

## PRESS RELEASE

### Heidelberg Pharma Announces Financial Figures for Fiscal Year 2019 and Provides Business Update

- Preparation of the clinical trial with HDP-101 advanced
- Material supply of partners with Amanitin established
- Partnership with Magenta opens up new areas of application for ATAC technology
- Pivotal Phase III trial initiated by collaboration partner Telix
- Significant year-over-year revenue growth
- Financing commitment of up to EUR 15 million from main shareholder dievini
- Conference call to be held on 19 March 2020 at 3:00 p.m. CET

**Ladenburg, Germany, 19 March 2020** – Heidelberg Pharma AG (FSE: WL6) today published its financial results and annual report for fiscal year 2019 (1 December 2018 – 30 November 2019) and its outlook for 2020.

Dr. Jan Schmidt-Brand, Chief Executive Officer and Chief Financial Officer of Heidelberg Pharma AG, said: “We achieved important milestones in the development of our ATAC technology during the 2019 fiscal year and are getting closer to reaching our goal of testing Antibody Targeted Amanitin Conjugates in cancer patients for the first time. Together with our partners, we are excited about the potential to apply the unique mode of action of ATACs to make a positive impact on the lives of cancer patients. In particular, our licensing partnership with Magenta has developed very successfully and the first ATAC candidate, MGTA-117, is being prepared for clinical development. We were delighted that Magenta also exercised their option for an additional target molecule; their preclinical data suggest that the ATAC technology could be used with suitable antibodies not only for oncology but also autoimmune diseases. On the supply front, we are now able to produce GMP-quality Amanitin not only for our own projects but also for our partners, which has enabled us to generate additional sales revenue. Due to the Company’s positive economic development, we were able to almost double our sales revenue compared to the previous year.”

“Despite the excellent progress we made in 2019, we also had to overcome some unexpected challenges with our own development candidate HDP-101, as the pharmaceutical formulation of the clinical compound had to be redesigned, which led to delays in the development program. Our plan is now to complete preclinical testing with the new trial material during 2020; the application to initiate the first clinical trial in multiple myeloma can then be submitted to regulatory authorities. The year ahead will continue to be a busy one for us, and we are glad that the financing commitment of our main shareholder dievini has secured our development plans until mid-2021.”

#### Key events in fiscal year 2019 and operations outlook

- **Preparation of the clinical trial with HDP-101:** The Company continued to push ahead with preparations for formal preclinical and clinical development of HDP-101 in 2019. As part of this process, the tolerability of the clinical trial material must be demonstrated in a series of toxicity studies to ensure patient safety. In the first half of 2019, those studies revealed that the pharmaceutical formulation would have to be improved prior to use in patients. Heidelberg

Pharma and its external manufacturers jointly developed the necessary process adjustments. Implementing these changes and ensuring the necessary manufacturing capacities delayed the development schedule by approximately one year. Heidelberg Pharma expects the preclinical data package to be fully available during 2020, enabling the application to be made thereafter.

At the same time, certain parts of the toxicology program agreed with the authorities were completed successfully in 2019. The synopsis for the Phase I trial in the clinical development program for HDP-101 was completed, and 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 work on the documentation for submitting the clinical trial application has begun.

- **Providing partners with Amanitin material:** The successful technology transfer of Amanitin production to an industrial scale was a key milestone for safeguarding the supply of material for Heidelberg Pharma's own projects and those of its partners. In the meantime, processes for other Amanitin variants which extend beyond the derivative used for HDP-101 are being established. In a complementary move, Heidelberg Pharma developed organizational and contractual prerequisites to safeguard production plans for the timely supply of Amanitin not only for its own projects, but also for those of its partners. Framework agreements with GMP manufacturer Carbogen and licensees were signed to ensure that Heidelberg Pharma can offer to provide materials together with Carbogen. The Company has begun manufacturing several batches for its partners. Heidelberg Pharma now has the technology and organization in place to provide its licensing partners with the necessary GMP-quality Amanitin linker material.
- **Partnership with Magenta opens up new areas of application for ATAC technology:** After exercising the option for the further development of the target molecule CD117 in October 2018, licensing partner Magenta Therapeutics, Cambridge, MA, USA, (Magenta) also exercised the option for the target molecule CD45 in November 2019 and will proceed to develop Antibody Targeted Amanitin Conjugates based on these under an exclusive license agreement. Magenta presented first scientific works with CD45 and CD117 ADCs. Preclinical trials were used to successfully investigate the suitability of these ATACs in the conditioning (preparing) of patients for stem cell transplants. These trials showed very good data. Thus, further successful development of these approaches could open up innovative fields of application beyond oncology for diseases of the immune system.

