

PRESS RELEASE

Heidelberg Pharma announces financial figures for fiscal year 2018 and provides business update

- Key milestones reached for GMP manufacturing of HDP-101
- Preparation of the clinical trial with HDP-101 advanced
- Licensing partnerships to develop Antibody Targeted Amanitin Conjugates with Magenta and Takeda making progress
- Phase III trial submitted and started by collaboration partner Telix
- Significant year-over-year revenue growth
- Conference call to be held on 21 March 2019 at 3:00 p.m. CET

Ladenburg, Germany, 21 March 2019 – Heidelberg Pharma AG (FSE: WL6) today published its financial results and annual report for fiscal year 2018 (1 December 2017 – 30 November 2018) and its outlook for 2019.

“Fiscal year 2018 was highly successful. The Company’s financial position developed positively and in line with planning, with sales revenue nearly doubling. The loss for the year was somewhat smaller than projected, mainly due to the shifting of certain R&D expenses into 2019. Our ATAC technology business performed well. In addition to several research collaborations, we entered into another licensing partnership, and the first option for one of the target molecules under that agreement was already exercised last fall. Indeed, initial positive data from this project have already been presented at major medical conferences. We are delighted that our partner projects are making such good progress,” commented Dr. Jan Schmidt-Brand, Chief Executive Officer and Chief Financial Officer of Heidelberg Pharma AG.

“Regarding our proprietary development candidate HDP-101, the progress made in establishing GMP manufacturing for this program was a particularly important achievement. At the same time, we pushed ahead with preparations for the clinical development program for HDP-101 and were able to sign up well-known clinical centers to participate in our planned first-in-humans study in multiple myeloma. In the meantime, a more specific timeline for the manufacturing of the trial material has been determined, which should enable the Company to discuss details of the trial with the FDA and the Paul-Ehrlich-Institut in the fourth quarter of 2019. Approval of the planned Phase I trial is expected early next year.”

Key events in fiscal year 2018 and operational outlook

- **Establishing GMP manufacturing of HDP-101:** Heidelberg Pharma has successfully transferred the technology for the manufacturing of the Amanitin and the other basic components from its own laboratory to an industrial-scale facility. To the best of Heidelberg Pharma’s knowledge, this remains the world’s first and only industrial-scale source of chemically produced Amanitin. This technology transfer to industrial-scale production was a key milestone for securing the supply of material both for our own projects and those of our partners. The first technical batch of the development candidate HDP-101 based entirely on synthetic Amanitin and the BCMA antibody manufactured previously, was subsequently produced at our production partners. The material from this batch is currently being used for

the concluding toxicity studies run according to **Good Laboratory Practice (GLP)** guidelines in preparation for clinical trials. The complexity of the synthesis presented Heidelberg Pharma and its partners with a number of challenges that were successfully overcome by including additional process steps. The GMP manufacturing process has now been established, although with a delay to the original schedule.

- **Preparation of the clinical trial with HDP-101:** Work proceeded in parallel on the design of the clinical development program for HDP-101. During the presentation of this novel therapeutic approach to the regulatory authorities in Germany (Paul-Ehrlich-Institut) and the USA (FDA), the preclinical program was agreed on and Amanitin's potential for treating cancer was explained. The proprietary ATAC candidate HDP-101 shall be tested in patients with multiple myeloma for the first time. According to the clinical development strategy, applications for the Phase Ia (dose escalation) and Phase Ib (dose expansion) will be submitted simultaneously in the USA and Germany. In the meantime, a more specific timeline for the manufacturing of the trial material has been determined, which should enable the Company to discuss details of the trial with the FDA and the Paul-Ehrlich-Institut in the fourth quarter of 2019. Approval of the planned Phase I trial is expected early next year. The recruitment of patients is then expected to take place based on the activation of the clinical centers.

- **Licensing partnerships to develop ATACs with Magenta and Takeda:** Heidelberg Pharma has signed exclusive multi-target research agreements with Magenta Therapeutics, Cambridge, MA, USA, (March 2018) and Takeda Oncology, Cambridge, MA, USA, (June 2017). These partners are granted access to Heidelberg Pharma's ATAC platform technology for use on their antibodies and have the option of obtaining an exclusive license for the global development and commercialization rights to each of the product candidates resulting from this collaboration. Takeda has this option for up to three targets, Magenta for up to four.

In October 2018, Magenta exercised its option for the further development of a target molecule and will proceed to develop an ATAC based on this as part of an exclusive licensing agreement. Magenta also published its initial work with CD45 and CD117 antibodies. Preclinical trials used to investigate the suitability of these ATACs in the conditioning (preparing) of patients for bone marrow cell transplants delivered very positive data.

The partnership with Takeda is also proceeding as agreed, although no data have yet been published.

