

PRESS RELEASE

Heidelberg Pharma Advances to Cohort 9 in Phase I/IIa Trial of Lead ATAC Candidate HDP-101 in Multiple Myeloma

- HDP-101 continues to demonstrate a favorable safety profile with no dose-limiting toxicities observed
- Early evidence of clinical activity observed in Cohort 8, highlighted by a very good partial response observed in one patient

Ladenburg, Germany, 25 September 2025 – Heidelberg Pharma AG (FSE: HPHA), a clinical-stage biotech company developing innovative Antibody Drug Conjugates (ADCs), today announced the initiation of Cohort 9 in its ongoing Phase I/IIa dose escalation trial of HDP-101, the Company's lead ATAC candidate for the treatment of relapsed or refractory multiple myeloma.

The Safety Review Committee (SRC) has confirmed that the 140 µg/kg dose level administered in Cohort 8 was safe and well tolerated. Based on these findings, the study is now progressing into Cohort 9 with an escalated dose of 175 µg/kg, administered in one dosing arm. Cohort 9 has already opened.

Eight patients were dosed in Cohort 8 and all patients completed the observation period, demonstrated a favorable safety and tolerability profile throughout. Encouraging signs of clinical activity have also emerged. Patients showed biological activity of HDP-101, and a very good partial response has already been observed in one patient. This adds to earlier positive outcomes, including one patient from Cohort 5 who is still on treatment and achieved complete remission, with no detectable tumor cells after ongoing HDP-101 monotherapy following multiple prior treatments. In addition, several patients across different cohorts have shown objective responses and promising anti-tumor activity, further supporting the therapeutic potential of HDP-101 in heavily pretreated patients with relapsed or refractory multiple myeloma.

Dr. András Strassz, Chief Medical Officer at Heidelberg Pharma, said: “Our lead ATAC candidate HDP-101 continues to demonstrate a strong safety and tolerability profile across all treated patients. The results from Cohort 8 demonstrate encouraging signs of clinical activity of HDP-101, including a very good partial response in one patient. These early efficacy signals are promising as we advance HDP-101 through the ongoing dose escalation study.”

Heidelberg Pharma's Phase I/IIa clinical study is a non-randomized, open-label trial actively enrolling patients with relapsed or refractory multiple myeloma or other BCMA-expressing plasma cell disorders. The study is designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of HDP-101 in this patient population.

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. 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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