In January 2020, Magenta also announced the ATAC MGTA-117 as a clinical candidate for the targeted preparation of patients (conditioning) for stem cell transplants or gene therapies. MGTA-117 is an ATAC that consists of a CD117 antibody and the toxin Amanitin and was developed as part of the partnership with Heidelberg Pharma.

- **Participation in the Franco-German joint venture Emergence Therapeutics:** Since November 2019, Heidelberg Pharma has held an equity interest in the newly founded joint venture Emergence Therapeutics AG, Duisburg, Germany, together with French and German investors. Under a license and development agreement, Heidelberg Pharma will contribute its proprietary toxin linker technology for Antibody Targeted Amanitin Conjugates (ATACs), manufacture the experimental ATAC molecules and participate in research work as a co-partner of the joint venture.

- **Collaboration partner Telix initiates Phase III trial:** In August 2019, Telix Pharmaceuticals Limited, Melbourne, Australia, (Telix), the Company's collaboration partner for the imaging agent TLX250-CDx, initiated a Phase III trial (ZIRCON) with TLX250-CDx for the imaging of renal cancer using Positron Emission Tomography (PET). The study will be conducted as a global multicenter Phase III trial at sites in Europe, Australia and the USA, and enrolls around 250 renal cancer patients who are to undergo 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. Patient recruitment initially began in Australia and is now being carried out in Europe and the USA as well. Recruitment for the entire study is scheduled for completion in the second quarter of 2020.

#### Key events after the reporting period

- **Financing commitment by main shareholder dievini:** In January 2020, Heidelberg Pharma received a financing commitment in the amount of up to EUR 15 million from its main shareholder dievini Hopp Biotech holding GmbH & Co. KG, Walldorf, Germany, (dievini). With this additional commitment, the Company's cash reach is secured until mid-2021.
- **US patent rights granted for diagnosis and treatment of patients with TP53/RNA polymerase II deletion:** In March 2020, Heidelberg Pharma's partner MD Anderson Cancer Center, Houston, TX, USA, (MD Anderson) received patent rights from the US patent office for diagnosis and treatment of selected patient groups with TP53/RNA polymerase II deletion. The patent is based on research that was co-published by MD Anderson and Heidelberg Pharma in *Nature* in April 2015 and which was obtained with the proprietary ATAC technology and the compound Amanitin. Heidelberg Pharma holds an exclusive license to these patent rights.
- **Partner RedHill announces new study with MESUPRON®:** Heidelberg Pharma's partner RedHill Biopharma Ltd., Tel Aviv, Israel, (RedHill) announced in March 2020 that it will test upamostat (RHB-107/MESUPRON®) as a third arm in a Phase I/IIa combination study in the indication cholangiocarcinoma once an agreement with the FDA has been reached. The partner also intends to test upamostat in combination with other drug candidates in an exploratory COVID-19 program. Preclinical data showed indications of an anti-viral activity of upamostat.

#### Key financial figures of the Heidelberg Pharma Group for fiscal year 2019

Fiscal year 2019 ran from 1 December 2018 to 30 November 2019. The Heidelberg Pharma Group comprises two entities, Heidelberg Pharma AG and Heidelberg Pharma Research GmbH.

In the 2019 fiscal year, the Heidelberg Pharma Group generated **sales revenue** of EUR 7.3 million, thus almost doubling the prior-year figure of EUR 3.7 million. Sales revenue mainly stems from the cooperation agreements for the ATAC technology of Heidelberg Pharma Research (EUR 6.1 million). In addition to the service business of Heidelberg Pharma Research GmbH (EUR 0.6 million), the parent company contributed another EUR 0.6 million to sales revenue generated from the out-licensing of the product candidates TLX250-CDx and MESUPRON®.

At EUR 0.7 million, **other income** was on a level with the previous year. This figure includes government grants supporting Heidelberg Pharma Research projects in the amount of EUR 0.2 million (previous year: EUR 0.1 million). Furthermore, as in the preceding year, income of EUR 0.2 million was generated from the reversal of unutilized accrued liabilities. An amount of EUR 0.1 million was generated from passing on patent costs in the context of out-licensing (previous year: EUR 0.2 million). Other items amounted to income of EUR 0.2 million (previous year: EUR 0.2 million).

