# Heidelberg Pharma AG: Interim Management Statement on the First Nine Months of 2024

- HDP-101 clinical trial in Europe and US continues with adjusted protocol and dose optimization on track; sixth patient cohort dosed at 90 µg/kg and patients are still on treatment
- Sale of a portion of future royalties for TLX250-CDx to HealthCare Royalty
- New clinical data with HDP-101 presented at the International Myeloma Society (IMS) Annual meeting; one patient in complete remission
- Two R&D webinars with Key Opinion Leaders planned for October
- Guidance adjusted

**Ladenburg, Germany, 10 October 2024 –** Heidelberg Pharma AG (FSE: HPHA) reported today on its operational progress as well as on the Group's financial figures for the first nine months of fiscal year 2024 (1 December 2023 – 31 August 2024).

Professor Andreas Pahl, CEO of Heidelberg Pharma AG, commented: “Our development activities are on track. The patients in the sixth cohort of our clinical study with HDP-101 are currently still undergoing treatment, and we expect to complete the cohort in the next few weeks.

We are very pleased to have presented new clinical results from the fifth cohort at the renowned International Myeloma Society Annual Meeting. We see a complete remission with a full elimination of tumor cells in one of our heavily pretreated patients. This success confirms the potential of HPD-101 as a treatment option for multiple myeloma patients.

In October, we adjusted the guidance for our financial figures. This is due to significantly lower R&D costs than planned and higher revenue in 2024."

**Important operational developments and achievements**

- **HDP-101 development program:** HDP-101, an Antibody Targeted Amanitin Conjugate directed against the antigen BCMA, is being tested in a Phase I/IIa open-label, multicenter study for the treatment of relapsed or refractory multiple myeloma, a cancer of the bone marrow. The first part of the study is a Phase I dose escalation study to find the safe and optimal dosing of HDP-101 for the Phase IIa portion of the study. The first four patient cohorts and dose levels were completed with no evidence of dose limiting toxicities.

  In the fifth cohort, all patients at a dose of 100 µg/kg HDP-101 experienced a drop in thrombocyte count, which completely normalized after a few days and was clinically unremarkable. To mitigate this transient effect, the clinical team adjusted and optimized the medication regimen. Cohort 6 consists of three arms, with at least three patients enrolled in each arm. In consultation with the clinical investigators, the dose will be 90 µg/kg in order to test these three dosing regimens with as little risk to the patients as possible.

  Patients in Arm A will be treated with a single dose of HDP-101 on day 1 of each 21-day cycle following pre-medication. Arm B will receive a weekly dose of HDP-101, which means that the dose will be split, and patients will be treated proportionally on days 1, 8 and 15 of each cycle. Arm C receives a partial dose of HDP-101 on days 1 and 8 of the first cycle and then a single dose on day 1 of each of the following 21-day cycles. Patients are currently still being treated in the sixth cohort, which is expected to be completed in the next few weeks.

- **HDP-102 development program:** HDP-102 is an ATAC targeting CD37, which is overexpressed on B-cell lymphoma cells. Preclinical studies have shown excellent anti-tumor efficacy in *in vivo* studies as well as good tolerability. Heidelberg Pharma intends to develop HDP-102 for specific indications of non-Hodgkin lymphoma (NHL).

  All productions steps for HDP-102 have been completed and all necessary preclinical and toxicological studies have been conducted. The data package required for the clinical trial application will be finalized in Q4 of this year. As a first step, the application will be submitted to the regulatory authority in a non-EU European country, followed by a central submission to the EMA.

- **HDP-201 development program:** Since fall 2023, the company has been developing further ADC projects with other payloads. The first candidate of the second platform is HDP-201, an exatecan-based ADC. Exatecan is a topoisomerase I inhibitor that has proven itself in cancer therapy and is used in two already approved ADCs. Its mode of action differs from that of Amanitin, and thus expands the company's range of active ingredients.

  HDP-201 targets guanylyl cyclase-C (GCC), a receptor that is expressed on the surface of intestinal cells and cancer cells in various gastrointestinal tumors. Preclinical results show that the tolerability and efficacy of HDP-201 is at least comparable to already approved exatecan ADCs.

  Based on extensive preclinical efficacy and tolerability testing, the final development candidate for HDP-201 was selected and the indication determined in recent weeks. HDP-201 is to be developed for the treatment of colorectal cancer.

- **Agreement concluded on the partial sale of license fees to HealthCare Royalty:** In early March 2024, Heidelberg Pharma signed an agreement with HealthCare Royalty, Delaware, USA, (HCRx) for the sale of a portion of future royalties from global sales of TLX250-CDx. Heidelberg Pharma received an upfront payment of USD 25 million and is also entitled to receive up to an additional USD 90 million from the sale of royalties if defined milestones are reached. After HCRx has received a maximum cumulative amount, the royalties will revert to Heidelberg Pharma, and HCRx will receive a low single-digit percentage of Heidelberg Pharma's royalties.

