

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

- Application to initiate clinical trial of HDP-101 green-lighted by the FDA in February 2021
- Management team expanded
- New financing commitment for up to EUR 30 million obtained from main shareholder dievini
- New preclinical data from the ATAC technology platform presented at the AACR 2021 Annual Meeting

Ladenburg, Germany, 29 April 2021 - Heidelberg Pharma AG (FSE: HPHA) today reported on the first three months of fiscal year 2021 (1 December 2020 – 28 February 2021) and the Group's financial figures.

Dr. Jan Schmidt-Brand, CEO and CFO of Heidelberg Pharma AG, commented: "The FDA's approval of the study protocol for the Phase I/IIa trial of our ATAC candidate HDP-101 in the first quarter was an outstanding milestone for Heidelberg Pharma. We will start establishing the trial centers in the United States as soon as possible and plan to recruit the first patients in the second quarter of 2021. We submitted an application to the Paul-Ehrlich-Institut in March to conduct the clinical trial in Germany as well.

We also need to take appropriate financial measures to support the progress being made at an operating level and the upcoming start of clinical development of our first ATAC candidate, which is why we signed a EUR 15 million loan agreement with our main shareholder dievini back in mid-December. In March, we received a further financing commitment from dievini in the amount of up to EUR 30 million. We would like to thank dievini for the trust it has placed in us and for its excellent support. Our cash reach is now secured until mid-2022 and this will help us to expand our own pipeline and technology, which is attracting increasing interest from institutional investors and partners worldwide."

Important operational developments and achievements

- **HDP-101 (BCMA ATAC) development program:** At the beginning of the year, Heidelberg Pharma submitted the study protocol for HDP-101, a BCMA Antibody Targeted Amanitin Conjugate for treating multiple myeloma, to the US Food and Drug Administration (FDA). On 4 February 2021, the FDA gave clearance to begin the Phase I/IIa trial for HDP-101. Heidelberg Pharma also submitted the dossier to Germany's medical regulatory body, the Paul-Ehrlich-Institut, in March 2021. The trial centers in the United States will be activated as soon as possible to initiate the trial and, once Heidelberg Pharma gets the green light, a prompt start of the trial in Germany is planned as well. The first patients are set to be included in the course of the second quarter of 2021.
- **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, and scientists from Heidelberg Pharma. The Trastuzumab-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). The preclinical data from this exploratory study shows that the ATAC exhibits superior efficacy in treating aggressive tumors with a certain aggressive chromosomal change (17p deletion) compared to other ADCs and that it also has immunostimulatory potential. In the trial conducted, the Trastuzumab-ATAC induced an immunogenic cell death of the tumor cells, a type of cell death that elicits an immune response. Consequently, the ATAC could be effectively combined with immune checkpoint blockade therapy, as also demonstrated by data from the MD Anderson Cancer Center.

- **Shareholder loan and financing commitment by main shareholder dievini:** In December 2020, Heidelberg Pharma signed a loan agreement with subordination with its main shareholder dievini in the amount of EUR 15 million. The uncollateralized and indefinite loan bearing annual interest of 6% implements the financing commitment of 21 July 2020. Heidelberg Pharma AG drew down an initial tranche of EUR 5 million in the quarter just ended. A further tranche of EUR 5 million was drawn down in March 2021 after the reporting date.

In March 2021, the company received a further financing commitment from dievini in the amount of up to EUR 30 million. The details of the financing will be decided by the Executive Management Board and the Supervisory Board of Heidelberg Pharma with dievini at a later date. The financing commitment is intended to enable the continuation of business activities, without prejudice to potential alternative capital measures, in particular the implementation of the clinical phase I/IIa of HDP-101 and the further development of the candidates HDP-102 and HDP-103. With this additional commitment and based on current planning, the Company's cash reach is secured until mid-2022.

Events after the reporting period

- **Heidelberg Pharma expands its management team:** At the beginning of March, Dr. András Strassz, who had held the post of Senior Medical Officer in the company since April 2020, was appointed Chief Medical Officer, while Dr. Mathias Locher was named Chief Development Officer. Dr. Strassz has many years of experience in clinical development, particularly in oncology, and will build up this area at Heidelberg Pharma. Dr. Strassz joined Heidelberg Pharma from Affimed, where he had held the position of Medical Director. Prior to this, he had held roles in clinical development at companies like Sandoz and Amgen. Along with a doctorate in medicine, Dr. Strassz has an MBA from the University of Pécs, Hungary.

Dr. Mathias Locher has nearly 30 years of experience in drug development. He joins Heidelberg Pharma from Janssen (Pharmaceutical Companies of Johnson & Johnson), where he worked as Senior Director – External Innovation for J&J Innovation Centre, London. Prior to this, he had held executive positions at Covagen, Merck Serono, Micromet (now part of Amgen) and ASTA Medica. Dr. Locher has a PhD in biochemistry from the University of Tübingen.

- **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, 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 inhibitors. More information is available at <https://heidelberg-pharma.com/en/research-and-development/scientific-posters>.

- **Partner program updates:** The partner Telix announced in mid-April that the Phase I/II 'ZIRDAC-JP' clinical study of the renal cancer imaging product has reported results and met the study objectives, demonstrating safety and tolerability of TLX250-CDx (89Zr-girentuximab) in Japanese patients. The results showed no difference between Japanese and Caucasian patient populations for these endpoints as well as for pharmacology and dosing compared to previous studies. Based on these results, 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.

