Heidelberg Pharma AG: Interim management statement on the first nine months of 2018

- Key milestones reached for GMP manufacturing of HDP-101
- Final GLP preclinical studies set to start in the next few weeks
- Licensing partnerships to develop Antibody Targeted Amanitin Conjugates with Magenta and Takeda making progress
- Application for approval of a Phase III trial submitted by collaboration partner Telix
- Significant year-on-year revenue growth; costs shifted into following year

Ladenburg, 11 October 2018 – Heidelberg Pharma AG (FSE: WL6) today reported on the first nine months of fiscal year 2018 (1 December 2017 – 31 August 2018) and the Group's financial figures.

Dr. Jan Schmidt-Brand, CEO and CFO of Heidelberg Pharma AG, commented: “We have seen a positive trend in our revenues, and we are making good progress in all areas of the Company. The collaboration with our ATAC partners Takeda and Magenta is developing promisingly.

In recent months, Heidelberg Pharma has been focusing on establishing external GMP manufacturing capacity for our toxin Amanitin and our BCMA antibody drug conjugate HDP-101. The synthesis for Amanitin is highly complex and presented us with major challenges that have since been overcome by carrying out some additional process steps. As far as we are aware, this is the world’s first and so far only industrial source of chemically produced Amanitin, which is essential for both HDP-101 and our partner projects.

At the same time, we have been working on the design of our clinical development program for HDP-101. After presenting the preclinical program to the authorities in Germany and the USA in the second quarter, we were able to bring several important and renowned clinical centers in Germany, Spain and the USA on board for our HDP-101 project and will continue to push ahead with trial planning together with these institutions. As it is now easier to determine a timeline for production, we are planning to submit the trial application in the second quarter of 2019. Depending on how the approval procedure unfolds, the first patients could start receiving treatment in the second half of 2019.”

Important operational achievements

- **Establishing GMP production:** One of the key projects in recent months was the transfer of the manufacturing technology for both Amanitin and selected linkers from the Heidelberg Pharma laboratories to an industrial plant at production partner Carbogen Amcis AG, Bubendorf, Switzerland (“Carbogen”) in accordance with **G**ood **M**anufacturing **P**ractice (GMP) standards. Amanitin is manufactured on an industrial scale at Carbogen to enable Heidelberg Pharma to supply its own clinical studies and that of its partners going forward. The complexity of the synthesis posed new challenges that Heidelberg Pharma and Carbogen were able to overcome. Manufacturing has now been established, although with a delay to the original schedule. The compound is now available in the necessary quantity and quality, as is the BCMA antibody required for the production of HDP-101. The HDP-101 end product will be combined and synthesized in the next few weeks.

- **Preparation of the clinical trial:** As part of the preparations for the clinical trial of HDP-101, the novel therapeutic approach had to be presented to regulatory authorities, namely the Paul Ehrlich Institute in Germany and the FDA in the USA ("scientific advice" / "type C meeting"). This involved coordinating the preclinical program and outlining Amanitin's potential as a cancer therapy. The final GLP toxicology study will begin this year in accordance with **G**ood **L**aboratory **P**ractice. Another key component of this work is recruiting clinical centers and specialists to be used for the treatment of multiple myeloma. Several highly renowned centers have been enlisted for the trial, with Heidelberg Pharma acting as a trial design advisor.
- **Licensing partnerships to develop Antibody Targeted Amanitin Conjugates 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 have access to Heidelberg Pharma's Amanitin linker platform technology for use on their antibodies and have the option for an exclusive license for global development and commercialization rights to each of the product candidates resulting from this collaboration. Both partners are working on the selection and optimization of their antibodies and are conducting initial tests. The collaboration is going very well and progress is being made.
- **Partner Telix submits application for approval of a clinical trial:** In August 2018, Telix Pharmaceuticals Limited, Melbourne, Australia, the Company's collaboration partner for the imaging agent REDECTANE®, submitted a Clinical Trial Application (CTA) to initiate a Phase III trial in Europe for ^{89}Zr-DFO-girentuximab (TLX250) for the imaging of renal (kidney) cancer with Positron Emission Tomography (PET). Subject to regulatory approvals in the various jurisdictions, the trial will be conducted as a global multi-center Phase III study with 15 sites in Europe, up to four sites in Australia and six to eight sites in the US and enroll around 250 renal cancer patients undergoing kidney surgery. 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 Siemens settled:** Heidelberg Pharma AG offered to pay Siemens Corporation, Iselin, NJ, USA, USD 500 thousand including legal costs and interest to settle the legal dispute, which Siemens has accepted. This offer was preceded by a judgment requiring Heidelberg Pharma to pay USD 549 thousand. The amicable agreement ends the legal dispute. Heidelberg Pharma had previously recognized a provision covering almost the entire financial obligation.
- **Annual General Meeting of Heidelberg Pharma AG:** On 26 June 2018, the Annual General Meeting of Heidelberg Pharma AG took place in Heidelberg. In addition to the approval of the annual financial statements, the formal approval of the actions of the members of the Executive Management Board and Supervisory Board and the election of the auditor, the Annual General Meeting adopted the following resolutions: creation of new Authorized Capital 2018/I, authorization to grant stock options and approval of the system for the remuneration of the members of the Executive Management Board.

