Heidelberg Pharma AG: Interim Management Statement on the First Nine Months of 2023

- HDP-101 clinical trial in Europe and US continues with adjusted protocol and larger number of study sites in Europe; fifth patient cohort initiated at 100 µg/kg dosing
- Patient from third cohort continues to be dosed and shows stable disease
- Divestment of minority stake in Emergence leads to higher other income and additional cash inflows
- Sales and other income above plan, other financials in line with plan

Ladenburg, Germany, 12 October 2023 – Heidelberg Pharma AG (FSE: HPHA) reported today on its course of business as well as on the Group's financial figures for the first nine months of fiscal year 2023 (1 December 2022 – 31 August 2023).

Dr. Jan Schmidt-Brand, CEO of Heidelberg Pharma AG, commented: “After a turbulent start to the year at former partner Magenta and their strategic realignment, we were able to clarify issues regarding the ATAC technology platform and continue our study with HDP-101. Based on the experience at Magenta, additional safety measures were included in the study protocol. The good safety profile to date and the increase in the number of study sites have led to an accelerated recruitment of study participants, so that the fourth dose cohort has now been completed. The Safety Review Committee confirmed in early September that HDP-101 is safe and well tolerated at 80 ug/kg. The Committee recommended to escalate the dose for the next cohort.

Our financials performed in line with plan, with an exceptional income recorded. As part of the acquisition by an US pharmaceutical company, we sold our minority stake in Emergence Therapeutics. As a result of the transaction, we recorded a cash inflow of USD 7.4 million, which we mainly used for a partial loan repayment of EUR 5 million to the shareholder loan extended by dievini."

Important operational developments and achievements

- **HDP-101 development program:** HDP-101, an Antibody Targeted Amanitin Conjugate directed against the antigen BCMA, is being tested in a Phase I/IIa open-label, multicenter study for the treatment of relapsed or refractory multiple myeloma, a cancer of the bone marrow. The first part of the study is a Phase I dose escalation study to find the safe and optimal dosing of HDP-101 for the Phase IIa portion of the study. The first four patient cohorts and dose levels were completed with no evidence of dose limiting toxicities. Heidelberg Pharma had added additional safety measures to the clinical trial as a precautionary measure following the events at former partner Magenta. In order to accelerate the recruitment of the study, Heidelberg Pharma opened additional study centers, mainly in Poland and Hungary. This enabled rapid patient recruitment and the opening of the fourth cohort as early as June 2023, following adjustment of the study's protocol and receipt of all regulatory approvals. Further information can be found under "Events after the end of the reporting period".

  In the Phase IIa dose expansion portion, the recommended dose of HDP-101 will be administered to at least 30 patients. The primary objective of this second phase of the study is to provide an initial assessment of the anti-tumor activity of HDP-101 and to further evaluate the safety of the therapy.

- **Developments at partner Magenta:** Magenta reported earlier this year that a serious adverse event of grade 5 occurred that deemed to be possibly related to MGTA-117. For safety reasons, Magenta subsequently paused dosing in the clinical trial until further notice. Shortly thereafter, Magenta announced a change in strategy combined with the discontinuation of all current development programs and supply contracts. This resulted in Heidelberg Pharma losing sales revenue in the low single-digit million range for the financial year 2023. In April 2023, Heidelberg Pharma signed a termination agreement with Magenta under which all licensed ATAC rights and some MGTA patents were taken over by Heidelberg Pharma.

- **New preclinical data from ATAC technology platform presented at AACR Annual Meeting 2023:** At the American Association for Cancer Research (AACR) 2023 Annual Meeting in April, Heidelberg Pharma presented preclinical results from its ATAC technology. The first poster showed that in preclinical models, subcutaneous dosing of the ATACs used resulted in prolonged half-life and lower maximum serum levels compared with intravenous administration. This resulted in better tolerability while maintaining antitumor efficacy. Based on these preclinical models, subcutaneous administration could be a promising route of administration for ATACs in humans as well. A corresponding patent application for subcutaneous administration of ATACs has been filed by the company.

