**PRESS RELEASE**

# Heidelberg Pharma Announces Financial Figures for Fiscal Year 2021 and Provides Business Update

- Start of clinical trial with HDP-101 in multiple myeloma
- Signing of strategic partnership with Huadong Medicine
- Successful financing activities
- Financial figures in line with adjusted forecast
- Conference call to be held on 24 March 2022 at 3:00 p.m. CET

**Ladenburg, Germany, 24 March 2022 –** Heidelberg Pharma AG (FSE: HPHA) today published its financial results and Annual Report for fiscal year 2021 (1 December 2020 – 30 November 2021) and its outlook for 2022.

Dr. Jan Schmidt-Brand, Chief Executive Officer and Chief Financial Officer of Heidelberg Pharma AG, commented: "We look back on an action-packed year that enabled us to hit the ground running in 2022. We are excited about the landmark partnership with Huadong Medicine and the start of clinical development with the first antibody-amanitin conjugate from our ATAC® technology platform.

"Despite the constraints caused by the ongoing COVID-19 pandemic in the past year, we were able to complete the preparations for starting the clinical Phase I/IIa study of our drug candidate HDP-101 for treating multiple myeloma. We reached a key milestone with the dosing of the first patient with this ATAC® in February of this year. The trial is progressing as planned and we are eagerly awaiting first safety and tolerability data that should be available later this year.

"We are also excited about the progress made by our technology partner Magenta. In March 2022, the first patient was treated with their ATAC® candidate MGTA-117. Thus, following HDP-101, a second ATAC®-technology based candidate is now in clinical development.

"The strategic partnership with the Chinese company Huadong Medicine is transformative for Heidelberg Pharma. We are gaining an established licensing partner for our current ATAC® portfolio in Asia and a new strategic investor, who will become our second largest shareholder after completion of the planned equity investment. This partnership will allow us to accelerate our product development, expand our pipeline, and become a global ADC player."

## Key events in fiscal year 2021 / early 2022 and operational outlook

- **Start of clinical trial with HDP-101:** In February, Heidelberg Pharma received the approval from US regulatory authorities to initiate a Phase I/IIa clinical trial with HDP-101, a BCMA-ATAC. This was followed by approval from the German authority in July. Due to the COVID-19 pandemic, the trial could not be initiated at the planned clinical center and so a new center had to be onboarded. While this was supposed to happen in the second quarter, additional stability testing first was required by the new center. Although these tests were completed successfully, they delayed the initiation of the first trial centers and delivery of trial drug by about three months. During the fourth quarter, two trial centers in the US were opened:

Winship Cancer Institute of Emory University in Atlanta, Georgia, and MD Anderson Cancer Center in Houston, Texas. The first German trial center, Heidelberg University Hospital, was initiated soon thereafter.

In February 2022, the first patient was dosed with HDP-101 in the Phase I/IIa study. The open-label, multi-center study is evaluating HDP-101 for the treatment of relapsed or refractory multiple myeloma. 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.

- **Ongoing development projects and important research findings:** The ATACs HDP-102 and HDP-103 are on track in preclinical development and production. Submission of study applications for the first of these two candidates is planned for early 2023.

  At the American Association for Cancer Research (AACR) Annual Meeting, Heidelberg Pharma and a research group from the Indiana University School of Medicine, Indianapolis, Indiana, jointly presented new preclinical results indicating that combining ATACs with immune checkpoint inhibitors may be beneficial. The findings were also published in the peer-reviewed journal, Science Translational Medicine and support new potential development approaches.

- **Advances in ATAC® collaborations:** Partner Magenta prepared the development candidate MGTA-117, an ATAC® consisting of a CD117 antibody and Amanitin as payload, for clinical development. MGTA-117 is the first ATAC® clinical candidate to be used for targeted preparation, or conditioning, of patients for stem cell transplants or gene therapy. The ongoing Phase I/II trial is evaluating MGTA-117 in patients with relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome with excess blasts (MDS-EB).

