PRESS RELEASE

Heidelberg Pharma Announces First Patient Dosed with Antibody Targeted Amanitin Conjugate HDP-101 in Multiple Myeloma

Ladenburg, Germany, 15 February 2022 – Heidelberg Pharma AG (FSE: HPHA) today announced that the first patient has been dosed with HDP-101 in a Phase I/IIa study at the Winship Cancer Institute of Emory University, Atlanta, GA, USA. The open-label, multi-center Phase I/IIa study will evaluate HDP-101, a BCMA antibody-Amanitin conjugate, for the treatment of relapsed or refractory multiple myeloma, a bone marrow cancer with high unmet medical need.

Dr. András Strassz, Chief Medical Officer of Heidelberg Pharma, commented: “It is an important step for Heidelberg Pharma to have the first patient dosed in our study. This Phase I/IIa study will test a new mode of action in oncology and is the first trial to evaluate an antibody drug conjugate carrying Amanitin as active component in patients. Our goal is to demonstrate the safety and efficacy of our Amanitin-based ADC technology and we hope that our patients will benefit from this treatment.”

Dr. Jonathan Kaufman, Professor of Hematology and Medical Oncology, Emory University, Atlanta, USA, added: “Based on the preclinical results, I have high hopes for the study with HDP-101. The payload Amanitin is a novel agent in cancer therapy with a unique mode of action that differentiates it from other therapies and promises significant advantages for the treatment of malignancies. For many patients with multiple myeloma, currently available therapies lead to relapses despite initial success, necessitating further treatment options. We are eagerly waiting for first clinical data for HDP-101 and hope to be able to expand the treatment options available to these patients.”

The first part of the trial is a Phase I dose escalation study to determine either the maximum tolerated dose (MTD) or recommend a biologically active dose of HDP-101 for the Phase II part of the study. It is planned to treat up to 36 patients who will receive HDP-101 intravenously once every 3 weeks until disease progression, discontinuation at Investigator's discretion or patient withdrawal. During this part of the trial, tolerability of different dose levels will be evaluated.

During the Phase IIa dose expansion part, the recommended dose of HDP-101 will then be administered to 30 patients. The primary objective of the Phase IIa part of the trial is to assess the preliminary anti-tumor activity of HDP-101 along with further evaluation of the safety of the drug. Patients in this part will be stratified based on their 17p deletion status. Preclinical data show that Amanitin has the potential to be especially effective against tumor cells that harbor the 17p deletion, which allows them to bypass a cellular anti-tumor mechanism. Patients who have cancer with a 17p deletion usually show limited response to established therapies and have a poor 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 Amanitin-based therapies on tumors with a 17p deletion.

Heidelberg Pharma has currently initiated three sites: two US study sites (the MD Anderson Cancer Center in Houston, Texas, and the Winship Cancer Institute of Emory University in Atlanta, Georgia) and one German study site, the Heidelberg University hospital.

For more information on the Phase I clinical trial of HDP-101 in multiple myeloma, please visit: www.clinicaltrials.gov, NCT04879043.

About Multiple Myeloma

Multiple myeloma (MM) is rare but belongs to the most common type of bone and bone marrow cancer. Approximately six to eight new cases per 100,000 people are recorded annually in Western industrialized countries. The median age at diagnosis is 70 years and patients often suffer from bone pain and spontaneous fractures along with other complications. The 5-year survival rate is about 55%*. Current treatment options are chemotherapy, immunomodulatory drugs, proteasome inhibitors and autologous stem cell transplantation with a high impact on quality of life or significant side effects.

*https://seer.cancer.gov/statfacts/html/mulmy.html

About Heidelberg Pharma

Heidelberg Pharma AG is a biopharmaceutical company based in Ladenburg, Germany. It 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 is in clinical development. 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 http://www.heidelberg-pharma.com/.

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