

PRESS RELEASE

Heidelberg Pharma announces progress into Cohort 6 with its proprietary ATAC candidate HDP-101 in Phase I/IIa multiple myeloma study

- Data from HDP-101 dose escalation shows first objective responses and partial remissions in Cohort 5
- Amended protocol includes expanded Cohort 6 with dose optimization, including three parallel arms at different dosing regimens
- Revolutionizing treatment options for multiple myeloma patients with its proprietary novel payload with a unique mode of action

Ladenburg, Germany, 18 March 2024 – Heidelberg Pharma AG (FSE: HPHA), a clinical stage biotech company developing innovative Antibody Drug Conjugates (ADCs), today announces that it will be advancing into an expanded Cohort 6 dose escalation following submission of a protocol amendment to the US Food and Drug Administration (FDA) for its Phase I/IIa study with lead ATAC candidate HDP-101 for the treatment of multiple myeloma.

Multiple myeloma is a type of blood cancer that develops from plasma cells in the bone marrow and can affect more than one part of the body. Plasma cells are a type of blood cell that makes antibodies to fight infection, created by bone marrow. In myeloma, the bone marrow makes lots of abnormal (cancerous) plasma cells. The worldwide incidence of multiple myeloma is currently 160,000 with a mortality of 106,000.

Heidelberg Pharma's Phase I/IIa clinical study is an ongoing, non-randomised, open label study which is actively enrolling patients with relapsed or refractory multiple myeloma or other plasma cell disorders expressing BCMA. The study is designed to assess the safety, tolerability, pharmacokinetics, and efficacy of HDP-101 in patients with multiple myeloma when treated with intravenous infusion every 3 weeks at agreed dose levels in adult patients.

The Company submitted a protocol amendment to the FDA in February 2024 allowing planned modification and optimization of the medication regimen to lessen the initial transient and reversible reduction of thrombocyte count. Upon ethics committee approval patients will be enrolled in Cohort 6.

Data across the first four Cohorts have demonstrated HDP-101 to be safe and well tolerated. In Cohort 5 at multiple doses of 100 µg/kg HDP-101 objective responses were observed, including three partial remissions out of five patients continuously treated with 100 µg/kg, highlighting the potential of HDP-101 as a highly efficacious treatment option for multiple myeloma. Further data readouts will be reported at upcoming scientific conferences in 2024.

Prof. Dr. Andreas Pahl, Chief Executive Officer at Heidelberg Pharma, said: “Our proprietary ATAC candidate HDP-101 is showing exciting potential for treating multiple myeloma. First objective responses and partial remissions are highly encouraging with the prospect of HDP-101 becoming a game changer in prolonging life alongside good tolerability for sufferers of this incurable illness worldwide. With our proprietary toolbox of novel payloads, we are building a pipeline across multiple indications that further advances ADCs as a treatment modality for cancer.”

Heidelberg Pharma will be presenting data on HDP-101 at the upcoming [American Association for Cancer Research \(AACR\) Annual Meeting](#), being held in San Diego, California on the 5 - 10 April 2024. The Annual Report to be issued on 25 March 2024.

About Heidelberg Pharma

Heidelberg Pharma is an oncology specialist and the first company to develop the toxin Amanitin into cancer therapies using its proprietary ATAC technology and to advance the biological mode of action of the toxin as a novel therapeutic principle. The proprietary technology platform is being applied to develop the company’s own therapeutic ATACs as well as in third-party collaborations.

The proprietary lead candidate HDP-101 is a BCMA-ATAC in clinical development for multiple myeloma. Further ATAC candidates are being developed against different targets such as CD37, PSMA or GCC each in the indications non-Hodgkin’s lymphoma, metastatic castration-resistant prostate cancer or gastrointestinal tumors such as colorectal cancer.

Heidelberg Pharma AG is based in Ladenburg, Germany, and is listed on the Frankfurt Stock Exchange: ISIN DE000A11QVV0 / WKN A11QVV / Symbol HPHA. More information is available at <https://heidelberg-pharma.com/en/>

ATAC® is a registered trademark of Heidelberg Pharma Research GmbH in the EU and the USA.

About ATACs

Antibody Targeted Amanitin Conjugates are Heidelberg Pharma’s proprietary, engineered ADCs incorporating a novel payload, amanitin, that along with specific ADC characteristics confers a unique mode of action that promises optimal efficacy with low side effects in many difficult to treat, aggressive cancers such as multiple myeloma.

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