Heidelberg Pharma AG: Interim Management Statement on the First Nine Months of 2021

- Paul-Ehrlich-Institut follows the FDA in giving clearance to begin a Phase I/IIa trial of HDP-101; first trial centers initiated in the USA
- Gross issue proceeds of over EUR 20 million generated from private placement in June
- Significant advances made in partner projects
- Guidance revised

Ladenburg, Germany, 7 October 2021 – Heidelberg Pharma AG (FSE: HPHA) today reported on the first nine months of fiscal year 2021 (1 December 2020 – 31 August 2021) and the Group's financial figures.

Dr. Jan Schmidt-Brand, CEO and CFO of Heidelberg Pharma AG, commented: “We are delighted to have achieved important milestones in recent weeks and to have cleared several organizational hurdles for our initial clinical trial of HDP-101. The first two trial centers were initiated recently, and we are now eagerly awaiting the inclusion of the first patient.

Our partners also reported encouraging regulatory developments. Magenta Therapeutics was cleared by the FDA to open a clinical trial to evaluate its MGTA-117 ATAC® conditioning program. Our partner Telix announced that the FDA had accepted the IND application to undertake a clinical study of the radioimmunoconjugate TLX250 (^{177}Lu-DOTA-girentuximab) for treatment of advanced renal cancer. This means that the antibody girentuximab will be developed further for therapeutic purposes as well. RedHill, the partner for RHB-107 (upamostat), expanded the Phase II/III clinical trial in non-hospitalized COVID-19 patients from the US to South Africa. We are very pleased about these highly positive developments.

We have adjusted our guidance due to delays in development programs, the associated lower expenses, and due to lower revenue from licensing agreements caused by postponements of milestones by our partners into the next fiscal year. Overall, the operating result will improve and funding requirements for fiscal year 2021 will decrease."

Important operational developments and achievements

- **HDP-101 (BCMA ATAC) development program:** HDP-101 is a BCMA ATAC that will be evaluated for the treatment of multiple myeloma. In the first quarter, the FDA approved the IND (Investigational New Drug) application to conduct a Phase I/IIa clinical trial. This paved the way for accelerating preparations at the trial centers, obtaining approval from the responsible ethics committees, and supplying the trial drug. Because HDP-101 contains the toxin Amanitin, a special closed system transfer device (CSTD) must be used in the US to protect hospital staff from accidentally meeting the compound. In recent weeks, Heidelberg Pharma successfully performed the testing required to verify compatibility of HDP-101 with the systems used by the trial centers. This means that the CSTD can be used for the infusion of HDP-101 in the clinical trial. After a contract had been signed with MD Anderson in Houston, Texas, the trial drug had been shipped and medical staff had been trained, the first trial center was initiated at the end of September. At the beginning of October, the second center, the Winship Cancer Institute of Emory University in Atlanta, Georgia, was initiated.

  Heidelberg Pharma had also applied for a clinical trial to Germany’s medical regulatory body, the Paul-Ehrlich-Institut, in March which was approved in July. Preparations were advanced in parallel, enabling the first trial center in Germany to be initiated in the next weeks.

- **Capital increase and financing commitment by main shareholder dievini:** In June 2021, a capital increase was implemented, generating gross issue proceeds of approximately EUR 20 million. Heidelberg Pharma AG issued 3,106,637 new shares from authorized capital in a private placement, which corresponded to just under 10% of share capital. The new shares were allocated to new institutional investors, including Polar Capital Biotech Investment Fund and Invus, and 1,943,565 shares were placed with DH-LT-Investments GmbH, St. Leon-Rot, an investment company owned by Mr. Dietmar Hopp. The price per share was EUR 6.44, a markdown of approximately 3.9% on the day's closing price. The cash generated by the placement will be used to ensure further development of the ATAC® technology and of proprietary pipeline candidates, particularly clinical development of the lead project HDP-101. As a result of this corporate action and the remaining financing commitment of approximately EUR 17 million made by the main shareholder dievini Hopp BioTech holding GmbH & Co. KG (dievini), Heidelberg Pharma's financing is currently secured until mid-2022 based on current planning.
- **Heidelberg Pharma expands its management team:** At the beginning of March, Dr. András Strassz, who had held the position of Senior Medical Officer in the company since April 2020, was appointed Chief Medical Officer, while Dr. Mathias Locher was named Chief Development Officer. In addition to the two members of the Executive Management Board, Dr. Jan Schmidt-Brand and Prof. Andreas Pahl, the Executive Management Team of Heidelberg Pharma now consists of Dr. Strassz, Dr. Locher and Dr. George Badescu, Vice President Business Development.
- **New preclinical data on the immunomodulatory potential of Antibody Targeted Amanitin Conjugates:** At the American Association for Cancer Research (AACR) 2021 Annual Meeting in April, Heidelberg Pharma presented preclinical data on its novel ATAC® candidates HDP-102 (CD37 ATAC) and HDP-103 (PSMA ATAC) and, in another poster presentation, data on synergistic effects of ATACs with checkpoint inhibitors.