- **Advances with clinical license portfolio:** In 2021, there also was encouraging progress by our partners for the out-licensed clinical projects outside of the ATAC® portfolio. Telix, our licensing partner for the radiolabeled antibody girentuximab, has been conducting the Phase III ZIRCON study with TLX250-CDx since 2019. This international study with renal cancer patients undergoing kidney surgery is designed to determine the sensitivity and specificity of TLX250-CDx PET imaging to detect clear cell renal cell cancer (ccRCC) compared to standard histology as standard of truth determined from surgical resection specimens. The target enrollment of 252 patients was reached in March 2022, but recruitment will be continued for up to an additional three months to generate further data.

  In addition to oncology indications, RedHill is developing RHB-107 for the treatment of COVID-19. In 2021, the first part of a Phase II/III trial in an outpatient setting began in the US, and the first patient was dosed in February of last year. Enrollment for the Phase II part of the study is complete, with positive first data announced in March 2022.

- **Successful financing activities:** At the end of 2020, main shareholder dievini committed to a shareholder loan of EUR 15 million that was fully drawn down in tranches. In March 2021, dievini confirmed a further financing commitment of up to EUR 30 million to secure the financing of the Company, including the expanded development program.

  In June 2021, a capital increase was implemented in connection with a private placement generating gross 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 biotech specialist institutional investors and

DH-LT-Investments GmbH, St. Leon-Rot, an investment company owned by Dietmar Hopp. The price per share was EUR 6.44.

On 17 February 2022, dievini made a financing commitment of 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.

- **Licensing agreement and strategic partnership with Huadong:** Heidelberg Pharma and Huadong Medicine Co., Ltd., Hangzhou, China, announced on 28 February 2022, after the close of the reporting period, that the companies had entered into a strategic partnership. This partnership includes a licensing agreement for the ATAC® technology (exclusive development and commercialization rights for HDP-101 and HDP-103 in Asia), and the Company is eligible to receive 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. 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 transaction is still subject to various approvals from German and Chinese authorities, which are expected in the coming months.

**Key financial figures of the Heidelberg Pharma Group for fiscal year 2020**

The 2021 fiscal year concerns the period from 1 December 2020 to 30 November 2021. The Heidelberg Pharma Group includes two entities, Heidelberg Pharma AG and Heidelberg Pharma Research GmbH.

In fiscal year 2021, the Heidelberg Pharma Group generated **sales revenue** of EUR 1.7 million (previous year: EUR 8.5 million), which was mainly related to the research collaborations for the Heidelberg Pharma Research ATAC technology (EUR 1.2 million; previous year: EUR 7.8 million) and the service business (unchanged at EUR 0.5 million). In the 2020 comparative period, the parent company generated sales revenue of EUR 0.2 million through out-licensing.

**Other income** of EUR 0.6 million (previous year: EUR 1.1 million) consisted mainly of government grants to support Heidelberg Pharma Research projects, income from the reversal of unused accrued liabilities and income from charges on patent costs in the context of out-licensing.

**Operating expenses** including depreciation and amortization were unchanged at EUR 27.9 million in 2021 (previous year: EUR 27.9 million). **Research and development costs** rose to EUR 18.7 million (previous year: EUR 18.3 million) due to the expansion of cost-intensive external manufacturing of all three ATAC® product candidates and preclinical and regulatory preparations for the clinical trial with HDP-101. At 67 % of operating expenses, R&D remained the largest cost item. **Cost of sales** totaled EUR 4.7 million (previous year: EUR 5.6 million) and represented 17% of operating expenses. **Administrative costs** were EUR 4.0 million (previous year: EUR 3.6 million) and accounted for 14% of operating expenses. **Other expenses**, comprising the costs incurred for business development, marketing and commercial market supply, were EUR 0.5 million (previous year: EUR 0.4 million) and represented 2% of operating expenses.

The Heidelberg Pharma Group recognized **comprehensive income** and a **net loss** of EUR -26.1 million (previous year: EUR -18.4 million) in the 2021 fiscal year. **Loss per share** increased from EUR -0.61 in the previous year to EUR -0.80.

