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

- First efficacy data from the clinical trial with HDP-101 in multiple myeloma
- Professor Andreas Pahl becomes Chief Executive Officer
- Successful financing activities
- Sale of a portion of future royalties for Zircaix™ to HealthCare Royalty finances further development of the ADC pipeline

Ladenburg, Germany, 25 April 2024 - Heidelberg Pharma AG (FSE: HPHA) today reported on the first three months of fiscal year 2024 (1 December 2023 – 29 February 2024) and the Group’s financial figures.

Professor Andreas Pahl, CEO of Heidelberg Pharma AG, commented: “We are very pleased to see the first efficacy data in multiple myeloma in the clinical trial with our ATAC candidate HDP-101. In three patients from the fifth cohort, we have observed an objective improvement in the disease (“partial remission”). We will optimize the dosing regimen for the sixth cohort. HDP-101 was recently granted orphan drug status by the FDA for the treatment of multiple myeloma; this underlines the potential of our Amanitin-based ADC candidate in this indication.”

Walter Miller, CFO of Heidelberg Pharma AG, added: “In the first quarter of the financial year, we also successfully worked on financing the company and our ADC activities and concluded an attractive, non-equity-dilutive agreement with HealthCare Royalty in March. The upfront payment received at the end of March and the expected further payments from the partial sale of future royalties from the worldwide sale of Zircaix™ provide a very solid financing basis and will help us to accelerate the expansion of our ADC pipeline.”

Important operational developments and achievements

- **HDP-101 (BCMA ATAC) development program:** The ATAC product candidate HDP-101 is being evaluated in a Phase I/IIa clinical trial for the treatment of relapsed or refractory multiple myeloma. The first four patient cohorts and dose levels have been completed and proved to be safe and well tolerated. Since September 2023, patients in the fifth cohort have been treated with a dose of 100 µg/kg HDP-101. After the initial administration of HDP-101, a temporary drop in thrombocyte count occurred in all patients. However, this normalized within a few days, with counts returning to clinically unremarkable levels.

In order to mitigate the effect of the initial administration, an adjustment and optimization of the medication regimen was developed. The corresponding protocol adjustments were implemented and recruitment of the sixth cohort was started.

Encouragingly, the fifth cohort showed biological activity in three out of five patients, who continued on 100 µg/kg, and an objective improvement in the disease was detected (“partial remission”). In addition, one of the study participants from the third cohort has been treated with HDP-101 as a monotherapy since January 2023 and showed a stabilization of the course of disease (“stable disease”).

- **New Chief Executive Officer:** Dr. Jan Schmidt-Brand, long-standing CEO of Heidelberg Pharma AG and Managing Director of the subsidiary Heidelberg Pharma Research GmbH, stepped down from his positions on 31 January 2024 upon reaching retirement age. The Supervisory Board
appointed Professor Andreas Pahl as CEO with effect from 1 February 2024. Professor Pahl also assumed the role of Managing Director of the subsidiary. Professor Pahl has been Head of Research & Development at Heidelberg Pharma since 2012 and has been a member of the Executive Management Board since 2016. He holds a doctorate in chemistry and has more than 25 years of experience in the pharmaceutical industry as well as in research and teaching.

Events after the reporting period

- **Agreement closed with HealthCare Royalty on the sale of a portion of future royalties:** 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 Zircaix™. Heidelberg Pharma received a non-refundable upfront payment of USD 25 million and is also entitled to up to an additional USD 90 million from the sale of the royalties, if defined milestones are met. Once HCRx has received a maximum cumulative amount, the royalties will revert to Heidelberg Pharma and HCRx will receive a low single-digit percentage of royalties.

  Zircaix™ is a radiolabeled form of the antibody girentuximab which binds to the tumor-specific antigen CAIX on clear cell renal cell carcinomas. Heidelberg Pharma developed the antibody up to a first completed Phase III clinical trial prior to licensing it to Telix Pharmaceuticals Limited, a company based in Melbourne, Australia, in 2017. Telix submitted its Biologics License Application (BLA) under a rolling review submission with the US Food and Drug Administration (FDA) in December 2023 and expects market approval by the end of 2024. Recently, Telix announced that the BLA is due for completion by end-May 2024. Telix has requested a Priority Review as well.

