**PRESS RELEASE**

# Paul Ehrlich Institute Allows Heidelberg Pharma to Start a Phase I/IIa Clinical Trial with ATAC Candidate HDP-101

- Initiation of the first German study center planned within the next few months

**Ladenburg, Germany, 19 July 2021** – Heidelberg Pharma AG (FSE: HPHA) today announced that the German authority Paul Ehrlich Institute, Langen, Germany, (PEI) has approved the study design of the planned Phase I/IIa clinical trial with the ATAC candidate HDP-101. HDP-101 is a BCMA antibody-Amanitin conjugate that will be tested in the indication multiple myeloma, a blood cancer with high unmet medical need.

Dr. András Strassz, Chief Medical Officer of Heidelberg Pharma AG, commented: "We are very pleased that following the approval of the study by the FDA, the German regulatory authority, the Paul Ehrlich Institute, has now also approved the initiation of a study with our ATAC candidate HDP-101 in Germany. After approval by the ethics committee and signing the contracts, we will soon start with the initiation of the German study centers. In the US, preparations are already underway and we expect to enroll the first patient in the next few weeks."

## 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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