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

- First clinical trial with HDP-101 in multiple myeloma on track, third patient cohort started
- Significant progress achieved in partner projects and further ATAC® agreements signed with Chiome Bioscience and Takeda
- Rights issue with proceeds of approximately EUR 80 million conducted in August; strategic partnership with Huadong Medicine thus completed
- Significantly increased sales revenue due to license payment from Huadong led, among other things, to adjusted guidance

Ladenburg, Germany, 13 October 2022 – Heidelberg Pharma AG (FSE: HPHA) today reported on the development of its **A**ntibody **T**argeted **A**manitin **C**onjugate technology as well as on the Group's financial figures for the first nine months of fiscal year 2022 (1 December 2021 – 31 August 2022).

Dr. Jan Schmidt-Brand, CEO and CFO of Heidelberg Pharma AG, commented: “In the last nine months, we have worked very successfully on three major topics that will be transformative for Heidelberg Pharma. After intensive preparations, we have brought our first own ATAC® into clinical development and expect initial data on this towards the end of the year. We are also pleased that we were able to expand our network of partners for our ATAC® technology. Our longstanding partner Takeda has exercised the first option on a now specified ATAC® and has entered into a licensing agreement. With Chiome Bioscience, we have a new partner who is developing an already defined ATAC® candidate under a research and option agreement.

The strategic partnership that we agreed with Huadong Medicine earlier this year is a major milestone for us. In addition to a license agreement for the development and commercialization for four, to date proprietary ATAC® candidates, we also concluded an investment agreement under which Huadong invested approximately EUR 105 million in Heidelberg Pharma shares. Of this amount, Heidelberg Pharma received approximately EUR 80 million from the planned rights issue at the beginning of September, which will be used to conduct the ongoing phase I trial with HDP-101, to further develop the follow-on projects HDP-102 and HDP-103, and to advance the ATAC® technology. With the acquisition of additional shares from our main investor dievini, we now welcome Huadong as Heidelberg Pharma's second largest shareholder and look forward to our further cooperation. The first license payment from Huadong led to a significant increase in our sales revenue. As a result of this, and because some development expenses were postponed to next year, we expect a significantly improved operating result for the financial year 2022 than originally planned and a financing reach to mid-2025."

Important operational developments and achievements

- **HDP-101 (BCMA ATAC) development program:** Mid-February 2022, the first patient was dosed in the Phase I/IIa study with HDP-101. 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 designed to determine an optimal and safe dose of HDP-101 for the Phase IIa part of the study. During the Phase IIa dose expansion part, the recommended dose of HDP-101 will then be administered to at least 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.

The first two patient cohorts and dose levels have been completed with no evidence of side effects. The recruitment of patients to the third cohort is ongoing. There are six active study centers in the USA and Germany, with additional centers to be initiated in Europe.

- **Signing of a research and option agreement with Chiome Bioscience:** In July, Heidelberg Pharma and Chiome Bioscience Inc., Tokyo, Japan, (Chiome) signed an exclusive research and option agreement for the development of an ATAC® against one target with relevance for multiple solid tumor indications. Under the terms of the agreement, Chiome will have access to Heidelberg Pharma's Amanitin toxin-linker platform technology and has an option for an exclusive license for global development and commercialization rights to the product candidate resulting from the research collaboration. Heidelberg Pharma would be eligible to receive an option fee, development- and sales-related milestone payments of up to EUR 105 million as well as tiered royalties in the mid-upper single digit range.
- **Strategic partnership with Huadong and rights issue:** Heidelberg Pharma and Huadong Medicine Co., Ltd., Hangzhou, China, (Huadong) entered a strategic partnership at the end of February 2022. This partnership includes a licensing agreement for several ATAC® candidates as well as an agreement regarding an equity investment in Heidelberg Pharma. Pursuant to the investment agreement, Huadong committed to participate significantly in the rights issue of up to EUR 80 million to acquire approximately 26% of the new share capital of Heidelberg Pharma in a first step. In addition, Huadong agreed to purchase a certain number of existing shares from main shareholder dievini BioTech holding GmbH & Co. KG, Walldorf, (dievini) such that Huadong would hold a total of 35% of the share capital upon completion of the transaction.