- **Collaboration partner Telix submitted clinical trial application for Phase III study:** In 2018, Telix Pharmaceuticals Limited, Melbourne, Australia, the Company's collaboration partner for the imaging agent REDECTANE[®], submitted a Clinical Trial Application (CTA) to conduct a Phase III trial for ⁸⁹Zr-DFO-girentuximab (TLX250) for the imaging of renal (kidney) cancer with Positron Emission Tomography (PET). The study is currently conducted as a global multicenter Phase III trial at sites in Europe and Australia and is scheduled to enroll around 250 renal cancer patients who are to undergo kidney surgery. Subject to regulatory approvals, study centers are also expected to open in the United States and Canada during 2019. The study will determine the sensitivity and specificity of TLX250 PET imaging to detect clear cell renal cell cancer (ccRCC) in comparison with histologic ground truth determined from surgical resection specimens.
- **Legal dispute with Siemens settled:** Heidelberg Pharma AG reached an agreement with Siemens Corporation, Iselin, NJ, USA, on a payment of USD 500 thousand including legal costs and interest to finally settle the legal dispute regarding a rent guarantee for Nuclea

Biotechnologies. This settlement was preceded by a judgment requiring Heidelberg Pharma to pay USD 549 thousand. Heidelberg Pharma had previously recognized a provision covering almost the entire financial obligation.

- **Annual Meeting of the American Society of Hematology (ASH):** In December 2018, various abstracts were published at the 60th Annual Meeting of the American Society of Hematology (ASH) in San Diego. Licensing partner Magenta presented several posters with very positive preclinical data concerning the two ATAC projects (CD45 and CD117 antibodies) from its collaboration with Heidelberg Pharma. For HDP-101, data from the collaboration with the US-based MD Anderson Cancer Center were introduced in an oral presentation. These data show that ATACs have the potential, also in multiple myelomas, to preferentially attack tumor cells with aggressive progressions in connection with a 17p deletion.

Key events after the reporting period

- **IND approval and milestone payment from Link Health:** In January 2019, Heidelberg Pharma announced that the IND application submitted by Link Health for conducting clinical trials with MESUPRON® was approved. Due to changes in the trial regulations of the Chinese regulatory authority, there is now a chance that a Phase II trial can begin immediately based on earlier data from the USA and Europe. A milestone payment became payable to Heidelberg Pharma when the trial was granted approval in principle. In this context, EUR 421 thousand was recognized in profit or loss.

Key financial figures of the Heidelberg Pharma Group for fiscal year 2018

Fiscal year 2018 ran from 1 December 2017 to 30 November 2018. The Heidelberg Pharma Group comprises two entities, Heidelberg Pharma AG and Heidelberg Pharma Research GmbH.

In fiscal year 2018, the Heidelberg Pharma Group lifted **sales revenue** by 93% to EUR 3.7 million (previous year: EUR 1.9 million), which was mainly attributable to Heidelberg Pharma Research GmbH (EUR 3.5 million). Of this figure, the ATAC technology accounted for EUR 2.6 million and the service business for EUR 0.9 million. The parent company's sales revenue (EUR 0.2 million) was related to the out-licensing of REDECTANE®.

At EUR 0.7 million, **other income** was up compared to the previous year (EUR 0.6 million). This figure includes German and European grants, which support Heidelberg Pharma Research GmbH projects in the amount of EUR 0.1 million (previous year: EUR 0.2 million). Furthermore, income of EUR 0.2 million (previous year: EUR 0.3 million) was generated from the reversal of unutilized accrued liabilities and provisions, most of which were subject to limitation. The parent company generated EUR 0.2 million for the first time from passing on patent costs in the context of out-licensing. Other items amounted to income of EUR 0.2 million (previous year: EUR 0.1 million).

Operating expenses including depreciation and amortization rose to EUR 16.0 million in 2018 (previous year: EUR 13.2 million) as planned. **Research and development costs** rose year-over-year to EUR 10.7 million (previous year: EUR 9.3 million) according to plan, due to the expansion of cost-intensive external GMP production. At 67% of operating expenses, R&D remained the largest cost item. **Cost of sales** increased to EUR 2.2 million (previous year: EUR 1.0 million) and represented 14% of operating expenses. **Administrative costs** were EUR 2.9 million, up on the prior-year figure of EUR 2.7 million and accounted for 18% of operating expenses.

Other expenses for business development, marketing and commercial market supply activities were unchanged year-over-year at EUR 0.2 million. They accounted for 1% of operating expenses.

The Heidelberg Pharma Group recognized **earnings before tax** of EUR -11.7 million (previous year: EUR -11.0 million) in the 2018 fiscal year. **Net loss for the year** was also EUR 11.7 million (previous year: EUR 11.0 million). Despite the higher loss, basic **earnings per share** improved from EUR -0.76 in the previous year to EUR -0.41 in 2018 due to the increase in the average number of shares issued.