  A second poster presented preclinical data on ATACs targeting the protein GCC (Guanylyl Cyclase C). GCC is overexpressed in many gastrointestinal tumors, particularly in colorectal, esophageal, gastric and pancreatic cancers. In preclinical models, ATACs targeting GCC demonstrated high antitumor activity and inhibit tumor growth in preclinical models even at low concentrations after single or multiple dose treatment. These ATACs also showed a favorable safety profile and good tolerability and may represent a promising new therapeutic option against colorectal cancer. The posters are available on the website.[1]

- **New CFO appointed:** Walter Miller was appointed to the Executive Board with effect from 1 May 2023 and is responsible for the financial area as Chief Financial Officer. Dr. Jan Schmidt-Brand, who has served in a dual function since 2014, remains Spokesman of the Executive Board/CEO and handed over his duties as CFO to him.

  Walter Miller holds a degree in business administration and has many years of experience in corporate finance, M&A, strategic controlling as well as accounting and corporate development. He was most recently CFO of Optimapharm Group, headquartered in Zagreb, Croatia, a clinical research organisation (CRO), where he was responsible for finance, M&A and administration. Prior to that, Mr Miller was CFO at Mologen AG, Berlin and CFO at Nuvisan Group, headquartered in Neu-Ulm, Germany, and spent more than ten years in senior financial positions at Santhera Pharmaceuticals, Pratteln, Switzerland.

- **Minority interest in Emergence sold:** At the end of June, Heidelberg Pharma sold its minority stake in Emergence Therapeutics AG, Duisburg, (Emergence). The pharmaceutical company Eli Lilly and Company acquired all shares in Emergence. As a result of the transaction, Heidelberg Pharma received USD 7.4 million (EUR 6.8 million), the full amount of which was recognized in profit or loss. The cash was mainly used for a loan repayment of EUR 5 million on the shareholder loan extended by dievini. If defined guarantees are fulfilled and depending on clinical and regulatory milestones further inflows of up to USD 5 million (EUR 4.6 million) are possible.

[1] https://heidelberg-pharma.com/de/forschung-entwicklung/wissenschaftliche-poster

- **Partner Takeda reaches development milestone:** Partner Takeda reached a development milestone in August for starting a GLP (Good Laboratory Practice) toxicology study for an Antibody Targeted Amanitin Conjugate. Upon achievement of the milestone, Heidelberg Pharma received a milestone payment. The payment was already budgeted for in Heidelberg Pharma's financial forecast for financial year 2023.

  Takeda exclusively licensed the worldwide development and commercialization rights for the use of the ATAC technology with an antibody directed against a defined target and the resulting product candidates in 2022.

- **Expansion of ADC technology into a "toolbox":** Heidelberg Pharma is expanding its own ADC technology to include suitable active substances in order to develop the best possible ADCs for further targets and areas of application. This includes an ADC technology for a topoisomerase inhibitor, immunostimulatory agents and other new approaches. The first ADC candidate HDP-201 with a new payload is in the early development phase.

Update on partner programs outside ATAC technology

- **Progress at partner Telix:** TLX250-CDx, the Zirconium-89 radiolabeled antibody girentuximab (^{89}Zr-DFO-girentuximab), is a diagnostic imaging agent. It was developed at Heidelberg Pharma AG up to a first Phase III trial and out-licensed to the Australian company Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix) in 2017. Accumulation of this antibody in tumor tissue can be visualized by positron emission tomography (PET) scans. This could fundamentally change therapy planning for renal cancer patients and avoid potentially unnecessary surgery.

  TLX250-CDx was tested in a phase III trial (ZIRCON) with 300 patients for imaging diagnosis of kidney cancer using PET. In November 2022, Telix reported positive data and plans to submit applications for marketing approval as a diagnostic in ccRCC with the FDA and other regulatory authorities worldwide. According to Telix the submission of the application is planned for the fourth quarter of 2023. Potential future benefits could include active surveillance, surgical staging and treatment response monitoring for renal cancer.

  Telix is conducting further clinical trials to expand the indication. The first patient in the Phase II STARBURST study with TLX250-CDx was dosed in June. STARBURST is a prospective, open-label Phase II "basket" study to investigate CAIX expression in patients across a broad range of solid tumors for potential diagnostic and therapeutic use. Tumor types being studied include breast, cervical, colorectal, gastric, and esophageal cancers.[2]

  In parallel, Telix is preparing to launch an Expanded Access Program (EAP) in the US to provide patients with pre-approval access to TLX250-CDx. In Europe, the first study sites have been enrolled in the Early Access Program.[3]

  In addition to the development of the diagnostic antibody, Telix also plans to develop a therapeutic radioimmune conjugate (^{177}Lu-DOTA-girentuximab, TLX250) program based on the lutetium-177-labeled girentuximab antibody. TLX250 will be tested in two Phase II combination studies (STARLITE 1 and 2) with immunotherapies. The first patients will be treated with TLX250 in combination with the anti-PD-1 immunotherapy Opdivo® in the STARLITE 2 trial at Memorial Sloan Kettering Cancer Center in New York. The STARLITE 1 study is testing TLX250 in combination with Cabometyx® and Opdivo® for the treatment of advanced renal cancer.

