Heidelberg Pharma AG: Interim Management Statement on the First Nine Months of 2019

- Sales revenue continues its positive trend in third quarter
- 2019 guidance raised after year-on-year doubling of sales revenue
- Supply of GMP-quality Amanitin to partners established
- Schedule clarified for HDP-101 (BCMA-ATAC)
- Progress made by partners Link Health and Telix triggered milestone payments
- Further research grant received to continue MAGICBULLET EU project

Ladenburg, Germany, 10 October 2019 – Heidelberg Pharma AG (FSE: WL6) today reported on the first nine months of fiscal year 2019 (1 December 2018 – 31 August 2019) and the Group's financial figures.

Dr. Jan Schmidt-Brand, CEO and CFO of Heidelberg Pharma AG, commented: “We are pleased to see that sales revenue continued its positive trend in the third quarter. This is due to our successful collaborations and to the decision made at the beginning of the year to offer and coordinate the GMP-quality Amanitin material supply of the licensing partners within the framework of the respective license agreement. Our positive performance in this area reinforces our strategic decision to step up our involvement in the production and delivery process for Amanitin.

As regards our development candidate HDP-101, we are currently continuing to gradually work through the hurdles encountered in the second quarter in the formulation of the Antibody Drug Conjugate. Based on current planning, we should be in a position to submit the clinical trial application in the second half of 2020.”

Important operational developments and achievements

- **HDP-101 (BCMA ATAC) development program:** Heidelberg Pharma is working hard to finalize the manufacturing process and complete the preclinical data package for HDP-101, a BCMA Antibody Targeted Amanitin Conjugate for treating multiple myeloma. At the start of the year, the first batch of the HDP-101 development candidate was manufactured by our production partner Carbogen AMCIS AG, Bubendorf, Switzerland, (Carbogen) who is responsible for manufacturing the Amanitin linker material. In addition to a synthetic variant of Amanitin, the starting materials also include the BCMA antibody already manufactured by Celonic AG, Basel, Switzerland, (Celonic). This batch is being used to produce the final clinical trial material and must be formulated for use on patients to ensure stability. At the same time, the tolerability of the clinical trial material must be demonstrated in a series of toxicity studies. This has shown that the galenic formulation requires further optimization in the final step of the manufacturing process. Heidelberg Pharma is working with Carbogen on the necessary process adjustments. These additional process steps and the corresponding efforts to secure production capacity determine the time schedule and the development program. Heidelberg Pharma expects the preclinical data package to be fully available by mid-2020, enabling the application to be made thereafter.

  At the same time, the first parts of the toxicology program coordinated with the authorities were successfully completed in 2019, and the synopsis of the Phase I trial of the clinical

development program for HDP-101 was prepared. Clinical centers in the USA and Germany have been identified and enlisted for the program. Heidelberg Pharma signed a framework agreement with a service provider for the clinical trial and began working on the documentation for submitting the clinical trial application.

- **Amanitin production in accordance with Good Manufacturing Practice (GMP) – provision of material to partners (supply model):** The successful technology transfer of Amanitin production to an industrial scale was a key milestone for safeguarding the supply of material both for our own projects and for those of our licensees. As a result, Heidelberg Pharma now has the technology to provide its license partners with the necessary GMP-quality Amanitin linker material.

  Heidelberg Pharma signed framework agreements with GMP manufacturer Carbogen and licensees so that the material supply can be offered together with Carbogen. The Company has begun manufacturing several batches for the partners.

- **Progress with partner Link Health:** In January 2019, Heidelberg Pharma announced that the IND application submitted by the partner Link Health Co. Guangzhou, China, (Link Health) for a Phase I and II trial with MESUPRON® had been approved at the end of 2018.

- **Progress with partner Telix:** After licensing the imaging, radioactive labeled antibody TLX250-CDx (formerly REDECTANE®), Heidelberg Pharma's collaboration partner Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix), set up a new and modernized production process for the antibody Girentuximab. As part of this process, one of the contractually defined milestones was reached and a payment of USD 250 thousand was received in June. In August, the first patient in Australia was enrolled in the Phase III study (ZIRCON) with TLX250-CDx. At the end of August, Telix announced that it had received approval to carry out a Phase I/II study with TLX250-CDx in Japan. This acts as a bridging study to ZIRCON to demonstrate that the pharmacology and dosage for Japanese patients is comparable with existing results.

Events after the reporting period

- **EU-funded MAGICBULLET project continued:** In September, Heidelberg Pharma announced that the EU funding project MAGICBULLET is being continued. The project, which has been running since 2015 as part of the HORIZON 2020 program, is to be continued from 2019 to 2023 and will involve funding for all project partners amounting to up to EUR 3.9 million. The research field is being expanded from small molecule-drug conjugates to peptide-drug conjugates and will focus on candidates that stimulate the immune response to tumors and can overcome resistance to immunotherapies. Heidelberg Pharma is also planning to expand its Amanitin conjugate research to include peptide-Amanitin conjugates and will not only identify and validate tumor-specific drug conjugates during the new funding period but will also investigate their biological activity in *in vitro* and *in vivo* tests.