At the end of the fiscal year, **total assets** amounted to EUR 31.2 million, down EUR 10.3 million from the previous year (EUR 41.5 million), due mainly to the expense-related decrease in cash funds and the corresponding decrease in equity.

Heidelberg Pharma had **cash and cash equivalents** of EUR 19.4 million at the end of the fiscal year (30 November 2017: EUR 30.4 million). The expected decrease resulted from the liquidity outflow triggered by the operating business. Monthly cash use increased to EUR 0.9 million (previous year: EUR 0.7 million). The **Group's equity** amounted to EUR 25.9 million (30 November 2017: EUR 37.0 million). This corresponds to an equity ratio of 83.0% (30 November 2017: 89.2%).

Financial outlook on 2019 and strategy

The Heidelberg Pharma Group expects to generate between EUR 5.0 million and EUR 7.0 million in sales revenue and other income (2018: EUR 4.4 million) for the 2019 fiscal year. According to current plans, operating expenses should be in the range of EUR 14.0 million to EUR 18.0 million (2018: EUR 16.0 million). Earnings before interest and taxes (EBIT) for 2019 are projected to be between EUR -8.0 million and EUR -12.0 million (2018: EUR -11.7 million).

Heidelberg Pharma expects to require funds of EUR 10.0 million to EUR 14.0 million in 2019. Monthly cash use should be in the range of EUR 0.9 million to EUR 1.2 million.

This planning takes into account additional potential cash inflows from new licensing activities at Heidelberg Pharma Research. The Group's financing is secured until mid-2020 based on current planning.

Heidelberg Pharma's strategy focuses on the development and marketing of its proprietary ATAC technology. Its core elements are the expansion of the Company's own project pipeline, 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 21 March 2019, Heidelberg Pharma will hold a conference call for media, analysts and investors in English at 3:00 p.m. CET. Please dial in 10 minutes before the call using the following dial-in numbers:

1. Germany: +49 69 71044 5598
2. UK: +44 20 3003 2666
3. USA: +1 212 999 6659
4. USA Freephone: +1 866 966 5335

You will be welcomed by an operator who will ask for the password (Heidelberg Pharma) and take your name and company. The presentation for the conference (in English) will be available for download at www.heidelberg-pharma.com from 2:30 p.m. CEST.

Key figures for the Heidelberg Pharma Group

In EUR million	2018 ¹ EUR million	2017 ¹ EUR million
Earnings		
Sales revenue	3.7	1.9
Other income	0.7	0.6
Operating expenses	(16.0)	(13.2)
of which research and development costs	(10.7)	(9.3)
Operating result	(11.7)	(10.8)
Earnings before tax	(11.7)	(11.0)
Net loss for the year	(11.7)	(11.0)
Earnings per share in EUR (basic)	(0.41)	(0.76)
Balance sheet as of the end of the period		
Total assets	31.2	41.5
Cash and cash equivalents	19.4	30.4
Equity	25.9	37.0
Equity ratio ² in %	83.0	89.2
Cash flow statement		
Cash flow from operating activities	(10.0)	(7.9)
Cash flow from investing activities	(1.0)	(0.4)
Cash flow from financing activities	0	34.2
Employees (number)		
Employees at year end ³	66	58
Employees at year end ³ (full-time equivalents)	60	52

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>.

Contact

Heidelberg Pharma AG
Corporate Communications
Sylvia Wimmer
Tel.: +49 89 41 31 38-29
Email: investors[at]hdpharma.com
Schriesheimer Str. 101, 68526 Ladenburg

IR/PR support

MC Services AG
Katja Arnold (CIRO)
Managing Director & Partner
Tel.: +49 89 210 228-40
Cell: +49 (0)160 9360 3022
Email: katja.arnold[at]mc-services.eu

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 using its proprietary Antibody Targeted Amanitin Conjugate (ATAC) technology and to advance the biological mode of action of the toxin as a novel therapeutic principle. This proprietary technology platform is being applied to develop the Company's proprietary therapeutic ATACs as well as in third-party collaborations to create a variety of ATAC candidates. The proprietary lead candidate HDP-101 is a BCMA ATAC for multiple myeloma.

The Company has entered into partnerships to further develop and commercialize its clinical assets MESUPRON® and REDECTANE®, while RENCAREX® is available for out-licensing and further development. Heidelberg Pharma AG is listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol WL6. More information is available at www.heidelberg-pharma.com.

This communication contains certain forward-looking statements relating to the Company's business, which can be identified by the use of forward-looking terminology such as "estimates", "believes", "expects", "may", "will", "should", "future", "potential" or similar expressions or by a general discussion of the Company's strategy, plans or intentions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results of operations, financial condition, performance, achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Given these uncertainties, prospective investors and partners are cautioned not to place undue reliance on such forward-looking statements. We disclaim any obligation to update any such forward-looking statements to reflect future events or developments.