

## PRESS RELEASE

### Heidelberg Pharma Reports on First Half-Year 2021

- HDP-101: Application to initiate clinical trial green-lighted by the FDA in February 2021; Clinical trial centers prepare to receive their first patient; Clinical Trial Application submitted to the Paul Ehrlich Institute in Germany
- New preclinical data on the immunomodulatory potential of Antibody Targeted Amanitin Conjugates presented at the AACR 2021 Annual Meeting
- Various financing measures secure liquidity and development program until mid-2022
- Operating result in line with planning; progress made in development program leads to increased research and development costs
- Public conference call to be held on 8 July 2021 at 3:00 pm CEST

**Ladenburg, Germany, 8 July 2021** - Heidelberg Pharma AG (FSE: HPHA) today published its financial report on the first six months of 2021 (1 December 2020 - 31 May 2021).

Dr. Jan Schmidt-Brand, CEO and CFO of Heidelberg Pharma AG, commented: "FDA approval of the Phase I trial with HDP-101 was an important milestone for us as we move our first Antibody Targeted Amanitin Conjugate into clinical development. We were also able to raise EUR 20 million in a private placement to further advance our three proprietary ATAC programs. These are the next important steps for HDP-101: Approval of the study protocol for Germany by the Paul Ehrlich Institute and start of the trial in the US.

Before we can commence the study in the US, we need to fulfill specific – and previously unplanned – requirements for the clinical sites regarding the equipment used in the preparation of the infusion of HDP-101. Therefore, we now expect the trial in the US to start in the third quarter 2021.

Our half-year financials in terms of sales revenue, costs and cash use are at the lower end of expectations. However, a significant portion of sales revenue is not budgeted until the fourth quarter and costs will also increase as projects progress. We therefore maintain our guidance at this time."

#### Key events in the first six months of 2021

- **HDP-101 program in multiple myeloma is progressing:** The study protocol for HDP-101, a BCMA Antibody Targeted Amanitin Conjugate for treating multiple myeloma, was submitted to the FDA early this year. On 4 February 2021, the FDA gave clearance (IND) to begin the Phase I/IIa trial with HDP-101. The Clinical Trial Application was submitted to the German authority, the Paul Ehrlich Institute, in March 2021, with the decision expected to be made shortly. Training of study centers in the US has begun, and further logistical and organizational preparations are underway.
- **Results on HER2-ATAC for targeted immunotherapy of triple-negative breast cancer published in *Science Translational Medicine*:** In February, Heidelberg Pharma published new study results on Antibody Targeted Amanitin Conjugate (ATAC) technology in the journal *Science Translational Medicine* in a joint report by a research group from the School of Medicine, Indiana University, Indianapolis, IN, USA. ATrastuzumab-ATAC, which consists of the antibody Trastuzumab targeting HER2 and

the toxin Amanitin, demonstrated extraordinary efficacy in the treatment of certain triple-negative breast cancers (TNBC).

- **Shareholder loan and financing commitment by main shareholder dievini:** In late 2020, the Group's main shareholder dievini Hopp BioTech holding GmbH & Co. KG, Walldorf (dievini) committed to providing a loan in the amount of EUR 15 million, which is to be drawn down in several tranches in 2021. Heidelberg Pharma AG drew down two tranches of EUR 5 million each in the first half of 2021. On 19 March 2021, dievini made a further financing commitment for up to EUR 30 million to the Company, part of which was implemented by way of a private placement after the end of the reporting period (see report on post-balance sheet date events).
- **Heidelberg Pharma expands its management team:** At the beginning of March, Dr. András Strassz was appointed Chief Medical Officer and Dr. Mathias Locher was appointed Chief Development Officer, complementing the management team with many years of experience in clinical drug development.
- **New preclinical data from the ATAC technology platform presented at the AACR 2021 Annual Meeting:** 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 and HDP-103 and, in another poster presentation, data on synergistic effects of ATACs with checkpoint indicators.
- **Magenta, licensing partner for ATAC technology,** currently prepares the first clinical study with MGTA-117. The submission of the IND is planned for mid-year.
- **Out-licensed clinical projects** are on track at partners. RedHill has initiated a Phase II/III trial of RHB-107 (upamostat) with COVID-19 non-hospitalized patients in the US in early 2021. The partner Telix successfully completed the Phase I component of a Phase I/II study in Japan in mid-April evaluating TLX250-CDx for renal cancer imaging. Recruitment for the Phase III ZIRCON trial is expected to be completed later this year. Telix recently commenced a Phase I study with TLX250-CDx to explore an indication expansion to other cancers such as bladder cancer.

#### Report on post-balance sheet date events

- **Successful implementation of a corporate action:** On 15 June 2021, a capital increase was implemented in connection with a private placement, generating gross issue proceeds of approximately EUR 20 million. Heidelberg Pharma AG issued 3,106,637 new shares from authorized capital, which corresponded to just under 10% of share capital. The new shares were allocated to new institutional investors specializing in biotechnology, including Polar Capital Biotech Investment Fund and Invus. 1,943,565 shares were placed with DH-LT-Investments GmbH, St. Leon-Rot, an investment company owned by Mr. Dietmar Hopp, as part of the financing commitment made in March.
- **Extension of the research agreement with Takeda:** Heidelberg Pharma's partner Takeda extended its option agreement in June 2021 for a further 18 months until the end of 2022 and will conduct preclinical testing of the ATAC technology on a new target molecule. In return, Heidelberg Pharma will receive payment for technology access.

