Heidelberg Pharma AG: Interim Management Statement on the First Three Months of 2022

- Start of clinical trial with HDP-101 in multiple myeloma
- Financing commitment of up to EUR 36 million obtained from main shareholder dievini
- Signing of a strategic partnership with Huadong Medicine with an overall volume of up to one billion US dollars
- Financials in line with planning still without taking into account the partnership with Huadong

Ladenburg, Germany, 28 April 2022 - Heidelberg Pharma AG (FSE: HPHA) today reported on the first three months of fiscal year 2022 (1 December 2021 – 28 February 2022) and the Group's financial figures.

Dr. Jan Schmidt-Brand, CEO and CFO of Heidelberg Pharma AG, commented: "The past few months have been busy and highly successful. In mid-February, the first patient was treated with HDP-101 in a dose escalation study in patients with multiple myeloma. We are pleased to have reached this important milestone and that the study is proceeding according to plan.

"In order to secure the financing of our steadily growing activities, our major shareholder dievini made a renewed financing commitment in February. At the time, this was intended to secure our funding needs until mid-2023, independent of potential transactions.

"At the end of February, we signed a groundbreaking strategic partnership with the Chinese company Huadong Medicine. This transaction comprises a license/option and commercialization agreement for Asia for four of our ATAC® projects including HDP-101. In addition, Huadong intends to invest up to EUR 105 million in Heidelberg Pharma and thus acquire up to 35% of shares outstanding. With Huadong, we have gained a strong pharmaceutical partner for the Asian region and are convinced that this partnership will accelerate our product development, expand our product portfolio, and positively influence our business development."

Important operational developments and achievements

- **HDP-101 (BCMA ATAC) development program:** Mid-February, the first patient was dosed in the Phase I/IIa study with HDP-101, an BCMA antibody-Amanitin conjugate. The open-label, multi-center study is evaluating HDP-101 for the treatment of relapsed or refractory multiple myeloma, a bone marrow cancer. The Phase I dose escalation part of the study is to determine an optimal and safe dose of HDP-101 for the Phase IIa part of the study. It is planned to treat up to 36 patients who will receive HDP-101 intravenously once every 3 weeks until disease progression, discontinuation at Investigator's discretion or patient withdrawal. During this part of the trial, tolerability of different dose levels will be evaluated. During the Phase IIa dose expansion part, the recommended dose of HDP-101 will then be administered to 30 patients. The primary objective of this second phase of the study is to assess an initial anti-tumor activity of HDP-101 along with further evaluation of the safety of the drug.
- **Financing commitment by main shareholder dievini:** In February 2022, the main shareholder dievini Hopp BioTech holding GmbH & Co. KG, Walldorf, Germany, (dievini) made a financing commitment of up to EUR 36 million. The funds pledged will be made available if and to the extent that this amount is not secured through alternative capital measures. This commitment replaces the not yet fully used financing commitment from March 2021.

- **Signing of licensing agreement and strategic partnership with Huadong:** Heidelberg Pharma and Huadong Medicine Co., Ltd., Hangzhou, China, (Huadong) announced at the end of February that the companies had entered a strategic partnership. This partnership includes a licensing agreement for the development and commercialization of the ATAC® candidates HDP-101 and HDP-103 in Asia with an upfront payment of USD 20 million (EUR 17.5 million) and milestone payments of up to USD 449 million (EUR 400 million), as well as tiered royalties ranging from single to low double-digit percentages for each candidate. Huadong also receives the exclusive option for the research candidates HDP-102 and HDP-104 for Asia with milestone payments in a total amount of up to USD 461 million (EUR 410 million). In addition, Huadong intends to make an equity investment in Heidelberg Pharma totaling EUR 105 million, which will represent 35% of total shares outstanding after the transaction. The investment consists of a capital increase with rights issue (up to EUR 80 million) and a share transfer from the pool of the main shareholder dievini. After the end of the reporting period, Huadong obtained the exemption from the duty to make an offer issued by the Federal Financial Supervisory Authority (BaFin) and received the certificate of no-objection to carry out the planned transaction from the Federal Ministry of Economic Affairs and Climate Action (BMWK).