**Operating expenses** including depreciation and amortization rose to EUR 18.1 million in 2019 (previous year: EUR 16.0 million). **Research and development costs** at EUR 10.9 million (previous year: EUR 10.7 million) remained stable despite the expansion of cost-intensive external good manufacturing practice (GMP) production due to the postponement of expenses for clinical development. At 60% of operating expenses, R&D remained the largest cost item. **Cost of sales** totaled EUR 3.7 million (previous year: EUR 2.2 million) and represented 21% of operating expenses. **Administrative costs** were EUR 3.2 million, up on the prior-year figure of EUR 2.9 million, and accounted for 17% of operating expenses.

**Other expenses** for business development, marketing and commercial market supply activities, which mainly comprise staff and travel costs, were EUR 0.3 million. They were higher than in the previous year (EUR 0.2 million) and represented 2% of operating expenses.

The Heidelberg Pharma Group recognized **earnings before tax** of EUR -10.1 million (previous year: EUR -11.7 million) in the 2019 fiscal year. **Net loss for the year** was also EUR 10.1 million (previous year: EUR 11.7 million). Undiluted **Earnings per share** thus improved from EUR -0.41 in the previous year to EUR -0.36.

At the end of the fiscal year, **total assets** amounted to EUR 23.0 million, down EUR 8.2 million from the previous year (EUR 31.2 million), due mainly to the expense-related decrease in cash funds and the corresponding decrease in equity.

The Group had **cash and cash equivalents** of EUR 9.9 million at the close of the fiscal year (30 November 2018: EUR 19.4 million). The decrease resulted from the liquidity outflow triggered by the operating business.

**Monthly cash use** decreased slightly to EUR 0.8 million (previous year: EUR 0.9 million). **Equity** of the Heidelberg Pharma Group at the end of the reporting period was EUR 16.3 million (30 November 2018: EUR 25.9 million). This corresponds to an equity ratio of 70.9% (30 November 2018: 83.0%).

### Financial outlook on 2020 and strategy

The Heidelberg Pharma Group expects to generate between EUR 8.0 million and EUR 10.0 million in sales revenue and other income (2019: EUR 8.0 million) for the 2020 fiscal year. Based on current planning, operating expenses are expected to be in the range of EUR 20.0 million to EUR 24.0 million, higher than in the reporting year (EUR 18.1 million). Earnings before interest and taxes (EBIT) for 2020 are expected to be between EUR -11.0 million and EUR -15.0 million (2019: EUR -10.1 million).

The Company expects to require funds of EUR 11.0 million to EUR 15.0 million in 2020. Monthly cash use should be in the range of EUR 0.9 million to EUR 1.3 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-2021 based on current planning.

Heidelberg Pharma believes that Amanitin is an innovative toxin with very attractive properties for the development of ATACs and will continue its strategy for the development and marketing of its proprietary ATAC technology. The strategy's core elements are the expansion of the Company's own project pipeline, the development of the pipeline projects until clinical proof of concept, 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 19 March 2020, 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](http://www.heidelberg-pharma.com) from 2:30 p.m. CET.

## Key figures for the Heidelberg Pharma Group

In EUR million	2019 <sup>1</sup> EUR million	2018 <sup>1</sup> EUR million
<b>Earnings</b>		
Sales revenue	7.3	3.7
Other income	0.7	0.7
Operating expenses	(18.1)	(16.0)
of which research and development costs	(10.9)	(10.7)
Operating result	(10.1)	(11.7)
Earnings before tax	(10.1)	(11.7)
Total comprehensive income	(10.1)	(11.7)
Earnings per share in EUR (basic)	(0.36)	(0.41)
<b>Balance sheet as of the end of the period</b>		
Total assets	23.0	31.2
Cash and cash equivalents	9.9	19.4
Equity	16.3	25.9
Equity ratio <sup>2</sup> in %	70.9	83.0
<b>Cash flow statement</b>		
Cash flow from operating activities	(8.6)	(10.0)
Cash flow from investing activities	(1.0)	(1.0)
Cash flow from financing activities	0	0
<b>Employees (number)</b>		
Employees at year end <sup>3</sup>	75	66
Employees at year end <sup>3</sup> (full-time equivalents)	70	60

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>.



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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 [www.heidelberg-pharma.com](http://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.