

## PRESS RELEASE

# Heidelberg Pharma Reports on First Half-Year 2023 and the Course of Business

- Clinical trial with HDP-101 continues with adjusted protocol and larger number of study sites in Europe
- Patient from 3<sup>rd</sup> cohort continues to be dosed and shows stable disease
- Partnership with Magenta terminated due to clinical events and strategy change at Magenta
- Walter Miller appointed Chief Financial Officer
- Financials in line with plan
- Divestment of minority stake in Emergence leads to higher cash inflows

**Ladenburg, Germany, 13 July 2023** - Heidelberg Pharma AG (FSE: HPHA) published today its financial report on the first six months of 2023 (1 December 2022 - 31 May 2023).

Dr. Jan Schmidt-Brand, CEO of Heidelberg Pharma AG, commented: "After a turbulent start to the first half of 2023, marked by the events at Magenta and the impact on us, we can now look back on very positive developments. We are very pleased to have received full regulatory approvals for the precautionary amendment of our study protocol and some study sites are already enrolling patients in the fourth cohort of the study with our ATAC candidate HDP-101. We are now focused on successful patient enrollment and further data analysis in the fourth quarter of 2023.

In May, we welcomed our new Chief Financial Officer, Walter Miller, to Heidelberg Pharma, and at the end of June, we announced an extraordinary cash inflow of USD 7 million from the sale of our company shares in ADC developer Emergence Therapeutics."

### Key events in the first six months of 2023

- **HDP-101 (BCMA-ATAC) program:** Heidelberg Pharma presented preliminary safety data from the clinical trial with HDP-101. The first three patient cohorts and dose levels were concluded and has so far been shown to be safe and well tolerated. Following completion of the third dose level, in March 2023, a data review was conducted by the Safety Review Committee (SRC). The SRC recommended to escalate the dose.

The safety review of study data does not indicate that the side effects experienced at Magenta Therapeutics, Cambridge, MA, USA, (Magenta), could be a class effect of all Amanitin-based ADCs. Due to the events at Magenta, further safety measures were implemented for the patients as an extra precaution.

The BCMA Antibody Amanitin Candidate HDP-101 is being evaluated in a Phase I/IIa clinical trial for treatment of relapsed or refractory multiple myeloma, a cancer affecting bone marrow.

- **Partnership with Binghamton University:** In December 2022, Heidelberg Pharma Research has entered into a research and exclusive option agreement with Binghamton University, State University of New York, Binghamton, NY, USA, related to a novel and proprietary immunostimulatory technology platform. The platform includes potent novel immunostimulatory compounds and Antibody Drug Conjugate (ADC) technology for the specific delivery of these compounds to tumor tissue. These immunostimulatory agents

are synergistic with cytotoxic agents, including ADCs generated by Heidelberg Pharma's ATAC technology.

- **Development at the partner Magenta:** Magenta announced in January 2023 that in the third dose level of the MGTA-117 clinical trial, a grade 5 serious adverse event occurred that deemed to be possibly related to MGTA-117. For safety reasons, Magenta subsequently paused dosing in the clinical trial until further notice and announced shortly thereafter, following an internal review, that further development of all programs including the ATACs would be halted. At the end of February 2023, the Amanitin linker supply contract was terminated by Magenta, followed by the signing of a termination agreement in April 2023. This resulted in Heidelberg Pharma losing sales revenue, which is reflected in the current guidance.
- **New preclinical data from the ATAC technology platform presented at the AACR 2023 Annual Meeting:** At the American Association for Cancer Research (AACR) 2023 Annual Meeting in April, Heidelberg Pharma presented preclinical data of 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. The second poster included preclinical data on ATACs targeting the protein GCC, including the candidate HDP-104. ATACs targeting GCC demonstrated high antitumor activity and inhibit tumor growth in preclinical models even at low concentrations.
- **Chief Financial Officer appointed:** Walter Miller has been appointed to the board effective 1<sup>st</sup> May 2023, and is responsible for the finance area as Chief Financial Officer. Dr. Jan Schmidt-Brand, who has served in a dual role since 2014, will remain Spokesman of the Management Board/CEO and handed over his duties as CFO to Walter Miller.
- **Encouraging progress on out-licensed clinical project TLX250-CDx:** Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix) reported positive data in November 2022 and plans to submit applications for marketing approval as a diagnostic in clear cell renal cell carcinoma (ccRCC) to the FDA and other regulatory authorities worldwide. Furthermore, Telix is also preparing the launch of an Expanded Access Program (EAP) to provide patients with pre-approval access to TLX250-CDx.

