PRESS RELEASE

Heidelberg Pharma's Lead ADC Candidate HDP-101 Granted Fast Track Designation by US FDA for the Treatment of Multiple Myeloma

- Recognizes the potential of HDP-101 to address a serious or life-threatening condition with high unmet medical needs
- Enables more frequent engagement with FDA and eligibility for rolling review to support expedited development and review

Ladenburg, Germany, 23 October 2025 – Heidelberg Pharma AG (FSE: HPHA), a clinical-stage biotech company developing innovative Antibody Drug Conjugates (ADCs), today announced that HDP-101 (INN: pamlectabart tismanitin), the Company's lead Amanitin-based ADC candidate, has been granted Fast Track Designation by the US Food and Drug Administration (FDA).

This designation was supported by nonclinical data as well as clinical data from the ongoing Phase I/IIa study with HDP-101 (INN: pamlectabart tismanitin), evaluating the safety and antitumor activity of the candidate in patients with relapsed or refractory multiple myeloma.

Professor Andreas Pahl, Chief Executive Officer of Heidelberg Pharma, commented: "The FDA's granting of Fast Track Designation is fantastic news for Heidelberg Pharma and underscores the potential of HDP-101 for the treatment of severely ill and heavily pretreated patients. This designation will support our efforts to advance our lead ADC candidate efficiently toward patients with multiple myeloma who continue to face significant unmet medical needs."

Fast Track Designation is intended to accelerate the development and review of therapies that address serious or life-threatening conditions with unmet medical needs. This status enables more frequent engagement with the FDA, allows Rolling Review of the Biologics License Application (BLA), and may provide eligibility for Priority Review or Accelerated Approval.

HDP-101 (INN: pamlectabart tismanitin) is an investigational product that has not yet received marketing approval by any regulatory authority, including the FDA. The safety and efficacy of this investigational compound is currently being evaluated and is not yet established.

About Heidelberg Pharma

Heidelberg Pharma is a biopharmaceutical company working on a new treatment approach in oncology and developing novel drugs based on its ADC technologies for the targeted and highly effective treatment of cancer. ADCs are antibody-drug conjugates that combine the specificity of antibodies with the efficacy of toxins to fight cancer. Selected antibodies are loaded with cytotoxic compounds, the so-called payloads, that are transported into diseased cells. Inside the cells, the toxins then unleash their effect and kill the diseased cells.

Heidelberg Pharma is the first company to use the compound Amanitin from the green death cap mushroom in cancer therapy. The biological mechanism of action of the toxin represents a new therapeutic modality and is used as a compound in the Amanitin-based ADC technology, the so-called ATAC technology.

The lead candidate HDP-101 is a BCMA ATAC in clinical development for multiple myeloma. A second ATAC candidate, HDP-102, has recently started clinical development in Non-Hodgkin Lymphoma and is currently on a temporary hold. HDP-103 against metastatic castration-resistant prostate cancer and HDP-104 targeting gastrointestinal tumors such as colorectal cancer have completed preclinical development. Heidelberg Pharma is open for partnering.

The company 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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