**Monthly cash use** increased to EUR 2.3 million exclusive of the capital increase (previous year: EUR 1.6 million). The Group had **cash and cash equivalents** of EUR 6.1 million at the close of the fiscal year (30 November 2020: EUR 5.0 million). The addition resulted mainly from the shareholder loan from dievini and the capital increase implemented in the third quarter, which together more than compensated for the cash outflow due to expanded operating activities.

At the end of the fiscal year, **total assets** amounted to EUR 21.7 million, up EUR 2.1 million from the previous year (EUR 19.6 million). **Equity** of the Heidelberg Pharma Group at the end of the reporting period was EUR 6.7 million (30 November 2020: EUR 12.9 million). This corresponds to an equity ratio of 30.8% (30 November 2020: 65.7%).

### Financial outlook for 2022 and strategy

Given that the recently announced license agreement and investment agreement with Huadong Medicine are still subject to various approvals, Heidelberg Pharma is not including the effects of this partnership in the 2022 forecast at this time. The license agreement also requires a separate assessment with regard to revenue recognition under IFRS 15. Both agreements 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 currently expects the Heidelberg Pharma Group to generate between EUR 7.5 million and EUR 9.5 million in revenue and other income in the 2022 fiscal year (2021: EUR 2.3 million). These will primarily comprise the sales revenue generated by Heidelberg Pharma Research GmbH and, to a lesser extent, potential milestone payments to Heidelberg Pharma AG. Sales revenue is expected to increase due to the licensing agreement with Huadong.

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). With preliminary inclusion of the licensing agreement with Huadong, Heidelberg Pharma expects to post a significantly improved operating result.

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 believes that Amanitin is an innovative toxin with attractive properties for the development of ATACs and will continue its strategy for the development and marketing of the proprietary ATAC® technology. The strategy’s core elements are the expansion of the company's proprietary project pipeline, the development of the pipeline projects until clinical proof of concept, the initiation of research and option agreements and their extension to include long-term license agreements, as well as the broadening of the technology base.

**Invitation to the financial results press conference**

On 24 March 2022, Heidelberg Pharma will hold a conference call for media, analysts, and investors in English at 3:00 p.m. CET/10 a.m. EDT. Please register at least 10 minutes in advance using the following link:

https://us06web.zoom.us/webinar/register/WN_ybHcQIw8QAu-AEWoa7zVqA

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 million | 2021 [1] EUR million | 2020 [1] EUR million |
|---|---|---|
| **Earnings** | | |
| Sales revenue | 1.7 | 8.5 |
| Other income | 0.6 | 1.1 |
| Operating expenses | (27.9) | (27.9) |
| of which research and development costs | (18.7) | (18.3) |
| Operating result | (25.6) | (18.3) |
| Earnings before tax | (26.1) | (18.4) |
| Total comprehensive income | (26.1) | (18.4) |
| Earnings per share in EUR (basic) | (0.80) | (0.61) |
| | | |
| **Balance sheet as of the end of the period** | | |
| Total assets | 21.7 | 19.6 |
| Cash and cash equivalents | 6.1 | 5.0 |
| Equity | 6.7 | 12.9 |
| Equity ratio[2] in % | 30.8 | 65.7 |
| | | |
| **Cash flow statement** | | |
| Cash flow from operating activities | (26.6) | (17.9) |
| Cash flow from investing activities | (1.4) | (1.3) |
| Cash flow from financing activities | 29.1 | 14.3 |
| | | |
| **Employees (number)** | | |
| Employees at year end[3] | 96 | 84 |
| Employees at year end[3] (full-time equivalents) | 89 | 78 |

1) The reporting period begins on 1 December and ends on 30 November.
2) Equity / total assets
3) Including members of the Executive Management Board
Rounding of exact figures may result in differences.

The Annual Report, including the consolidated financial statements in accordance with International Financial Reporting Standards (IFRS), is available at https://heidelberg-pharma.com/en/press-and-investors/announcements/financial-reports.

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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 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 listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol HPHA. More information is available at http://www.heidelberg-pharma.com/.

ATAC® is a registered trademark of Heidelberg Pharma AG.