[2] https://telixpharma.com/news-views/first-patient-dosed-in-phase-ii-starburst-study-of-tlx250-cdx-exploring-indication-expansion/
[3] https://telixpharma.com/wp-content/uploads/2023/08/20230823-H1-2023-Results-Deck-vFINAL.pdf

Preparations are currently underway to enroll patients in the trial. In collaboration with Merck KGaA, Telix is also testing TLX250 in an open-label, single-arm, multicenter Phase Ib dose escalation and dose expansion study in combination with the DNA protein kinase inhibitor peposertib, a DNA damage response inhibitor (DDRi). The first patient in this STARSTRUCK study was dosed in July.

- **Progress at partner RedHill**: Redhill Biopharma Ltd (RedHill; NASDAQ: RDHL) is developing the out-licensed serine protease inhibitor upamostat (RHB-107 at RedHill) for the treatment of COVID-19, among other diseases. RHB-107 has shown both antiviral and potential tissue-protective activity, with RHB-107 strongly inhibiting SARS-CoV-2 replication in a preclinical human bronchial tissue study.

  At the end of July, the company announced that RHB-107 was included in the US government-supported “Austere environments Consortium for Enhanced Sepsis Outcomes” (ACESO) multinational PROTECT platform trial for early outpatient treatment of COVID-19, to be conducted in the US, Thailand, Ivory Coast and South Africa. In addition, it was announced that the Phase II study, predominantly funded by the US Government Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), has received FDA clearance to start and is estimated to be completed by end of 2024.

Events after the end of the reporting period

- **Phase I/IIa clinical update with HDP-101:** After the end of the reporting period, Heidelberg Pharma announced that recruitment of patients for the fifth patient cohort at a dose of 100 µg/kg has started. The evaluation of the patient data of the fourth cohort by the Safety Review Committee (SRC) showed that no dose-limiting toxicities have occurred to date. The first four dose levels have shown to be safe and well tolerated. So far 12 patients have been treated in the trial.
- **Study participant with "stable disease":** A study participant who received the first dose (60 µg/kg) of HDP-101 in January 2023 has shown no progression of the disease for nine months (stable disease). The patient receives monotherapy with HDP-101 and was treated so far with twelve doses. With the approval of the fourth cohort by the Safety Review Committee this patient is now being offered a higher dose of 80 µg/kg.

Results of operations, financial position and net assets

The Heidelberg Pharma Group, consisting of Heidelberg Pharma AG and its subsidiary Heidelberg Pharma Research GmbH reports consolidated figures as at the balance sheet date. The reporting period referred to below relates to the period from 1 December 2022 to 31 August 2023 (9M 2023).

In the first nine months of the 2023 business year, the Group generated sales revenues and income totaling EUR 13.9 million (previous year: EUR 16.8 million), which is above plan. The **sales revenues** included in this figure amounted to EUR 6.6 million, a significant decrease compared to the previous year's total of EUR 15.7 million, which was exceptionally high caused by a payment for a license taken by the partner Huadong. Due to the unplanned sale of the Emergence shares, **other income** increased to EUR 7.3 million and was thus significantly above the previous year's level of EUR 1.1 million.

Operating expenses, including depreciation, amounted to EUR 30.0 million in the reporting period (previous year: EUR 27.6 million) and break down as follows: **Cost of sales** decreased significantly to EUR 3.1 million (previous year: EUR 5.2 million) and correspond to 10% of total costs. **Research and development costs** of EUR 22.1 million increased compared to the same period last year (EUR 17.7 million) due to the ongoing clinical trial with HDP-101 and the expansion of cost-intensive

external manufacturing for the ATAC projects. R&D costs continue to be the largest cost block, accounting for 74% of operating expenses. **Administrative costs**, which include the costs of holding activities and the stock exchange listing, were lower at EUR 3.6 million compared to the same period last year (EUR 4.1 million), which showed increased legal and consulting costs due to the Huadong transaction. **Other expenses** for business development, marketing and commercial market supply activities, which mainly include personnel and travel expenses, increased year-on-year to EUR 1.2 million (previous year EUR 0.6 million) and represented 4% of operating expenses.