Partner program updates

- **Progress made by our licensing partner Magenta:** The Company's partner Magenta Therapeutics, Cambridge, MA, USA, (NASDAQ: MGTA) is developing MGTA-117 as its first clinical ATAC® technology-based candidate for the targeted preparation, or conditioning, of patients for stem cell transplants or gene therapy. MGTA-117 is an ATAC® that consists of a CD117 antibody and the toxin Amanitin, and which was developed by Magenta based on a license granted by Heidelberg Pharma. The GLP toxicology studies have been completed and the material required has been successfully manufactured according to GMP standards and delivered by Heidelberg Pharma. Magenta filed an Investigational New Drug (IND) application with the FDA in June for a Phase I/II dose escalation study in conditioning of transplant patients with relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). The FDA requested that prior to accepting the application Magenta develop an additional bioassay to be used in conjunction with pharmacokinetic and pharmacodynamic models to facilitate dose escalation decisions. In September 2021, Magenta announced that the FDA had no objections to initiating the trial. The multi-center, open-label Phase I/II trial is expected to begin in the fourth quarter of 2021. In addition, Magenta is planning clinical trial collaborations for gene therapy with its partners AVROBIO and Beam Therapeutics to evaluate the potential utility of MGTA-117 for conditioning gene therapy patients without the use of toxic chemotherapies.
- **Progress made by our partner Telix:** Telix Pharmaceuticals Limited, Australia, (ASX: TLX) has been conducting an international Phase III study (ZIRCON) with TLX250-CDx (^{89}Zr-girentuximab) for diagnosing renal cancer using positron emission tomography (PET) since 2019. A total of 34 study sites are currently taking part in the trial, with enrollment expected to be completed by the end

of the year. Telix plans to submit its Biologics License Application (BLA) to the US Food and Drug Administration in 2022. It is planned that the consultation process will commence by year-end.

In parallel to the ZIRCON trial, Telix has also completed a Phase I/II bridging study (ZIRDAC-JP) with TLX250-CDx in Japan and demonstrated that the pharmacology and dosage as well as safety and tolerability for Japanese patients is comparable with already existing data from Caucasian patient populations. Based on these data, Telix will consult with the Japanese regulator to confirm the design of the next stage of development for TLX250-CDx in Japan, with the objective of bridging to Telix's Phase III ZIRCON study.

In June 2021, Telix also launched a Phase I study (ZiP-UP) of TLX250-CDx in patients with bladder cancer to evaluate whether the scope of indications could be broadened to include other types of cancer. ZiP-UP is the first in a series of studies that will harness TLX250-CDx to evaluate CAIX expression in cancers other than renal cancer. A Phase II study evaluating TLX250-CDx in triple-negative breast cancer (OPALESCENCE) was subsequently announced in August, with other collaborations in preparation for ovarian, colorectal, head and neck, lung, and pancreatic cancers. On 5th October 2021, Telix announced the dosing of the first patient.

In addition to developing the diagnostic antibody, Telix is also planning the development of a therapeutic radioimmunoconjugate (^{177}Lu-DOTA-girentuximab, TLX250) program based on the lutetium-177-labeled girentuximab antibody. In September, the IND application to conduct the STARLITE 2 trial was accepted by the FDA. TLX250 shall be tested in the single-arm STARLITE 2 study in patients with advanced clear cell renal cell carcinoma (ccRCC).

- **Progress made by our partner RedHill:** Our partner RedHill Biopharma (Nasdaq: RDHL) is developing RHB-107 (upamostat), a drug candidate outlicensed from Heidelberg Pharma, as a once-daily oral pill treatment for COVID-19. RedHill has an ongoing US Phase II/III trial with RHB-107 in symptomatic non-hospitalized COVID-19 patients who are early in the course of the disease. The first patient of 310 planned was dosed in mid-February 2021. In September, RedHill expanded the number of US sites and announced the expansion of the study to South Africa to further accelerate patient enrollment.

  RHB-107 targets human serine proteases involved in the virus's entry into target cells. Due to its targeting of human cell factors, and not the virus itself, RHB-107 is expected to be effective against emerging viral variants with mutations as well. This is underpinned by in-vitro data showing that RHB-107 effectively inhibits SARS-CoV-2 replication in human bronchial tissue. In May 2021, RedHill announced receipt of a Notice of Allowance from the US Patent and Trademark Office (USPTO) covering RHB-107 as a method for the treatment of COVID-19.

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 2020 to 31 August 2021 (9M 2021).

In the first nine months of the 2021 fiscal year, the Group generated sales revenue and income totaling EUR 1.6 million (previous year: EUR 8.3 million). The **sales revenue** included in this figure (EUR 1.1 million; previous year: EUR 7.5 million) comprises the collaboration agreements of Heidelberg Pharma Research, including their deliveries of Amanitin linkers for the ATAC® technology (EUR 0.7 million), and the service business (EUR 0.4 million).

At EUR 0.5 million, **other income** was also down on the prior-year figure (EUR 0.8 million). It primarily consisted of government grants, the passing on of patent costs and the reversal of unutilized accrued liabilities and provisions.