Events after the reporting period

- **Milestone payment from partner Magenta received:** Partner Magenta Therapeutics, Cambridge, MA, USA, (Magenta; NASDAQ: MGTA) dosed the first patient with MGTA-117 in a Phase I/II study in March. The achievement of this milestone triggered a payment to Heidelberg Pharma. MGTA-117 is an Antibody Amanitin Conjugate based on Heidelberg Pharma's proprietary ATAC® technology and developed by Magenta. A dose escalation study will test the tolerability, pharmacokinetics, pharmacodynamics, and safety of MGTA-117 in patients with relapsed/refractory acute myeloid leukemia and myelodysplasia-excess blasts. According to a press release published in mid-April, Magenta believes - based on a preliminary review of the data from the trial - that the data suggest early signals of positive pharmacodynamic activity and that MGTA-117 has been well-tolerated.

- **New preclinical data from the ATAC® technology platform presented at the AACR 2022 Annual Meeting:** At the American Association for Cancer Research (AACR) 2022 Annual Meeting, Heidelberg Pharma presented preclinical data on its ATAC® technology. Data were shown on the synergy of ATACs® together with immune checkpoint inhibitors, as well as data indicating that repeated treatment with ATACs® in preclinical models results in better tolerability without compromising efficacy. More information is available at https://heidelberg-pharma.com/en/research-and-development/scientific-posters.

- **Partner program updates:** Partner Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix) announced in March that the Phase III trial of TLX250-CDx (ZIRCON) for renal cancer imaging in 35 study sites in Europe, Turkey, Australia, Canada, and the US is nearing completion, having reached the planned enrolment target of 252 patients. Recruitment into the study will continue for up to three additional months, with a data read out expected in the second half of 2022. The project has been classified as a "breakthrough" by the FDA and therefore has the chance of an accelerated submission in the so-called rolling procedure. Heidelberg Pharma AG is entitled to milestone payments and a double-digit percentage share of sales if the product receives marketing approval.

  In March, partner RedHill Biopharma Ltd., Tel Aviv, Israel, (RedHill; NASDAQ: RDHL) announced initial positive data from a Phase II/III trial of the orally administered RHB-107 against COVID-19 in an outpatient setting. RHB-107 delivered positive efficacy results

demonstrating a 100% reduction in hospitalizations due to COVID-19 and an 87.8% reduction in reported new severe COVID-19 symptoms. RedHill is discussing the next steps with the authorities.

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 2021 to 28 February 2022 (Q1 2022). As not all necessary requirements for the full recognition of the license agreement with Huadong have yet been met, this matter could not yet be reflected in the results of operations, financial position and net assets for the first quarter.

In the first three months of fiscal year 2022, the Group generated **sales revenue and income** totaling EUR 0.8 million (previous year: EUR 0.5 million). This figure includes **sales revenue** of EUR 0.7 million (previous year: EUR 0.4 million) generated by the ATAC® technology (EUR 0.6 million) and the service business (EUR 0.1 million).

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

Operating expenses including depreciation and amortization totaled EUR 7.9 million in the reporting period (previous year: EUR 6.7 million). **Cost of sales** decreased to EUR 0.6 million (previous year: EUR 1.1 million) and concern costs directly related to sales revenue. **Research and development costs** rose by EUR 0.8 million year-on-year to EUR 5.7 million (previous year: EUR 4.9 million) as planned due to the expansion of cost-intensive external good manufacturing practice (GMP) production for the follow-up projects as well as start-up costs for the clinical trial with HDP-101. At 72% of operating expenses, R&D was the largest cost item. **Administrative costs** increased to EUR 1.4 million in the first quarter of fiscal year 2022 compared to the prior-year period (EUR 0.7 million), also as a result of transaction-related consulting costs. 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, doubled from EUR 0.1 million to EUR 0.2 million year-on-year.

The Heidelberg Pharma Group's **net loss** for the first three months of the fiscal year increased to EUR 7.2 million, as planned (previous year: EUR 6.3 million). Basic earnings per share based on the weighted average number of shares issued during the reporting period fell from EUR -0.20 in the previous year to EUR -0.21 in the reporting quarter as a result of the higher loss.