As part of its planned indication expansion, Telix announced in June that the first patient in the Phase II STARBURST study has been dosed with TLX250-CDx. STARBURST is a prospective, open-label Phase II "basket" study designed to evaluate CAIX expression in patients across a broad range of solid tumors for potential diagnostic and therapeutic use.

#### Events after the reporting period

- **Precautionary adjustment of the HDP-101 study plan and continuation of patient recruitment:** Adaptations to the study protocol have been made in recent months, and initial study sites are continuing patient enrollment with the fourth cohort after receiving all regulatory approvals and the approval of the relevant ethics committees. Several centers are enrolling patients in the study since June. One of the study participants from the third cohort has so far shown no progression of the disease (stable disease). He has now been on monotherapy of HDP-101 for over six months and is in good condition. The patient has since been treated with seven doses of HDP-101. The data are not yet conclusive, but it is very encouraging for the patient with multiple myeloma and limited treatment options that he has been able to benefit from the therapy so far.

- **Selling of minority shareholding in Emergence:** After the end of the reporting period, Heidelberg Pharma sold its minority shareholding in Emergence Therapeutics AG, Duisburg, Germany, (Emergence) at the end of June. The US pharma company Eli Lilly and Company acquired all outstanding shares in Emergence. As a result of the transaction, Heidelberg Pharma expects a cash inflow in 2023 of about USD 7 million (EUR 6.4 million), which will mainly be used for a loan repayment of € 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.

### Financial results for the first six months of fiscal year 2023

The Heidelberg Pharma Group (Heidelberg Pharma) – comprising Heidelberg Pharma AG and its subsidiary Heidelberg Pharma Research GmbH – reports consolidated figures.

In the first six months of the 2023 fiscal year, the Heidelberg Pharma Group **generated sales revenue and income** totaling EUR 4.7 million, thus significantly decreasing the previous year's total of EUR 12.2 million, which was exceptionally high due to a payment for a license taken from the partner Huadong.

**Sales revenue** totaling EUR 4.4 million comprises the group-wide collaboration agreements for ATAC technology (EUR 4.3 million) and the service business of Heidelberg Pharma Research (EUR 0.1 million).

**Other income** of EUR 0.3 million was at the previous year's figure and comprised income from the reversal of unused accrued liabilities (EUR 0.2 million) and other items (EUR 0.1 million).

**Operating expenses**, including depreciation, amortization and impairment, amounted to EUR 20.7 million in the reporting period (previous year: EUR 18.5 million).

The **net loss** posted by the Heidelberg Pharma Group for the first six months of 2023 came to EUR 16.0 million (previous year: EUR 8.6 million). The significant increase is as planned and due to substantially lower income and higher expenses. **Earnings per share** amounted to EUR -0.34 and, taking into account the higher number of shares, developed positively compared with the previous year (EUR -0.42).

At the end of the reporting period, Heidelberg Pharma had **cash** in the amount of EUR 57.4 million and were thus below the year-end figure of EUR 81.3 million and above the previous year's half-year figure as of 31 May 2022 (EUR 18.0 million).

Excluding the financing effects, Heidelberg Pharma's had an average **cash requirement** of EUR 3.2 million per month, compared with an average cash inflow of EUR 1.2 million per month in the same reporting period of the previous year.

**Total assets** as of 31 May 2023 amounted to EUR 78.0 million, up from EUR 100.6 million as of the 30 November 2022 reporting date. **Equity** as of the end of the reporting period was EUR 50.9 million (30 November 2022: EUR 66.6 million). This corresponded to an equity ratio of 65.3% (30 November 2022: 66.3%).