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 2018 to 31 August 2019 (9M 2019).

In the first nine months of the 2019 fiscal year, the Group generated sales revenue and income totaling EUR 6.7 million (previous year: EUR 3.5 million). This figure includes **sales revenue** of EUR 6.2 million, which represents a doubling compared with the previous year's total of

EUR 3.1 million and stems from the collaboration agreements including the supply of Amanitin linkers for the ATAC technology (EUR 5.0 million), the service business (EUR 0.5 million) and income from license agreements signed by the parent company (EUR 0.7 million).

At EUR 0.5 million, **other income** was up slightly on the prior-year figure of EUR 0.4 million. It primarily consisted of the charging on of patent costs, of German and European grants and of the reversal of unutilized accrued liabilities and provisions.

Operating expenses including depreciation and amortization amounted to EUR 12.4 million in the reporting period (previous year: EUR 10.9 million). **Cost of sales** rose to EUR 2.8 million (previous year: EUR 1.3 million) due to the ATAC collaborations including material supply. **Research and development** costs, which were EUR 7.4 million the previous year, fell slightly to EUR 7.2 million in the reporting period as a result of delays in the manufacturing process and the postponement of cost items for required and outstanding GLP toxicity studies. However, at 59% of operating expenses, this category remained the largest cost item.

Administrative costs edged up slightly to EUR 2.2 million compared to the prior-year period (EUR 2.1 million). Among others, this figure includes holding company costs and costs related to the stock market listing.

Other expenses for business development and marketing of the technology in the reporting period totaled EUR 0.2 million (previous year: EUR 0.1 million) due to an expansion of activities.

The **net loss** for the first nine months of the fiscal year fell to EUR 5.6 million (previous year: EUR 7.4 million) as a result of the items described above.

Earnings per share thus improved from EUR -0.26 in the previous year to EUR -0.20.

Cash and cash equivalents as of the end of the third quarter amounted to EUR 12.7 million (30 November 2018: EUR 19.4 million). This represents an average monthly cash outflow of EUR 0.75 million in the first nine months of the fiscal year (previous year: EUR 0.85 million). No corporate actions were implemented during the reporting period.

Total assets as of 31 August 2019 decreased to EUR 25.9 million compared to the 30 November 2018 reporting date (EUR 31.2 million) as a result of a decrease in cash and cash equivalents. At EUR 20.6 million, **equity** was also down compared to the end of fiscal year 2018 (EUR 25.9 million). This corresponds to an equity ratio of 79.4% (30 November 2018: 83.0%). The exercise of (mandatory) convertible bonds from a previous corporate action in the first nine months of the fiscal year resulted in 24,707 new no par value shares that increased the share capital of Heidelberg Pharma AG from EUR 28,133,308 to EUR 28,158,015, divided into 28,158,015 no par value bearer shares.

Financial outlook for 2019

Given the positive trend in sales revenue and cost postponements into 2020, Heidelberg Pharma raises its full-year financial guidance for 2019 issued for the Heidelberg Pharma Group in mid-March.

The Heidelberg Pharma Group expects to generate between EUR 7.5 million and EUR 8.5 million in sales revenue and other income for the 2019 fiscal year (previously: between EUR 5.0 million and EUR 7.0 million). According to current plans, operating expenses will be in the range of EUR 15.5 million to EUR 17.5 million (previously EUR 14.0 million to EUR 18.0 million). Earnings before interest and taxes (EBIT) for 2019 are projected to be between EUR -7.5 million and EUR - 9.5 million (previously: between EUR -8.0 million and EUR -12.0 million).

Heidelberg Pharma expects to require funds of EUR 8.0 million to EUR 10.0 million in 2019 (previously: EUR 10.0 million to EUR 14.0 million). Monthly cash use should be in the range of EUR 0.7 million to EUR 0.9 million (previously: between EUR 0.9 million and EUR 1.2 million). Based on the updated planning, the Company's financing remains secured until mid-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 10 October 2019".

Key figures for the Heidelberg Pharma Group

In EUR thsd.	**9M 2019** [1] **EUR thsd.**	**9M 2018** [1] **EUR thsd.**
Earnings		
Sales revenue	6,180	3,052
Other income	561	417
Operating expenses	(12,385)	(10,886)
of which research and development costs	(7,241)	(7,344)
Operating result	(5,644)	(7,417)
Earnings before tax	(5,644)	(7,417)
Net loss for the period	(5,649)	(7,417)
Basic earnings per share in EUR	(0.20)	(0.27)
Balance sheet as of the end of the period		
Total assets	25,912	34,881
Cash and cash equivalents	12,709	22,709
Equity	20,582	30,009
Equity ratio[2] in %	79.4	86.0
Cash flow statement		
Cash flow from operating activities	(5,921)	(6,859)
Cash flow from investing activities	(800)	(811)
Cash flow from financing activities	0	0
Employees (number)		
Employees as of the end of the period[3]	70	62
Full-time equivalents as of the end of the period[3]	65	56

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®. Heidelberg Pharma AG is listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol WL6. More information is available at http://www.heidelberg-pharma.com.