Operating expenses including depreciation and amortization amounted to EUR 20.1 million in the reporting period (previous year: EUR 20.7 million). **Cost of sales** fell to EUR 3.0 million (previous year: EUR 4.5 million).

Research and development costs rose compared to the last year to EUR 14.1 million (previous year: EUR 13.5 million) due to the expansion of cost-intensive external manufacturing for all three ATAC® projects and preparations for the clinical trial with HDP-101. At 70% of operating expenses, R&D remained the largest cost item.

Administrative costs increased to EUR 2.6 million compared to the prior-year period (EUR 2.4 million). Among others, this figure includes holding company costs and costs related to the stock market listing.

Other expenses for business development and marketing the technology in the reporting period totaled EUR 0.4 million (previous year: EUR 0.3 million) due to an expansion of activities.

The **financial result**, which mainly consists of interest expenses, amounts to EUR -0.3 million (previous year: EUR -7 thousand).

The **net loss** for the first nine months of the fiscal year rose to EUR 18.9 million (previous year: EUR 12.5 million) as a result of the items described above. In line with this and taking into account the higher number of shares, the loss **per share** widened from EUR -0.42 in the previous year to EUR -0.59.

Cash and cash equivalents as of the end of the third quarter amounted to EUR 13.6 million (30 November 2020: EUR 5.0 million; 31 August 2020: EUR 9.2 million). Not considering the capital increase implemented in June, this represents an average monthly cash outflow of EUR 2.29 million in the first nine months of the fiscal year (previous year: EUR 1.66 million).

Total assets as of 31 August 2021 amounted to EUR 28.5 million, up from the figure of EUR 19.6 million shown as of the 30 November 2020 reporting date. At EUR 13.7 million, **equity** was also up compared to the end of fiscal year 2020 (EUR 12.9 million).

The capital increase implemented in the third quarter of the fiscal year and the exercise of stock options during the year resulted in the creation of 3,111,137 new no par value shares that increased the share capital of Heidelberg Pharma AG from EUR 31,061,872 to EUR 34,173,009, divided into 34,173,009 no par value bearer shares.

Financial outlook for 2021

On 1st October 2021, the Company revised its guidance for the current fiscal year issued for the Heidelberg Pharma Group in mid-March 2021. This is due to lower development expenses because clinical testing and manufacturing orders were delayed. Planned sales revenue from license agreements will not be recognized until the next fiscal year as some of the partners will reach milestones later than projected. Overall, the operating result will improve and funding requirements for fiscal year 2021 will decrease.

The Heidelberg Pharma Group expects or the financial year 2021 sales and other income between EUR 2.0 million and EUR 2.5 million (previously: EUR 5.5 million to EUR 7.5 million). Operating expenses will range between EUR 26.0 million and EUR 28.5 million (previously: EUR 36.0 million to EUR 40.0 million). Based on these adjustments, an operating result (EBIT) between EUR -23.5 million and EUR -26.5 million is expected (previously: EUR -30.0 million to EUR -34.0 million).

For 2021, Heidelberg Pharma anticipates cash requirements of EUR 26.5 million to EUR 29.0 million (previously: EUR 30.0 million to EUR 34.0 million). Monthly cash consumption is expected to range between EUR 2.2 million and EUR 2.4 million per month (previously: EUR 2.5 million and EUR 2.8 million). Based on the updated planning and the existing financing commitment of the main shareholder dievini the company's financing is still secured until mid-2022.

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 7 October 2021”.

Key figures for the Heidelberg Pharma Group

In EUR thsd.	9M 2021 [1] EUR thsd.	9M 2020 [1] EUR thsd.
Earnings		
Sales revenue	1,126	7,488
Other income	426	787
Operating expenses	(20,069)	(20,736)
of which research and development costs	(14,096)	(13,546)
Operating result	(18,517)	(12,461)
Earnings before tax	(18,851)	(12,468)
Net loss for the period	(18,851)	(12,468)
Basic earnings per share in EUR	(0.59)	(0.42)
Balance sheet as of the end of the period		
Total assets	28,547	25,398
Cash and cash equivalents	13,598	9,226
Equity	13,747	18,604
Equity ratio[2] in %	48.2	73.3
Cash flow statement		
Cash flow from operating activities	(19,399)	(13,958)
Cash flow from investing activities	(1,175)	(973)
Cash flow from financing activities	29,190	14,283
Employees (number)		
Employees as of the end of the period[3]	92	81
Full-time equivalents as of the end of the period[3]	85	70

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.

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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. Its proprietary technology platform is being applied to develop the Company's proprietary therapeutic ATACs as well as in third-party collaborations. The proprietary lead candidate HDP-101 is a BCMA ATAC for multiple myeloma that is about to enter clinical development. Both HDP-102, a CD37 ATAC to treat non-Hodgkin lymphoma, and HDP-103, a PSMA ATAC to treat metastatic castration-resistant prostate cancer, are in preclinical testing.

Heidelberg Pharma AG is listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol HPHA. More information is available at www.heidelberg-pharma.com.