  Based on a securities prospectus that has been approved by the German Federal Financial Supervisory Authority on 12 August, Heidelberg Pharma commenced a rights issue in cash on 16 August. 12,408,648 shares were offered to all shareholders for subscription. The main shareholder dievini and related entities had agreed in advance to transfer their subscription rights to Huadong. In addition, Huadong took over all unsubscribed new shares. The closing of the rights issue took place after the end of the reporting period on 2 September. For further information, please refer to the section "Report on post-balance sheet date events".
- **Presentation of new preclinical data of the ATAC® technology platform at the AACR 2022 Annual Meeting:** At the American Association for Cancer Research (AACR) 2022 Annual Meeting in April, Heidelberg Pharma presented preclinical results for 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® results in better tolerability without compromising efficacy in preclinical models.

Partner program updates

- **Progress made by our licensing partner Magenta:** The partner Magenta Therapeutics, Cambridge, MA, USA, (Magenta; NASDAQ: MGTA) is developing MGTA-117 as its first clinical ATAC® technology-based candidate for the targeted preparation, or conditioning, of patients for stem cell transplants or gene therapy. MGTA-117 is an ATAC® that consists of a CD117 antibody and the toxin Amanitin, and was developed by Magenta based on a license granted by Heidelberg Pharma.

  MGTA-117 is currently being tested in a dose escalation clinical trial to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of MGTA-117 as a single dose in patients with relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome with excess blasts (MDS-EB). With the dosing of the first patient in March, a milestone payment was

due to Heidelberg Pharma. Based on a preliminary review of the initial data from the trial, Magenta believes that these indicate early signals of positive pharmacodynamic activity and that MGTA-117 was well-tolerated. Publication of clinical data is planned for the end of 2022.

Magenta is also working on the preclinical validation of a second product candidate, a CD45-ATAC, in various transplant and autoimmune diseases models. Successful development of these approaches could open the doors for the ATAC® technology for innovative applications beyond oncology for diseases of the immune system.

- **Progress made by our partner Telix:** TLX250-CDx (^{89}Zr-DFO-girentuximab) is an antibody radioactively labeled with zirconium-89 and has been tested by Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix) in the ZIRCON-study for imaging diagnostics of renal cancer using PET since August 2019. The study was carried out as a global multicenter Phase III trial at 35 study sites in Europe, Turkey, Australia, Canada and the USA, enrolling around 250 renal cancer patients who were to undergo kidney surgery. It determined the sensitivity and specificity of TLX250-CDx PET imaging to detect clear cell renal cell cancer (ccRCC) in comparison with histology as standard of truth determined from surgical resection specimens. In July, Telix announced that the last patient had been dosed and that expanded enrollment in the study was now complete. Data are 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.

  Telix's Chinese distributor, China Grand Pharmaceutical Limited, submitted an Investigational New Drug application to the Chinese regulatory agency in the summer of 2022 to conduct a pivotal Phase III registration trial, which was approved by the agency in late September. The bridging study is required to provide supplementary data obtained in a Chinese population to establish that the diagnostic efficacy of this investigational product is equivalent in Chinese and Western populations. The multi-center Phase III bridging study is expected to enroll 100 patients.

  Under Telix's direction, a number of studies with TLX250-CDx have been initiated, supporting the goal of validating indication expansion. The currently ongoing Phase I trial (ZiP-UP) is testing TLX250-CDx in urothelial carcinoma or bladder cancer. Another Phase I trial (PERTINENCE) in six patients with non-muscle invasive bladder cancer completed enrollment in August 2022. This study is based on a licensing and research agreement with Telix's partner ATONCO S.A.S. Provided the results are promising, the next step is to radiolabel the TLX250 antibody with ATONCO's proprietary radionuclide astatin-211 and test it as a therapeutic in this indication in further studies. Additional collaborative studies for ovarian, colorectal, head and neck, lung and pancreatic cancers are in preparation.

  In addition to developing the diagnostic antibody, Telix also plans to develop a therapeutic radio-immune conjugate (^{177}Lu-DOTA-girentuximab, TLX250) based on the lutetium-177 labeled antibody girentuximab. TLX250 will be tested in two Phase II combination studies (STARLITE 1 and 2) with immunotherapies. First patients are being 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 start of STARLITE 1 has been approved by the US regulatory authority and is in preparation.