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 2017 to 31 August 2018 (9M 2018).

In the first nine months of the 2018 fiscal year, the Group generated sales revenue and income totaling EUR 3.5 million (previous year: EUR 1.6 million). This figure includes **sales revenue** of EUR 3.1 million (previous year: EUR 1.4 million), which stems from the collaboration agreements for the ATAC technology (EUR 2.0 million), the service business (EUR 0.8 million) and income from license agreements signed by the parent company (EUR 0.3 million).

At EUR 0.4 million, **other income** was up on the prior-year figure (EUR 0.2 million). It primarily consisted of German and European grants and of the reversal of unutilized accrued liabilities and provisions.

Operating expenses including depreciation and amortization amounted to EUR 10.9 million in the reporting period (previous year: EUR 9.1 million). **Cost of sales** concerns costs were incurred for the service business and the ATAC collaborations; they amounted to EUR 1.3 million (previous year: EUR 0.6 million). **Research and development (R&D) costs** of EUR 7.4 million were up EUR 1.0 million compared to the prior-year period (EUR 6.4 million) due to an increase in costs related to preparations for GMP production and GLP studies incurred by Heidelberg Pharma Research GmbH. At 67% of operating expenses, R&D was by far the largest cost item as expected. **Administrative costs** in the third quarter of 2018 edged up slightly to EUR 2.1 million compared to the prior-year period (EUR 2.0 million). Among others, this figure includes holding company costs and costs related to the stock market listing. **Other expenses** for business development, marketing and commercial market supply activities in the current reporting period remained steady year-over-year at EUR 0.1 million.

The **net loss** for the first nine months of the fiscal year fell to EUR 7.4 million (previous year: EUR 7.6 million).

Earnings per share improved from EUR -0.55 in the previous year to EUR -0.27, mainly due to the higher average number of shares.

Total assets as of 31 August 2018 decreased to EUR 34.9 million compared to the 30 November 2017 reporting date (EUR 41.5 million) as a result of a decrease in cash and cash equivalents. At EUR 30.0 million, **equity** was also down compared to the end of fiscal year 2017 (EUR 37.0 million). This corresponds to an equity ratio of 86.0% (30 November 2017: 89.2%). The exercise of (mandatory) convertible bonds in the first nine months of the fiscal year resulted in 5,677,174 new no par value shares that increased the share capital of Heidelberg Pharma AG from EUR 22,452,570 to EUR 28,129,744, divided into 28,129,744 no par value bearer shares.

No corporate actions were implemented during the reporting period.

Cash and cash equivalents as of the end of the quarter amounted to EUR 22.7 million (30 November 2017: EUR 30.4 million). This represents an average monthly cash outflow of EUR 0.85 million in the first nine months of the fiscal year (previous year: EUR 0.56 million without taking into account the capital increase in May 2017).

Financial outlook for 2018

Heidelberg Pharma has adjusted its full-year financial guidance issued for Heidelberg Pharma Group in mid-March 2018. This is due to costs being shifted into the following year.

The Group expects to generate between EUR 3.5 million and EUR 4.5 million in sales revenue and other income (previously: EUR 3.0 million to EUR 5.0 million; 2017: a total of EUR 2.5 million) for the 2018 fiscal year. According to current plans, operating expenses should be in the

range of EUR 14.0 million to EUR 16.0 million (previously: EUR 16.0 million to EUR 20.0 million; 2017: EUR 13.2 million). Earnings before interest and taxes (EBIT) for the 2018 fiscal year are projected to be between EUR -10.0 million and EUR -12.0 million (previously: EUR -12.0 million and EUR -16.0 million; 2017: EUR -10.8 million).

Heidelberg Pharma expects to require funds of EUR 10.0 million to EUR 13.0 million in 2018 (previously: EUR 13.0 million to EUR 17.0 million). Monthly cash use should be in the range of EUR 0.8 million and EUR 1.1 million (previously: EUR 1.1 million and EUR 1.4 million). Based on the updated planning, the Company's financing remains secured into 2020.

Heidelberg Pharma will not host a conference call on this interim management statement. 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 11 October 2018”.

Key figures for the Heidelberg Pharma Group

In EUR thsd.	9M 2018 [1] EUR thsd.	9M 2017 [1] EUR thsd.
Earnings		
Sales revenue	3,052	1,393
Other income	417	235
Operating expenses	(10,886)	(9,079)
of which research and development costs	(7,344)	(6,407)
Operating result	(7,417)	(7,451)
Earnings before tax	(7,417)	(7,619)
Net loss for the period	(7,417)	(7,619)
Basic earnings per share in EUR	(0.27)	(0.55)
Balance sheet as of the end of the period		
Total assets	34,881	15,112
Cash and cash equivalents	22,709	4,491
Equity	30,009	7,208
Equity ratio[2] in %	86.0	47.7
Cash flow statement		
Cash flow from operating activities	(6,859)	(4,705)
Cash flow from investing activities	(811)	(333)
Cash flow from financing activities	0	4,975
Employees (number)		
Employees as of the end of the period[3]	62	55
Full-time equivalents as of the end of the period[3]	56	50

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 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.