The **financial result**, which mainly consists of net interest income amounts to EUR 0.5 million (previous year: EUR -0.6 million).

The **net loss** for the first nine months of the financial year increased to EUR 15.8 million compared to the previous year's figure of EUR 13.2 million. The increase is due to lower sales revenues and higher expenses. **Earnings per share** improved from EUR 0.39 in the previous year to EUR 0.34, considering the significantly higher number of shares.

Cash amounted to EUR 50.7 million at the end of the third quarter (30 November 2022: EUR 81.3 million; 31 August 2022: EUR 10.5 million). In the first nine months of the financial year, Heidelberg Pharma had an average cash outflow of EUR 2.3 million per month (previous year: EUR 0.1 million), excluding the loan repayment of EUR 10 million. If the one-time inflows from the sale of the Emergence investment are excluded, the monthly cash consumption without financing activities amounts to EUR 3.0 million.

Total assets as of 31 August 2023 amounted to EUR 74.3 million and were thus below the value of the comparative reporting date of 30 November 2022 (EUR 100.6 million). **Equity** (EUR 51.5 million) also decreased as a result of the loss for the period compared to the end of the 2022 financial year (EUR 66.6 million).

Financial outlook for 2023

For the 2023 financial year, the Executive Board planned revenues and other income totaling between EUR 7.0 million and EUR 10.0 million (2022: EUR 19.9 million). Due to the emergence transaction, other income could be increased significantly; accordingly, the annual planning will be exceeded.

Operating expenses will develop in line with the planning between EUR 37.0 million and EUR 41.0 million and thus at a comparable level to the 2022 financial year (EUR 37.0 million). For 2023, an operating result (EBIT) of between EUR -28.5 million and EUR -32.5 million is expected (2022: EUR -17.2 million), which should, however, improve due to the volume of the Emergence transaction.

Cash consumption for the business operations of the Heidelberg Pharma Group will also increase in line with the operating business and range between EUR 32.5 million and EUR 36.5 million. This corresponds to an average cash consumption per month of EUR 2.7 million to EUR 3.1 million (2022: EUR 0.7 million).

Based on the current planning, the Group is financed until mid-2025.

The complete set of figures for the interim financial statements is available at http://www.heidelberg-pharma.com/ "Press & Investors > Announcements and Reports > Financial Reports > Interim announcement of 12 October 2023. A conference call on this interim announcement will not be offered.

Key figures for the Heidelberg Pharma Group

In EUR thsd.	9M 2023 [1] EUR thsd.	9M 2022 [1] EUR thsd.
Earnings		
Sales revenue	6,635	15,695
Other income	7,259	1,149
Operating expenses	(29,985)	(27,611)
of which research and development costs	(22,065)	(17,676)
Operating result	(16,091)	(10,767)
Earnings before tax	(15,561)	(11,347)
Net loss for the period	(15,838)	(13,224)
Basic earnings per share in EUR	(0.34)	(0.39)
Balance sheet as of the end of the period		
Total assets	74,328	29,805
Cash	50,675	10,523
Equity	51,488	(6,073)
Equity ratio[2] in %	69.3	(20.4)
Cash flow statement		
Cash flow from operating activities	(26,494)	(1,201)
Cash flow from investing activities	5,871	(282)
Cash flow from financing activities	(10,024)	4,932
Employees (number)		
Employees as of the end of the period[3]	111	104
Full-time equivalents as of the end of the period[3]	101	97

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 is an oncology specialist and the first company to develop the toxin Amanitin into cancer therapies using its proprietary ATAC technology and to advance the biological mode of action of the toxin as a novel therapeutic principle. The proprietary technology platform is being applied to develop the company's own therapeutic ATACs as well as in third-party collaborations.

The proprietary lead candidate HDP-101 is a BCMA-ATAC in clinical development for multiple myeloma. Further ATAC candidates are being developed against different targets such as CD37, PSMA or GCC each in the indications non-Hodgkin's lymphoma, metastatic castration-resistant prostate cancer or gastrointestinal tumors such as colorectal cancer.

Heidelberg Pharma AG is based in Ladenburg, Germany, and is listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol HPHA.

More information is available at http://www.heidelberg-pharma.com/