- **Orphan drug designation granted by FDA for HDP-101:** At the end of March, Heidelberg Pharma announced that the US Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for the treatment of multiple myeloma to its lead candidate HDP-101. Orphan Drug Designation is granted for a drug or biological product that is intended for the prevention, diagnosis, or treatment of rare diseases or disorders that affect fewer than 200,000 people in the US. The designation provides significant incentives to promote the development of the drug including tax credits for qualified clinical trials, prescription drug user-fee exemptions, and potential seven-year marketing exclusivity upon FDA approval.

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 2023 to 29 February 2024 (Q1 2024).

In the first three months of fiscal year 2024, the Group generated **sales revenue and income** totaling EUR 1.9 million (previous year: EUR 2.2 million). This figure includes **sales revenue** of EUR 1.3 million (previous year: EUR 2.1 million), which is made up of a roughly from deferred sales.

**Other income** amounted to EUR 0.6 million (previous year: EUR 0.1 million) and primarily consisted of the reversal of unutilized provisions that were subject to the statute of limitations.

**Operating expenses** including depreciation and amortization totaled EUR 6.6 million in the reporting period (previous year: EUR 8.7 million). **Cost of sales** amounted to just under EUR 30 thousand and was therefore significantly below the previous year’s figure of EUR 1.4 million, which is due to the high proportion of deferred income in sales. **Research and development costs** decreased year-on-year to EUR 5.1 million (previous year: EUR 5.8 million). 
and represented the largest cost item at 77%. Both periods were primarily characterized by the cost-intensive external manufacturing for the ATAC projects and the ongoing clinical trial with HDP-101. **Administrative costs** increased slightly to EUR 1.2 million in the first quarter of fiscal year 2024 compared to the prior-year period (EUR 1.1 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, halved from EUR 0.4 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 decreased to EUR 4.5 million, as planned (previous year: EUR 6.6 million). **Basic earnings per share** based on the weighted average number of shares issued during the reporting period improved from EUR -0.14 in the previous year to EUR -0.10 in the reporting quarter as a result of the lower loss.

**Total assets** as of 29 February 2024 amounted to EUR 61.7 million and were lower compared to the 30 November 2023 reporting date (EUR 70.4 million) as a result of the loss for the period and reduced liabilities and the associated lower cash. At EUR 45.1 million, **equity** was also significantly lower compared to the end of fiscal year 2023 (EUR 49.3 million). This corresponds to an equity ratio of 73.2% (30 November 2023: 70.1%). No corporate actions were implemented during the reporting period. The share capital of Heidelberg Pharma AG therefore remained steady at EUR 46,604,977, divided into 46,604,977 no par value bearer shares.

**Cash** as of the end of the quarter amounted to EUR 32.6 million (30 November 2023: EUR 43.4 million). Heidelberg Pharma thus recorded an average cash outflow of EUR 3.6 million per month in the first quarter of the fiscal year (previous year: EUR 3.7 million).

**Financial outlook for 2024**

The Executive Management Board expects the Heidelberg Pharma Group to generate between EUR 11.0 million and EUR 15.0 million in sales revenue and other income (2023: EUR 16.8 million) in the 2024 fiscal year. This does not yet include the upfront payment of USD 25 million received from HCRx and its effects on operational planning. This inflow was used to repay the remaining shareholder loan of EUR 5 million and substantial additional funds from the partial sale of royalties will be used in the short term to accelerate further ADC projects. Sales revenue from major new license agreements was not included in this planning.

Operating expenses in 2024 are expected to be between EUR 36.0 million and EUR 40.0 million if business develops as planned, and thus roughly at the level of the 2023 reporting year (EUR 38.0 million). This guidance does not include any adjustments to the R&D budget due to the cash inflow from HCRx.

An operating result of between EUR -23.5 million and EUR -27.5 million is expected for 2024 (2023: EUR -21.2 million).