**Update on partner programs outside ATAC technology**

- **Progress at partner Telix:** TLX250-CDx is a radiolabeled form of the antibody girentuximab, which binds to the tumor-specific antigen CAIX on clear cell renal cell carcinoma (ccRCC) and possibly other tumor types. Accumulation of this antibody in tumor tissue can be visualized by positron emission tomography (PET) scans. This could fundamentally change therapy planning for renal cancer patients and avoid potentially unnecessary surgery. The diagnostic agent may also prove suitable for monitoring treatment response, detecting metastases, and diagnosing other kinds of tumors.

  The antibody was developed at Heidelberg Pharma AG up to a first Phase III trial and outlicensed to the Australian company Telix in 2017.

  Telix had successfully completed a second Phase III trial and, based on these positive Phase III results, completed the submission of a rolling New Drug Application in the United States in June 2024. The company announced at the end of July that the FDA had not accepted the application for approval at that time because of a manufacturing issue. Evidence of adequate sterility assurance during filling of the substance must be provided. Telix plans to resubmit the revised

application in the fourth quarter of this year. The application for priority review remains unchanged.

**Events after the end of the reporting period**

- **New clinical data on HDP-101 presented at International Myeloma Society Annual Meeting 2024:** At the 21st International Myeloma Society (IMS) Annual Meeting held in Rio de Janeiro, Brazil, at the end of September, Professor Marc-Steffen Raab, Head of the Myeloma Center at the University Hospital Heidelberg and clinical investigator of the study, presented new clinical findings from five patient cohorts of the trial with the BCMA-targeting ATAC HDP-101. Clinical data from the fifth cohort demonstrated complete remission in one patient who had been heavily pre-treated. This patient showed an objective improvement ("partial response") in the 2nd cycle of treatment and complete remission was confirmed after the 11th cycle.
- **R&D webinars planned:** Heidelberg Pharma will host a webinar on 15 October 2024, focusing on the presentation of clinical data from the HDP-101 trial to date. Another webinar, scheduled for 29 October 2024, will go into more detail on the importance of ADCs in cancer therapy. The data presented will be shared by Heidelberg Pharma's management team and key opinion leaders (KOLs) in the myeloma field. Both events are open to investors, analysts, journalists and other interested parties.

**Results of operations, financial position and net assets**

The Heidelberg Pharma Group, consisting of Heidelberg Pharma AG and its subsidiary Heidelberg Pharma Research GmbH reports consolidated figures as at the balance sheet date. The reporting period referred to below relates to the period from 1 December 2023 to 31 August 2024 (9M 2024).

In the first nine months of the 2024 business year, the Group generated sales revenues and income totaling EUR 7.6 million (previous year: EUR 13.9 million) and is in line with the updated planning. The **sales revenues** included in this figure fell from EUR 6.6 million the previous year to EUR 5.2 million. **Other income** amounted to EUR 2.4 million and was therefore significantly lower than the previous year's level of EUR 7.3 million due to the unscheduled sale of the Emergence stake.

**Operating expenses**, including depreciation, amounted to EUR 22.8 million in the reporting period (previous year: EUR 30.0 million) and are broken down as follows: **Cost of sales** decreased to EUR 1.5 million (previous year: EUR 3.1 million) and correspond to 7% of total costs. **Research and development costs** of EUR 15.7 million decreased compared to the same period last year (EUR 22.1 million). In the 2024 financial year, fewer costs have been incurred for the Phase I/IIa trial than originally planned. Some of the projected expenses for this will be incurred in the further course of the study in the next financial year. R&D costs continue to be the largest cost block, accounting for 68% of operating expenses. **Administrative costs**, which include the costs of holding activities, the stock exchange listing and the executive management board, increased to EUR 4.7 million compared to the same period last year (EUR 3.6 million), which is due to higher personnel costs including stock options issued. Administrative costs account for 21% of operating expenses. **Other expenses** for business development, marketing and commercial market supply activities, which mainly include personnel and travel expenses, decreased year-on-year to EUR 1.0 million (previous year EUR 1.2 million) and represented 4% of operating expenses.

**The financial result,** which is mainly made up of interest income on bank balances, amounted to EUR 1.0 million (previous year: EUR 0.5 million). The significant improvement is due to the now

complete repayment of the shareholder loan, as well as interest income from a higher investment volume.

The **net loss** for the first nine months of the financial year decreased to EUR 14.3 million compared to the previous year's figure of EUR 15.8 million. Despite lower sales revenues, the improvement is mainly due to lower expenses. **Earnings per share** improved accordingly from EUR -0.34 in the previous year to EUR-0.31 in the reporting period.

**Cash** amounted to EUR 36.6 million at the end of the third quarter (30 November 2023: EUR 43.3 million; 31 August 2023: EUR 50.7 million). Excluding financing effects (shareholder loans, sale of receivables), Heidelberg Pharma recorded an average cash outflow of EUR 2.6 million per month in the first nine months of the fiscal year (previous year: EUR 2.3 million).