For the other partner projects by Magenta, Takeda, and RedHill, there are no significant changes compared to the information already published.

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 28 February 2021 (Q1 2021).

In the first three months of fiscal year 2021, the Group generated sales revenue and income totaling EUR 0.5 million (previous year: EUR 1.8 million). This figure includes **sales revenue** of EUR 0.4 million (previous year: EUR 1.5 million) generated by the ATAC technology (EUR 0.3 million) and the service business (EUR 0.1 million). In the same quarter of the previous year, sales were positively influenced by revenues from the supply of Amanitin linkers to partners. Due to the higher yields achieved in the last production campaigns and the associated higher delivery volumes, demand for Amanitin linker has been satisfied for the time being.

Other income amounted to EUR 0.1 million (previous year: EUR 0.3 million) and primarily consisted of government grants and the reversal of unutilized accrued liabilities and provisions.

Operating expenses including depreciation and amortization totaled EUR 6.7 million in the reporting period (previous year: EUR 6.3 million). **Cost of sales** amounted to EUR 1.1 million (previous year: EUR 1.5 million) and concern costs directly related to sales revenue. These showed a disproportionate development in the short period under review of the first fiscal quarter as a result of IFRS accounting policies and the fact that they also serve as a basis for sales revenue generated at a later time. **Research and development costs** rose by EUR 1.0 million year-on-year to EUR 4.9 million (previous year: EUR 3.9 million) as planned due to the expansion of cost-intensive external good manufacturing practice (GMP) production and preclinical and regulatory preparations for the clinical trial with HDP-101. At 72% of operating expenses, R&D was the largest cost item. **Administrative costs** decreased to EUR 0.7 million in the first quarter of fiscal year 2021 compared to the prior-year period (EUR 0.8 million). Among others, this figure includes holding company costs and costs related to the stock market listing. **Other expenses**, comprising the costs incurred for business development, marketing and commercial market supply, were EUR 0.1 million, the same as in the previous year.

The Heidelberg Pharma Group's **net loss** for the first three months of the fiscal year increased to EUR 6.3 million, as planned (previous year: EUR 4.6 million). Basic **earnings per share** based on the weighted average number of shares issued during the reporting period fell from EUR -0.16 in the previous year to EUR -0.20 in the reporting quarter as a result of the higher loss.

Total assets as of 28 February 2021 decreased to EUR 17.5 million compared to the 30 November 2020 reporting date (EUR 19.6 million) due to a decrease in cash and cash equivalents. At EUR 6.6 million, **equity** was also down compared to the end of fiscal year 2020

(EUR 12.9 million). This corresponds to an equity ratio of 37.8% (30 November 2020: 65.7%). No corporate actions were implemented during the reporting period. The share capital of Heidelberg Pharma AG therefore remained steady at EUR 31,061,872, divided into 31,061,872 no par value bearer shares.

Cash and cash equivalents as of the end of the quarter amounted to EUR 2.9 million (30 November 2020: EUR 5.0 million). This represents an average monthly cash outflow of EUR 2.36 million in the first quarter of the fiscal year (previous year: EUR 1.66 million) (not including the inflow from the loan of EUR 5 million).

Financial outlook for 2021

The Heidelberg Pharma Group confirms its full-year financial guidance issued on 25 March 2021. The Executive Management Board expects the Heidelberg Pharma Group to generate between EUR 5.5 million and EUR 7.5 million in sales revenue and other income (2020: EUR 9.6 million) for the 2021 fiscal year.

Based on current planning, operating expenses are expected to be in the range of EUR 36.0 million to EUR 40.0 million, higher than in the previous year (EUR 27.9 million). Earnings before interest and taxes (EBIT) for 2021 are expected to be between EUR -30.0 million and EUR -34.0 million (2020: EUR -18.3 million).

Heidelberg Pharma expects to require funds of EUR 30.0 million to EUR 34.0 million in 2021. Monthly cash use should be in the range of EUR 2.5 million to EUR 2.8 million. Based on current planning and factoring in the financing commitment made by dievini, the Company's financing is 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 on the first three months of 2021.

Key figures for the Heidelberg Pharma Group (unaudited)

In EUR thsd.	Q1 2021 ¹ EUR thsd.	Q1 2020 ¹ EUR thsd.
Earnings		
Sales revenue	370	1,498
Other income	91	267
Operating expenses	(6,745)	(6,333)
of which research and development costs	(4,864)	(3,879)
Operating result	(6,284)	(4,567)
Earnings before tax	(6,321)	(4,571)
Net loss for the period	(6,321)	(4,571)
Earnings per share in EUR (basic)	(0.20)	(0.16)
Balance sheet as of the end of the period		
Total assets	17,541	19,026
Cash and cash equivalents	2,915	4,903
Equity	6,628	11,899
Equity ratio ² in %	37.8	62.5
Cash flow statement		
Cash flow from operating activities	(6,601)	(4,636)
Cash flow from investing activities	(434)	(332)
Cash flow from financing activities	4,975	(24)
Employees (number)		
Employees as of the end of the period ³	89	77
Full-time equivalents as of the end of the period ³	82	72

¹ The reporting period begins on 1 December and ends on 29/28 February.

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 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 is listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol HPHA. More information is available at 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.