Gross funds used are expected to be between EUR 28.0 million and EUR 32.0 million in the 2024 financial year. This corresponds to an average monthly use of cash of between EUR 2.3 million and EUR 2.7 million (2023: EUR 3.2 million). Based on current planning, the Group is financed until mid-2025, but assumes that the cash reach will be extended due to further expected payments from the agreement with HCRx.

A conference call on this interim management statement will not take place. The complete figures for the interim financial statements can be downloaded from [http://www.heidelberg-pharma.com/ "Press & Investors > Announcements > Financial Reports > Interim management statement on the first three months of 2024"].
Key figures for the Heidelberg Pharma Group (unaudited)

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<th>Q1 2024(^1)</th>
<th>Q1 2023(^1)</th>
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<tr>
<td><strong>Earnings</strong></td>
<td></td>
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<tr>
<td>Sales revenue</td>
<td>1,267 EUR thsd.</td>
<td>2,075 EUR thsd.</td>
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<td>Other income</td>
<td>592 EUR thsd.</td>
<td>95 EUR thsd.</td>
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<tr>
<td>Operating expenses</td>
<td>(6,566 EUR thsd.)</td>
<td>(8,718 EUR thsd.)</td>
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<tr>
<td>of which research and development costs</td>
<td>(5,073 EUR thsd.)</td>
<td>(5,751 EUR thsd.)</td>
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<tr>
<td>Operating result</td>
<td>(4,707 EUR thsd.)</td>
<td>(6,548 EUR thsd.)</td>
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<tr>
<td>Earnings before tax</td>
<td>(4,445 EUR thsd.)</td>
<td>(6,484 EUR thsd.)</td>
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<tr>
<td>Net loss for the period / Comprehensive income</td>
<td>(4,494 EUR thsd.)</td>
<td>(6,563 EUR thsd.)</td>
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<td>Earnings per share in EUR (basic)</td>
<td>(0.10) EUR</td>
<td>(0.14) EUR</td>
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**Balance sheet as of the end of the period**

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<tr>
<td>Total assets</td>
<td>61,666 EUR thsd.</td>
<td>86,476 EUR thsd.</td>
</tr>
<tr>
<td>Cash</td>
<td>32,650 EUR thsd.</td>
<td>65,011 EUR thsd.</td>
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<tr>
<td>Equity</td>
<td>45,114 EUR thsd.</td>
<td>60,165 EUR thsd.</td>
</tr>
<tr>
<td>Equity ratio(^2) in %</td>
<td>73.2 %</td>
<td>69.6 %</td>
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**Cash flow statement**

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<tr>
<td>Cash flow from operating activities</td>
<td>(10,748) EUR thsd.</td>
<td>(10,740) EUR thsd.</td>
</tr>
<tr>
<td>Cash flow from investing activities</td>
<td>(42) EUR thsd.</td>
<td>(302) EUR thsd.</td>
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<tr>
<td>Cash flow from financing activities</td>
<td>(29) EUR thsd.</td>
<td>(5,026) EUR thsd.</td>
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**Employees (number)**

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<tr>
<td>Employees as of the end of the period(^3)</td>
<td>111</td>
<td>109</td>
</tr>
<tr>
<td>Full-time equivalents as of the end of the period(^3)</td>
<td>98</td>
<td>100</td>
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1 The reporting period begins on 1 December and ends on 28/29 February.
2 Equity / total assets
3 Including members of the Executive Management Board
Rounding of exact figures may result in differences.
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 specificity of antibodies with the efficacy of toxins to fight cancer. Selected antibodies are loaded with cytotoxic compounds, 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 therapy by exploiting the toxin's biological mechanism of action with its innovative ATAC technology as a new therapeutic modality. It offers the opportunity to overcome resistance of cancer cells against therapeutic agents currently used and to eliminate dormant tumor cells, which typically survive current therapies and are responsible for tumor relapse and metastasis. 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 a BCMA-ATAC for the indication multiple myeloma, which is currently in clinical development.

In addition to Amanitin, alternative payloads also expand 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 www.heidelberg-pharma.com.

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