PRESS RELEASE

Heidelberg Pharma Provides Update on Phase I/IIa Clinical Trial with Lead Candidate HDP-101

- First four patient cohorts and dose levels have been completed and proved to be safe and well tolerated
- Enrollment for fifth cohort with a dose of 100 µg/kg has already started
- Patient from third cohort continues to be dosed and shows no progression of disease (stable disease)

Ladenburg, Germany, 19 September 2023 – Heidelberg Pharma AG (FSE: HPHA) announced today that the clinical Phase I/IIa study with the lead development candidate HDP-101 has already started to recruit patients for the fifth patient cohort with a dosing of 100 µg/kg. The Safety Review Committee's (SRC) evaluation of patient data concluded that no dose-limiting toxicities have occurred to date. The first four dose levels have shown to be safe and well tolerated. So far 12 patients have been treated in the trial.

With the expansion of study sites this summer, patient enrollment has significantly accelerated. One patient from the third cohort has now been on HDP-101 monotherapy for over nine months and has been treated with eleven doses.

Dr. András Strassz, Chief Medical Officer of Heidelberg Pharma, commented: “We are delighted that our first Amanitin-based antibody drug conjugate HDP-101 is well tolerated and does not show any dose-limiting toxicities to date. The dose escalation will continue as planned with the fifth cohort.”

The BCMA antibody Amanitin conjugate HDP-101 is being tested in an open-label, multicenter study for the treatment of relapsed or refractory multiple myeloma, a cancer of the bone marrow.

About the Phase I/IIa study with HDP-101

The first part of the study is a Phase I dose escalation study to determine the maximum tolerated dose of HDP-101. These findings will be used to determine the dose for the Phase IIa part, the primary objective of which is to initially evaluate the anti-tumor activity of HDP-101.

The open-label, multicenter Phase I/IIa trial is expected to enroll up to 36 patients in the first part and up to 30 patients in the second part. Patients in Phase IIa will be stratified based on 17p deletion status. Preclinical data show that Amanitin has the potential to work particularly well on those tumors that have been genetically altered by a so-called 17p deletion to bypass a particular protective mechanism of cells. Patients with such a deletion generally respond less well to standard therapies and have a significantly poorer prognosis. Phase IIa will not only validate the efficacy of HDP-101 in patients with multiple myeloma, but also the clinical relevance of the 17p deletion.

About Heidelberg Pharma

Heidelberg Pharma is an oncology specialist and the first company to develop the toxin Amanitin into cancer therapies using its proprietary ATAC technology and to advance the biological mode of action of the toxin as a novel therapeutic principle. The proprietary technology platform is being applied to develop the company's own therapeutic ATACs as well as in third-party collaborations.

The proprietary lead candidate HDP-101 is a BCMA-ATAC in clinical development for multiple myeloma. Further ATAC candidates are being developed against different targets such as CD37, PSMA or GCC each in the indications non-Hodgkin's lymphoma, metastatic castration-resistant prostate cancer or gastrointestinal tumors such as colorectal cancer.

Heidelberg Pharma AG is based in Ladenburg, Germany, and 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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