- **Progress made by our partner RedHill:** RedHill Biopharma (Nasdaq: RDHL) is developing RHB-107 (upamostat), a serine-protease inhibitor outlicensed from Heidelberg Pharma, in various oncology, gastrointestinal and inflammatory lung diseases. In March 2022, RedHill

announced that 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. In early October, RedHill announced study results demonstrating in vitro efficacy against the currently dominant Omicron COVID-19 sub-variant BA.5 by its two candidates, RHB-107 and opaganib.

RedHill is currently in advanced discussions with regulatory authorities regarding further development steps. RHB-107 is planned to be tested in oncology in combination with RedHill's other development candidate, opaganib, among others.

Report on post-balance sheet date events

- **Completion of a rights issue:** In August 2022, Heidelberg Pharma offered all shareholders a total of 12,408,648 new shares for subscription at a price of EUR 6.44 each. Pursuant to the agreement dated 27 February 2022, the partner Huadong participated significantly in the rights issue and acquired 9,374,156 shares from subscription rights from the main shareholder dievini and its affiliated companies. In addition, Huadong acquired a further 2,464,496 shares which were not subscribed by other shareholders and thus held 25% of Heidelberg Pharma shares. In order to achieve the target shareholding of 35%, Huadong acquired a further 4,465,908 shares from dievini at a price of EUR 6.44.

  Heidelberg Pharma received total gross proceeds of around EUR 80 million from the capital increase, which will mainly be used to conduct the ongoing phase I trial with HDP-101 and to further develop the follow-on projects HDP-102 and HDP-103 and the proprietary ATAC® technology.

  After the registration of the capital increase in the Commercial Register of the Mannheim Local Court on 2 September, the new share capital of the Company amounts to EUR 46,584,457.00 and is divided into 46,584,457 no-par value bearer shares. The Authorized Capital 2020/I available for the issue of new shares was almost fully utilized with this measure. On 28 June 2022, the Annual General Meeting 2022 approved the creation of new Authorized Capital 2022/I in the amount of EUR 20,992,228.00, which has already been entered in the Commercial Register.

- **License Agreement with Takeda:** On 9 September, Heidelberg Pharma announced the signing of a license agreement with Takeda. Takeda was granted an exclusive license to commercially develop an Antibody Targeted Amanitin Conjugate directed towards a previously selected, but undisclosed target molecule. The license agreement was concluded following Takeda’s exercise of its option for exclusive licensing. Heidelberg Pharma receives an undisclosed milestone payment in return and is eligible to receive potential future clinical development, regulatory and sales-related milestone payments.

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 31 August 2022 (9M 2022).

In the first nine months of the 2022 fiscal year, the Group generated sales revenue and income totaling EUR 16.8 million (previous year: EUR 1.6 million). The **sales revenue** included in this figure (EUR 15.7 million; previous year: EUR 1.1 million) comprises the collaboration agreements of Heidelberg Pharma Research, including their deliveries of Amanitin linkers for the ATAC® technology (EUR 15.3 million), and the service business (EUR 0.4 million). At EUR 1.1 million, **other income**

was also significantly higher than in the previous year (EUR 0.5 million). It primarily consisted of exchange rate gains and government grants, the passing on of patent costs and the reversal of unutilized accrued liabilities and provisions.

Operating expenses including depreciation and amortization amounted to EUR 27.6 million in the reporting period (previous year: EUR 20.1 million) and break down as follows: **Cost of sales** increased to EUR 5.2 million (previous year: EUR 3.0 million) in the wake of higher sales and corresponds to 19% of total costs. **Research and development costs** rose compared to the last year to EUR 17.7 million (previous year: EUR 14.1 million) due to the expansion of cost-intensive external manufacturing for all three ATAC® projects and preparations for the clinical trial with HDP-101. At 64% of operating expenses, R&D remained the largest cost item. **Administrative costs** increased to EUR 4.1 million compared to the prior-year period (EUR 2.6 million). Among others, this figure includes holding company costs and costs related to the stock market listing as well as, in particular, consulting services relating to the strategic partnership with Huadong. **Other expenses** for business development and marketing the technology in the reporting period totaled EUR 0.6 million (previous year: EUR 0.4 million) due to an expansion of activities.

