pharma AG was held in virtual format on 22 July 2020 in accordance with the COVID-19 Act. The Annual General Meeting approved all resolutions proposed by the management by a large majority (between 98.65% and 99.99%). Among other items on the agenda, the Supervisory Board of Heidelberg Pharma AG was elected for a five-year term. Professor Christof Hettich, Dr. Georg F. Baur, Dr. Friedrich von Bohlen und Halbach, Dr. Birgit Kudlek and Dr. Mathias Hothum were re-elected to the Supervisory Board.

Update of partner programs

- **Progress with licensing partner Magenta:** In January 2020, the partner Magenta Therapeutics, Cambridge, MA, USA, (Magenta) (NASDAQ: MGTA) announced MGTA-117, utilizing ATAC technology, as a clinical development candidate for the targeted preparation (conditioning) of patients for stem cell transplants or gene therapy. MGTA-117 consists of a CD117 antibody in combination with the toxin Amanitin and was developed based on an ATAC technology license granted by Heidelberg Pharma. Initial preclinical data were presented by Magenta at various conferences in the first half of the year. Magenta is currently conducting further preclinical studies and preparing the manufacturing and clinical development of MGTA-117, which is expected to be in the clinic in 2021.

  Magenta is also working on the preclinical validation of the second candidate, a CD45-ATAC, for the treatment of autoimmune diseases.

- **Progress with partner Telix:** Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix) (ASX: TLX) has been conducting a Phase III study (ZIRCON) with TLX250-CDx (^{89}Zr-Girentuximab) since 2019 for the imaging diagnosis of kidney cancer using positron emission tomography (PET) in Australia and Europe. In early 2020, the IND in the U.S. was approved for this study and patient recruitment for the trial started. Due to the COVID-19 lockdown, patient recruitment had to be suspended, but was resumed in Europe in mid-June and in Australia in September. Telix expects recruitment to commence in the United States and Canada during October, with completion of recruitment for the entire study anticipated during the first quarter of 2021.

  On 1 July 2020, Telix received a *Breakthrough Therapy Designation* from the US FDA for TLX250-CDx. This status offers a number of significant benefits to Telix, including eligibility for fast track designation, more frequent and intensive interactions with the FDA, and the opportunity to submit a “rolling” Biological License Application (BLA) for TLX250-CDx, where the application can be submitted in separate modules to streamline the FDA review process for approval.

  In parallel to the ZIRCON trial, a Phase I/II bridging study (ZIRDAC-JP) with TLX250-CDx is being conducted in Japan to demonstrate that the pharmacology and dosage in Japanese patients are comparable to the already available results. The first Japanese patient was enrolled in August and treated with TLX250-CDx.

Events after the reporting period

- **Milestone payment received from partner Magenta:** Heidelberg Pharma AG announced in mid-September that it has received a milestone payment from its cooperation partner Magenta associated with the initiation of the GLP toxicology study for the development candidate MGTA-117.
- **Progress with the out-licensed product candidate upamostat:** The partner RedHill Biopharma Ltd, Tel Aviv, Israel and Raleigh, NC, USA, (RedHill) (Nasdaq: RDHL) announced in September 2020 that it has conducted an *in vitro* study with the development candidate RHB-107 (upamostat) against SARS-CoV-2, the virus that causes coronavirus disease (COVID-19). The study showed potent inhibition of SARS-CoV-2 viral replication by RHB-107. A Phase II/III study with RHB-107 in patients with COVID-19 is planned to be initiated later this year.

  Additionally, RedHill announced in August 2020 that recent pre-clinical findings, presented at the American Association for Cancer Research (AACR) annual meeting, demonstrated that treatment with RHB-107 in combination with its novel drug candidate, Opaganib, resulted in tumor regression and that the combination of both drugs was potent and well tolerated in animal models. In light of these findings, RedHill plans to add an additional cohort to its ongoing Phase IIa study of Opaganib in advanced cholangiocarcinoma, evaluating Opaganib in combination with RHB-107, subject to discussions with the FDA.

Results of operations, financial position and net assets

The Heidelberg Pharma Group – as of the reporting date comprising Heidelberg Pharma AG and its subsidiary Heidelberg Pharma Research GmbH – reports consolidated figures. The reporting period referred to below concerns the period from 1 December 2019 to 31 August 2020 (9M 2020).

In the first nine months of the 2020 fiscal year, the Group generated sales revenue and income totaling EUR 8.3 million (previous year: EUR 6.7 million). This figure includes **sales revenue** of EUR 7.5 million, an increase from the previous year's total of EUR 6.2 million, that stems from the collaboration agreements including the supply of Amanitin linkers for the ATAC technology (EUR 7.0 million), the service business (EUR 0.3 million) and income from license agreements signed by the parent company (EUR 0.2 million).

At EUR 0.8 million, **other income** was up slightly on the prior-year figure of EUR 0.6 million. It primarily consisted of the charging on of patent costs, of German and European grants and of the reversal of unutilized accrued liabilities and provisions.

Operating expenses including depreciation and amortization amounted to EUR 20.7 million in the reporting period (previous year: EUR 12.4 million). **Cost of sales** rose to EUR 4.5 million (previous year: EUR 2.8 million) due to the ATAC collaborations including material supply.

Research and development costs in the amount of EUR 13.5 million increased as planned compared to the prior-year period (EUR 7.2 million) due to external Good Manufacturing Practice (GMP) production, and preclinical and regulatory preparations for the clinical trial with HDP-101. In addition, first payments for the production of antibodies for HDP-102 and HDP-103 had been made to a CDMO. R&D costs continue to represent the largest cost block with 65% of operating expenses.