The full-year financial guidance issued on 24 March 2023 for the Heidelberg Pharma Group is confirmed at this time. Sales revenue and other income are in line with our planning as of the first six months of the fiscal year 2023. The majority of income will be generated in the second half of the year as other income will increase significantly due the Emergence transaction. Given that expenses might rise higher than the forecast, the operating result is

expected to be unchanged as the higher income may be offset by higher expenses for new study centers in the trial with HDP-101.

<b>Financial outlook</b>	<b>H1 2023 EUR million</b>	<b>Actual 2022 EUR million</b>	<b>2023 Plan EUR million</b>
Sales revenue and other income	4.7	19.9	7.0 – 10.0
Operating expenses	(20.7)	(37.0)	37.0 – 41.0
Operating result	(16.0)	(17.2)	(28.5) – (32.5)
Total funding requirement for operations and capex <sup>1</sup>	(18.9)	(8.9)	32.5 – 36.5
Funds required per month <sup>1</sup>	(3.2)	(0.7)	2.7 – 3.1

<sup>1</sup> Not including any corporate actions

## Invitation to the analyst and press conference call

On Thursday, 13 July 2023, Heidelberg Pharma will hold a conference call for media, analysts, and investors in English at 3:00 pm CEST/9:00 am EDT. Please register at least 10 minutes in advance using the following link:

[https://us06web.zoom.us/webinar/register/WN\\_dQGJt0zKSv-GZCDY1la-xw](https://us06web.zoom.us/webinar/register/WN_dQGJt0zKSv-GZCDY1la-xw)

You will receive an e-mail with your registration confirmation, which contains the link to participate in the audio webcast as well as dial-in numbers for participation by phone. Please note that asking oral or written questions is only possible for online participants.

## Key figures for the Heidelberg Pharma Group

In EUR thsd.	H1 2023 <sup>1</sup> EUR thsd.	H1 2022 <sup>1</sup> EUR thsd.
<b>Earnings</b>		
Sales revenue	4,391	11,935
Other income	277	235
Operating expenses	(20,704)	(18,517)
of which research and development costs	(14,772)	(11,839)
Operating result	(16,036)	(6,348)
Earnings before tax	(15,774)	(6,736)
Net loss for the period	(15,951)	(8,605)
Earnings per share in EUR	(0.34)	(0.25)
<b>Balance sheet as of the end of the period</b>		
Total assets	77,965	33,937
Cash and cash equivalents	57,379	18,017
Equity	50,891	(1,576)
Equity ratio <sup>2</sup> in %	65.3	(4.6)
<b>Cash flow statement</b>		
Cash flow from operating activities	(18,153)	7,063
Cash flow from investing activities	(788)	(135)
Cash flow from financing activities	(5,008)	4,953
<b>Employees (number)</b>		
Employees as of the end of the period <sup>3</sup>	113	102
Full-time equivalents as of the end of the period <sup>3</sup>	103	93

<sup>1</sup> The reporting period begins on 1 December and ends on 31 May

<sup>2</sup> Equity / total assets

<sup>3</sup> Including members of the Executive Management Board

Rounding of exact figures may result in differences.

The full half-yearly financial report including the consolidated financial statements prepared in accordance with International Financial Reporting Standards (IFRS) was published at <http://heidelberg-pharma.com/en/press-and-investors/announcements/financial-reports>.

**Contact**

Heidelberg Pharma AG  
Corporate Communications  
Sylvia Wimmer  
Gregor-Mendel-Str. 22, 68526 Ladenburg  
Tel.: +49 89 41 31 3829  
Email: [investors@hdpharma.com](mailto:investors@hdpharma.com)

**IR/PR support**

MC Services AG  
Katja Arnold (CIRO)  
Managing Director & Partner  
Tel.: +49 89 210 22840  
Email: [katja.arnold@mc-services.eu](mailto:katja.arnold@mc-services.eu)

**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 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/>.

ATAC<sup>®</sup> is a registered EU trademark of Heidelberg Pharma Research GmbH.

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