PRESS RELEASE

Heidelberg Pharma Progresses into Cohort 7 in a Phase I/IIa Study with BCMA ATAC Candidate HDP-101 Targeting Multiple Myeloma

- HDP-101 is well tolerated to date, with no signs of dose-limiting toxicities
- Complete remission observed in one patient from Cohort 5
- Proprietary novel payload with a unique mode of action, representing new treatment options for patients with relapsed or refractory multiple myeloma

Ladenburg, Germany, 13 January 2025 – Heidelberg Pharma AG (FSE: HPHA), a clinical-stage biotech company developing innovative Antibody Drug Conjugates (ADCs), today announced that it is advancing into Cohort 7 in a Phase I/IIa dose escalation study with lead ATAC candidate HDP-101 for the treatment of relapsed or refractory multiple myeloma.

Previously, in Cohort 6, dose optimization regimens were introduced with three different settings. These included premedication or different dose distribution to ameliorate the short-term reduction in platelet count that was observed with the prior dosing regimen. HDP-101 was well tolerated across all 10 patients in Cohort 6 dosed with 90 µg/kg, with no dose-limiting toxicities (DLTs) detected in any of the three parallel treatment arms. The Safety Review Committee (SRC) recommended to progress into Cohort 7 with an escalated dose above 100 µg/kg, in two parallel treatment arms with different split dosing. One arm will include additional premedication. First patients of Cohort 7 have already been dosed.

Dr. András Strassz, Chief Medical Officer at Heidelberg Pharma, said: "Our lead ATAC candidate, HDP-101, is demonstrating promising data as it advances into Cohort 7. The adapted dosing strategies showed a positive effect by limiting the platelet count reduction seen in prior cohorts. Using these new dosing regimens allows us to escalate the dose further. HDP-101 was well tolerated in Cohort 6, and we are looking forward to publishing first efficacy and additional safety data of this patient group at forthcoming scientific conferences in 2025."

Heidelberg Pharma's Phase I/IIa clinical study is an ongoing, non-randomised, open label study that is actively enrolling patients with relapsed or refractory multiple myeloma or other plasma cell disorders expressing BCMA (B-cell maturation antigen). The study is currently assessing the safety, tolerability, pharmacokinetics, and efficacy of HDP-101 in patients with multiple myeloma.

Clinical data from Cohort 5 demonstrated complete remission in one patient who had been heavily pre-treated across nine prior lines of therapy, including another BCMA-targeting agent. This patient showed an objective improvement ("partial response") in the 2nd cycle of treatment, with complete remission observed after the 11th cycle and continues sustaining response for more than a year. In addition, several other patients showed biological activity and objective responses demonstrating the potential of HDP-101 as a promising treatment option for patients with the disease.

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 uses several compounds and has built up an ADC toolbox that overcomes tumor resistance via numerous pathways and addresses different types of cancer using various antibodies. The goal is to develop targeted and highly effective ADCs for the treatment of a variety of malignant hematologic and solid tumors.

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 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.

Contact

Heidelberg Pharma AG
Sylvia Wimmer
Director Corporate Communications
Tel.: +49 89 41 31 38-29
E-Mail: investors@hdpharma.com
Gregor-Mendel-Str. 22, 68526 Ladenburg

IR/PR-Support
MC Services AG
Katja Arnold (CIRO)
Managing Director & Partner
Tel.: +49 89 210 228-40
E-Mail: katja.arnold@mc-services.eu

International IR/PR-Support
Optimum Strategic Communications
Mary Clark, Zoe Bolt, Katie Flint
Tel: +44 20 3882 9621
Email: HeidelbergPharma@optimumcomms.com