## Financial results for the first six months of fiscal year 2021

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 2021 fiscal year, the Heidelberg Pharma Group generated **sales revenue and income** totaling EUR 1.1 million, thus falling short of the prior-year figure of EUR 3.8 million.

**Sales revenue** totaling EUR 0.8 million comprises the collaboration agreements for Heidelberg Pharma Research's ATAC technology (EUR 0.6 million) and from its service business (EUR 0.2 million). Sales revenue in the prior-year quarter was boosted by revenue generated from supplying the Amanitin linker to partners. Due to the higher yields achieved in the last production campaigns and the higher delivery volumes resulting from this, demand for Amanitin linkers has been satisfied for the time being. A significant portion of sales revenue is not budgeted until the fourth quarter.

**Other income** of EUR 0.3 million was also lower than the previous year's figure of EUR 0.7 million and comprised income from the reversal of unused accrued liabilities (EUR 0.1 million), government grants (EUR 0.1 million) and other items (EUR 0.1 million).

**Operating expenses**, including depreciation, amortization and impairment, amounted to EUR 14.0 million in the reporting period and were, as planned, higher than in the previous year (EUR 13.2 million), due to the expansion of cost-intensive external manufacturing for all three ATAC projects and preparations for the HDP-101 clinical trial.

The **net loss** posted by the Heidelberg Pharma Group for the first six months of 2021 came to EUR 13.1 million (previous year: EUR 9.4 million). Loss per share was EUR 0.42, up from EUR 0.33 in the previous year.

Heidelberg Pharma had **cash and cash equivalents** of EUR 0.9 million as of 31 May 2021 (30 November 2020: EUR 5.0 million). Excluding the financing effects, Heidelberg Pharma had an average cash requirement of EUR 2.3 million per month in the first six months of the respective financial year (previous year: EUR 1.5 million).

**Total assets** as of 31 May 2021 amounted to EUR 15.7 million, down from EUR 19.6 million as of the 30 November 2020 reporting date. **Equity** as of the end of the reporting period was EUR -0.1 million (30 November 2020: EUR 12.9 million). This corresponded to an equity ratio of -0.5% (30 November 2020: 65.7%).

The Heidelberg Pharma Group confirms its full-year financial guidance issued on 25 March 2021. Heidelberg Pharma still plans to generate the majority of sales revenue in the second half of the year. However, like expenses and funds used, sales revenue has been at the lower end of expectations so far.

Financial outlook	Actual 2020 EUR million	2021 Plan EUR million
Sales revenue and other income	9.6	5.5 – 7.5
Operating expenses	27.9	36.0 – 40.0
Operating result	(18.3)	(30.0) – (34.0)
Total funding requirement	19.2	30.0 – 34.0 <sup>1</sup>
Funds required per month	1.6	2.5 – 2.8 <sup>1</sup>

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

## Key figures for the Heidelberg Pharma Group

In EUR thsd.	H1 2021 <sup>1</sup> EUR thsd.	H1 2020 <sup>1</sup> EUR thsd.
<b>Earnings</b>		
Sales revenue	818	3,120
Other income	264	637
Operating expenses	(14,001)	(13,173)
of which research and development costs	(10,111)	(8,703)
Operating result	(12,919)	(9,417)
Earnings before tax	(13,089)	(9,423)
Net loss for the period	(13,089)	(9,423)
Earnings per share in EUR	(0.42)	(0.33)
<b>Balance sheet as of the end of the period</b>		
Total assets	15,691	29,075
Cash and cash equivalents	930	15,129
Equity	(74)	21,530
Equity ratio <sup>2</sup> in %	(0.5)	74.1
<b>Cash flow statement</b>		
Cash flow from operating activities	(13,135)	(8,298)
Cash flow from investing activities	(872)	(733)
Cash flow from financing activities	9,959	14,289
<b>Employees (number)</b>		
Employees as of the end of the period <sup>3</sup>	94	78
Full-time equivalents as of the end of the period <sup>3</sup>	87	73

<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>.

### **Invitation to the conference call**

On 8 July 2021, Heidelberg Pharma will hold a public conference call for media, analysts and investors in English at 3:00 pm CEST. Please dial in five minutes before the conference call using the following dial-in numbers:

Berlin: +49 (0) 30 3001 90612

New York: +1 212 999 6659

Paris: +33 (0) 1 7037 7166

UK-Wide: +44 (0) 33 0551 0200

You will be welcomed by an operator who will ask for the password (Heidelberg Pharma) and take your name and company. The presentation for the conference (in English) will be available for download at [www.heidelberg-pharma.com](http://www.heidelberg-pharma.com) from 2:30 pm CEST.

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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. The 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 and will enter clinical development shortly. HDP-102, a CD37 ATAC for Non-Hodgkin's lymphoma and HDP-103, a PSMA ATAC for 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](http://www.heidelberg-pharma.com).

This communication contains certain forward-looking statements relating to the Company's business, which can be identified by the use of forward-looking terminology such as "estimates", "believes", "expects", "may", "will", "should", "future", "potential" or similar expressions or by a general discussion of the Company's strategy, plans or intentions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results of operations, financial condition, performance, achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Given these uncertainties, prospective investors and partners are cautioned not to place undue reliance on such forward-looking statements. We disclaim any obligation to update any such forward-looking statements to reflect future events or developments.