Total assets as of 28 February 2022 amounted to EUR 20.7 million and were lower compared to the 30 November 2021 reporting date (EUR 21.7 million) in particular due to the lower cash and cash equivalents. At EUR -0.4 million, **equity** was also significantly lower compared to the end of fiscal year 2021 (EUR 6.7 million). This corresponds to an equity ratio of -1.8% (30 November 2021: 30.8%). No corporate actions were implemented during the reporting period. The share capital of Heidelberg Pharma AG therefore remained steady at EUR 34,175,809, divided into 34,175,809 no par value bearer shares.

Cash and cash equivalents as of the end of the quarter amounted to EUR 4.5 million (30 November 2021: EUR 6.1 million). This represents an average monthly cash outflow of EUR 2.2 million in the first quarter of the fiscal year (previous year: EUR 2.4 million) (not including the inflow from the loan of EUR 5.0 million). Immediately prior to the publication of this Interim Management Statement a payment of USD 18 million (EUR 16.8 million) was received from Huadong.

Financial outlook for 2022

Given that the recently announced license agreement and investment agreement with Huadong are still subject to various approvals, Heidelberg Pharma is not including the effects of this partnership in the 2022 forecast at this time. Both agreements concluded will have an impact on Heidelberg Pharma's results of operations, financial position and net assets; so, the financial outlook will be adjusted in due course.

The Executive Management Board anticipated sales revenues and other income for the Heidelberg Pharma Group between EUR 7.5 million and EUR 9.5 million in the 2022 fiscal year (2021: EUR 2.3 million). Due to the licensing agreement with Huadong sales revenue is expected to increase.

Based on current planning, operating expenses are expected to be in the range of EUR 41.0 million to EUR 45.0 million, significantly higher than in the prior reporting year (EUR 27.9 million). Earnings before interest and taxes (EBIT) in the 2022 fiscal year are expected to be between EUR -32.5 million and EUR -36.5 million (2021: EUR -25.6 million).

Financing requirements in the 2022 fiscal year for Heidelberg Pharma AG's business operations are expected to increase compared to 2021. Funds used are expected to be in the range of EUR 33.0 million to EUR 37.0 million. This corresponds to an average monthly use of cash of EUR 2.8 million to EUR 3.1 million (2021: EUR 2.3 million). Based on current planning, including the financing commitment by dievini, the Group's financing is secured until at least mid-2023. If the planned rights issue is successfully implemented, the financing range will be significantly extended.

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 www.heidelberg-pharma.com "Press & Investors > Financial Reports > Interim management statement on the first three months of 2022.

For organizational reasons, the half-year financial report will not be published on Thursday, 14 July 2022 as planned, but already on Tuesday, 12 July 2022.

Key figures for the Heidelberg Pharma Group (unaudited)

In EUR thsd.	Q1 2022[1] EUR thsd.	Q1 2021[1] EUR thsd.
Earnings		
Sales revenue	716	370
Other income	113	91
Operating expenses	(7,913)	(6,745)
of which research and development costs	(5,717)	(4,864)
Operating result	(7,084)	(6,284)
Earnings before tax	(7,246)	(6,321)
Net loss for the period	(7,246)	(6,321)
Earnings per share in EUR (basic)	(0.21)	(0.20)
Balance sheet as of the end of the period		
Total assets	20,652	17,541
Cash and cash equivalents	4,515	2,915
Equity	(365)	6,628
Equity ratio[2] in %	(1.8)	37.8
Cash flow statement		
Cash flow from operating activities	(6,524)	(6,601)
Cash flow from investing activities	(84)	(434)
Cash flow from financing activities	4.977	4,975
Employees (number)		
Employees as of the end of the period[3]	97	89
Full-time equivalents as of the end of the period[3]	89	82

1 The reporting period begins on 1 December and ends on 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 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. HDP-102, a CD37 ATAC for Non-Hodgkin lymphoma and HDP-103, a PSMA ATAC for metastatic castration-resistant prostate cancer, are in preclinical testing.

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 www.heidelberg-pharma.com.