Ad hoc announcement
Inside information pursuant to Article 17 MAR

FDA Allows Heidelberg Pharma to Start a Phase I/IIa Clinical Trial with ATAC Candidate HDP-101

Ladenburg, Germany, 4 February 2021 – Heidelberg Pharma AG (FSE: HPHA) today announced that the US Food and Drug Administration (FDA) has informed the company it is safe to proceed with the Phase I/IIa study with the BCMA Antibody Targeted Amanitin Conjugate, HDP-101 that was submitted under its US IND. The study will evaluate HDP-101 for the treatment of multiple myeloma, a blood cancer with high unmet medical need.

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.

Contracts requiring approval from the clinical ethics committee are expected to be signed with the planned study sites in the US in the next weeks. Heidelberg Pharma expects the first patient to be enrolled and the first dose to be administered in the second quarter of 2021.

The next step is to submit the study protocol to the Paul-Ehrlich-Institut in Germany.

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Prof. Andreas Pahl, CSO of Heidelberg Pharma AG, commented: "We have been working towards this goal for many months and are delighted that the FDA has allowed us to proceed with the Phase I/IIa trial with HDP-101. Developing a completely novel drug candidate to the point of first-in-human testing is a complex process. Therefore, the start of clinical development of the first candidate from our ATAC platform is an important milestone for us."

About Heidelberg Pharma

Heidelberg Pharma is an oncology company 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.

Heidelberg Pharma AG has entered into partnerships to further develop and commercialize its clinical assets upamostat (formerly MESUPRON®) andTLX250-CDx (formerly REDECTANE®). 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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