**Total assets** as of 31 August 2024 amounted to EUR 65.8 million and were therefore below the figure as at the comparative reporting date of 30 November 2023 (EUR 70.4 million). **Equity** (EUR 35.8 million) also decreased as a result of the loss for the period compared to the end of the 2023 financial year (EUR 49.3 million).

**Financial outlook for 2024**

The guidance issued in June 2024 for the current financial year was adjusted downwards on the cost side and upwards on the revenue side on 1 October 2024.

For the financial year 2024, the Heidelberg Pharma Group expects sales and other income between EUR 10.0 million and EUR 12.0 million (previously: EUR 9.0 million to EUR 12.0 million). Operating expenses are expected to fall within a range of EUR 30.0 million and EUR 33.0 million (previously: EUR 36.0 million to EUR 40.0 million). In the 2024 financial year, fewer costs have been incurred for the Phase I/IIa trial than originally planned. Some projected expenses for this trial will be incurred in the further course of the study in the next financial year. Based on these adjustments, an operating result (EBIT) between EUR -19.0 million and EUR-22.0 million is expected (previously: EUR -25.5 million to EUR -29.5 million).

For 2024, Heidelberg Pharma anticipates cash requirements of EUR 13.0 million to EUR 16.5 million (previously: EUR 18.0 million to EUR 22.0 million). Monthly cash consumption is expected to range between EUR 1.1 million and EUR 1.4 million per month (previously: EUR 1.5 million and EUR 1.8 million). Based on the existing planning and available funds, the company's financing remains secured until mid-2025.

Taking into account a further expected payment of USD 75.0 million from HealthCare Royalty following approval of TLX250-CDx, the company anticipates a financial reach until the end of 2026, based on current medium-term planning.

The complete set of figures for the interim financial statements is available at http://www.heidelberg-pharma.com/ "Press & Investors > Announcements and Reports > Financial Reports > Interim announcement of 10 October 2024. A conference call on this interim announcement will not be offered.

## Key figures for the Heidelberg Pharma Group

| In EUR thsd. | 9M 2024 [1] EUR thsd. | 9M 2023 [1] EUR thsd. |
|---|---|---|
| **Earnings** | | |
| Sales revenue | 5,248 | 6,635 |
| Other income | 2,368 | 7,259 |
| Operating expenses | (22,849) | (29,985) |
| of which research and development costs | (15,650) | (22,065) |
| Operating result | (15,233) | (16,091) |
| Earnings before tax | (14,259) | (15,561) |
| Net loss for the period | (14,259) | (15,838) |
| Basic earnings per share in EUR | (0.31) | (0.34) |
| | | |
| **Balance sheet as of the end of the period** | | |
| Total assets | 65,775 | 74,328 |
| Cash | 36,569 | 50,675 |
| Equity | 35,823 | 51,488 |
| Equity ratio[2] in % | 54.5 | 69.3 |
| | | |
| **Cash flow statement** | | |
| Cash flow from operating activities | (22,749) | (26,494) |
| Cash flow from investing activities | (266) | 5,871 |
| Cash flow from financing activities | 16,106 | (10,024) |
| | | |
| **Employees (number)** | | |
| Employees as of the end of the period[3] | 109 | 111 |
| Full-time equivalents as of the end of the period[3] | 98 | 101 |

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.

**Contact**

**Heidelberg Pharma AG**
Sylvia Wimmer
Director Corporate Communications
Tel.: +49 89 41 31 38 29
Email: investors@hdpharma.com
Gregor-Mendel-Str. 22, 68526 Ladenburg

**IR/PR support**

MC Services AG
Katja Arnold (CIRO)
Managing Director & Partner
Tel.: +49 89 210 228 40
Email: katja.arnold@mc-services.eu

**About Heidelberg Pharma**

Heidelberg Pharma develops novel drugs based on its ADC technologies for the targeted and highly effective treatment of cancer. ADCs are antibody-drug conjugates that combine the high affinity and specificity of antibodies with the efficacy of toxins to fight cancer. Selected antibodies are loaded with various toxins, the so-called payloads, that are transported into diseased cells. Inside the cells, the toxins then unleash their effect and kill the diseased cells.

Heidelberg Pharma is the first company to use the mushroom toxin Amanitin in cancer therapies by exploiting the toxin's biological mechanism of action with its innovative ATAC technology as a new therapeutic modality. It offers the opportunity to not only overcome resistance of cancer cells against therapeutic agents currently used, but also has the ability to eliminate dormant tumor cells. This could lead to significant advances in cancer therapy - even for patients who no longer respond to any other treatment. The most advanced product candidate HDP-101 is an BCMA-ATAC for the indication multiple myeloma, which is currently in clinical development.

In addition to Amanitin, other payloads are expanding the ADC platform technologies of Heidelberg Pharma to develop targeted and highly effective ADCs for the treatment of a variety of malignant hematologic and solid tumors.

Heidelberg Pharma AG is a biopharmaceutical company 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/

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