Administrative costs edged up slightly to EUR 2.4 million compared to the prior-year period (EUR 2.2 million). Among others, this figure includes holding company costs and costs related to the stock market listing.

Other expenses for business development and marketing of the technology in the reporting period totaled EUR 0.3 million (previous year: EUR 0.2 million) due to an expansion of activities.

The **net loss** for the first nine months of the fiscal year increased to EUR 12.5 million (previous year: EUR 5.6 million) as a result of the items described above. **Earnings per share** fell from EUR -0.20 in the previous year to EUR -0.42.

Cash and cash equivalents as of the end of the third quarter amounted to EUR 9.2 million (30 November 2019: EUR 9.9 million; 31 August 2019: EUR 12.7 million). This represents an average monthly cash outflow of EUR 1.66 million in the first nine months of the fiscal year (previous year: EUR 0.75 million), excluding the capital increase carried out in April.

Total assets as of 31 August 2020 increased to EUR 25.4 million compared to the 30 November 2019 reporting date (EUR 23.0 million). At EUR 18.6 million, **equity** was higher compared to the end of fiscal year 2019 (EUR 16.3 million).

The capital increase in the first half of the financial year as well as the exercise of stock options in the first third quarter resulted in 2,837,461 new shares that increased the share capital of Heidelberg Pharma AG from EUR 28,209,611 to EUR 31,047,072, divided into 31,047,072 no par value bearer shares.

Financial outlook for 2020

The forecast for the current financial year issued in mid-March 2020 was adjusted for the Heidelberg Pharma Group in September 2020. This is due to increased operating expenses for the validation and manufacturing of the next two ATAC development candidates, which will be incurred during the year, as well as a better predictability for the expected sales and the overall result.

The Heidelberg Pharma Group expects operating expenses between EUR 26.0 million and EUR 28.0 million (previously: EUR 20.0 million to EUR 24.0 million). Sales and other income will continue to range between EUR 9.0 million and EUR 10.0 million (previously: EUR 8.0 million to EUR 10.0 million). Based on these adjustments, an operating result (EBIT) between EUR -16.0 million and EUR -19.0 million is expected (previously: EUR -11.0 million to EUR -15.0 million).

For 2020, Heidelberg Pharma anticipates cash requirements of EUR 18.0 million to EUR 20.0 million (previously: EUR 11.0 million to EUR 15.0 million). Monthly cash consumption is expected to range between EUR 1.5 million and EUR 1.7 million per month (previously: EUR 0.9 million and EUR 1.3 million). Based on the updated planning and the financing commitment of the main shareholder dievini Hopp BioTech holding GmbH & Co. KG, Walldorf, the company's financing is still secured until mid-2021.

Heidelberg Pharma will not host a conference call on this interim management statement. The complete figures for the interim financial statements can be downloaded from http://www.heidelberg-pharma.com/ ”Press & Investors > Financial Reports > Interim Management Statement of 8 October 2020”.

Key figures for the Heidelberg Pharma Group

In EUR thsd.	9M 2020 [1] EUR thsd.	9M 2019 [1] EUR thsd.
Earnings		
Sales revenue	7,488	6,180
Other income	787	561
Operating expenses	(20,736)	(12,385)
of which research and development costs	(13,546)	(7,241)
Operating result	(12,461)	(5,644)
Earnings before tax	(12,468)	(5,644)
Net loss for the period	(12,468)	(5,649)
Basic earnings per share in EUR	(0.42)	(0.20)
Balance sheet as of the end of the period		
Total assets	25,398	25,912
Cash and cash equivalents	9,226	12,709
Equity	18,604	20,582
Equity ratio[2] in %	73.3	79.4
Cash flow statement		
Cash flow from operating activities	(13,958)	(5,921)
Cash flow from investing activities	(973)	(800)
Cash flow from financing activities	14,283	0
Employees (number)		
Employees as of the end of the period[3]	81	70
Full-time equivalents as of the end of the period[3]	70	65

1 The reporting period begins on 1 December and ends on 31 August
2 Equity / total assets
3 Including members of the Executive Management Board
Rounding of exact figures may result in differences.

Contact

Heidelberg Pharma AG
Corporate Communications
Sylvia Wimmer
Tel.: +49 89 41 31 38-29
Email: investors[at]hdpharma.com
Gregor-Mendel-Str. 22, 68526 Ladenburg

IR/PR support

MC Services AG
Katja Arnold (CIRO)
Managing Director & Partner
Tel.: +49 89 210 228-40
Cell: +49 (0)160 9360 3022
Email: katja.arnold[at]mc-services.eu

About Heidelberg Pharma

Heidelberg Pharma AG is a biopharmaceutical company based in Ladenburg, Germany. Heidelberg Pharma is an oncology specialist and the first company to develop the toxin Amanitin into cancer therapies using its proprietary Antibody Targeted Amanitin Conjugate (ATAC) technology and to advance the biological mode of action of the toxin as a novel therapeutic principle. This proprietary technology platform is being applied to develop the Company's proprietary therapeutic ATACs as well as in third-party collaborations to create a variety of ATAC candidates. The proprietary lead candidate HDP-101 is a BCMA ATAC for multiple myeloma.

Heidelberg Pharma AG has entered into partnerships to further develop and commercialize its clinical assets upamostat (formerly MESUPRON®) and TLX250-CDx (formerly REDECTANE®). The Company is listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol HPHA. More information is available at http://www.heidelberg-pharma.com/.