PRESS RELEASE

Heidelberg Pharma Provides Update on Phase I/IIa Clinical Trial with ATAC Candidate HDP-101 in the US

- Compatibility tests for closed infusion system with HDP-101 successfully completed
- Shipping of study medication to the US in preparation
- Contract signed with first study center, MD Anderson Cancer Center; initiation of the center planned in the near future

Ladenburg, Germany, 7 September 2021 – Heidelberg Pharma AG (FSE: HPHA) today announced that preparations for the initiation of the Phase I/IIa clinical trial with HDP-101 have progressed and the initiation of the first study site, the MD Anderson Cancer Center, Houston, TX, US, is planned shortly.

The clinical trial will evaluate the ATAC candidate HDP-101 in patients with multiple myeloma, a type of bone marrow cancer with a high unmet medical need. As HDP-101 is an antibody drug conjugate loaded with a toxin, Amanitin, the use of a special closed system transfer device (CSTD) for infusion of the study medication is required in the US to protect hospital staff from accidental contact with the agent. The mandatory compatibility tests of HDP-101 with the device used by MD Anderson have been carried out in recent weeks and have been successfully completed. The CSTD can thus be used for the infusion of HDP-101 in the clinical trial. The documentation of the study medication is being updated accordingly and will then be sent to the US study site.

The contract with MD Anderson, the first of several planned study centers in the US, has been signed, and the physicians and medical staff have been trained to conduct the study. An official initiation of the study center is planned for the second half of September.

"We are pleased that we were able to advance our preparations for the start of the study in the US during the summer and that we are now close to initiating the first study site. Not only have our employees been working towards this moment for a long time, but patients with multiple myeloma and limited therapy options are also hoping for new treatment approaches," commented Prof. Dr. Andreas Pahl, Chief Scientific Officer of Heidelberg Pharma AG.

About the Phase I/IIa study with HDP-101

The first part of the trial is a Phase I dose escalation study to determine the maximum tolerated dose of HDP-101. The findings from Phase I will be used to establish the dose for the Phase IIa portion of the trial, the primary objective of which is to assess the preliminary anti-tumor activity of HDP-101.

The two parts of the open-label, multicenter Phase I/IIa study will enroll up to 36 and 30 patients, respectively. Patients in the Phase IIa part will be stratified based on their 17p deletion status. Preclinical data show that Amanitin has the potential to be especially effective against tumors that have changed due to so-called 17p deletion mutations to

bypass a special mechanism of cell protection. Patients with such a deletion usually show a poorer response to standard therapies and have a significantly worse prognosis. The Phase IIa part of the trial is intended to evaluate not only the efficacy of HDP-101 in multiple myeloma patients, but also the clinical relevance of the 17p deletion.

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. The proprietary technology platform is being applied to develop the Company's proprietary therapeutic ATACs as well as in third-party collaborations. The proprietary lead candidate HDP-101 is a BCMA ATAC for multiple myeloma and will enter clinical development shortly. HDP-102, a CD37 ATAC for Non-Hodgkin's lymphoma and HDP-103, a PSMA ATAC for metastatic castration-resistant prostate cancer, are in preclinical testing.

Heidelberg Pharma AG 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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