The **financial result**, which mainly consists of interest expenses for the shareholder loan from dievini, amounts to EUR -0.6 million (previous year: EUR -0.3 thousand).

The **net loss** for the first nine months of the fiscal year decreased to EUR 13.2 million (previous year: EUR 18.9 million) as a result of the items described above. In line with this and taking into account the higher number of shares, the earnings **per share** improved from EUR -0.59 in the previous year to EUR -0.39.

Cash and cash equivalents as of the end of the third quarter amounted to EUR 10.5 million (30 November 2021: EUR 6.1 million; 31 August 2021: EUR 13.6 million). Heidelberg Pharma had an average cash outflow of EUR 0.1 million (previous year: EUR 2.3 million) per month in the first nine months of the financial year excluding financing measures, as the license payment from Huadong and other payments from partner companies have already been received in full.

Total assets as of 31 August 2022 amounted to EUR 29.8 million, up from the figure of EUR 21.7 million shown as of the 30 November 2021 reporting date. At EUR -6.1 million, **equity** was lower than at the end of fiscal year 2021 (EUR 6.7 million) because the capital increase was entered in the commercial register after the balance sheet date on 2 September and was thus completed after the reporting period.

Financial outlook for 2022

On 4 October 2022, the Company revised its guidance for the current fiscal year issued for the Heidelberg Pharma Group in March 2022. The license agreement with Huadong and the corresponding license payment significantly increased Heidelberg Pharma's sales revenue. Development expenses increased compared to 2021, but remain below plan due to the later production of intermediate steps for the follow-on candidates. Both factors influence the operating result, which will improve substantially and reduce the funding requirement for the financial year 2022.

The Heidelberg Pharma Group expects for the financial year 2022 sales and other income between EUR 18.5 million and EUR 20.5 million (previously: EUR 7.5 million to EUR 9.5 million). Operating expenses will range between EUR 35.0 million and EUR 39.0 million (previously: EUR 41.0 million to EUR 45.0 million). Based on these adjustments, an operating result (EBIT) between EUR -16.0 million and EUR -20.0 million is expected (previously: EUR -32.5 million to EUR -36.5 million).

For 2022, Heidelberg Pharma anticipates cash requirements of EUR 8.0 million to EUR 11.0 million (previously: EUR 33.0 million to EUR 37.0 million). Monthly cash consumption is expected to range between EUR 0.6 million and EUR 0.9 million per month (previously: EUR 2.8 million and EUR 3.1 million). Based on the existing planning and the capital increase that was closed after the end of the reporting period, the company assumes a financing range until mid-2025.

The complete figures for the interim financial statements can be downloaded from http://www.heidelberg-pharma.com/ ”Press & Investors > Financial Reports > Interim Management Statement of 13 October 2022”. Heidelberg Pharma will not host a conference call on this interim management statement.

Key figures for the Heidelberg Pharma Group

In EUR thsd.	9M 2022 [1] EUR thsd.	9M 2021 [1] EUR thsd.
Earnings		
Sales revenue	15,695	1,126
Other income	1,149	426
Operating expenses	(27,611)	(20,069)
of which research and development costs	(17,676)	(14,096)
Operating result	(10,767)	(18,517)
Earnings before tax	(11,347)	(18,851)
Net loss for the period	(13,224)	(18,851)
Basic earnings per share in EUR	(0.39)	(0.59)
Balance sheet as of the end of the period		
Total assets	29,805	28,547
Cash and cash equivalents	10,523	13,598
Equity	(6,073)	13,747
Equity ratio[2] in %	(20.4)	48.2
Cash flow statement		
Cash flow from operating activities	(1,201)	(19,399)
Cash flow from investing activities	(282)	(1,175)
Cash flow from financing activities	4,932	29,190
Employees (number)		
Employees as of the end of the period[3]	104	92
Full-time equivalents as of the end of the period[3]	97	85

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 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 http://www.heidelberg-pharma.com/.