

## PRESS RELEASE

### **Heidelberg Pharma granted orphan drug designation by FDA for its proprietary ATAC candidate HDP-101**

**Ladenburg, Germany, 27 March 2024** – Heidelberg Pharma AG (FSE: HPHA), a clinical stage biotech company developing innovative Antibody Drug Conjugates (ADCs), is pleased to announce that the US Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for the treatment of multiple myeloma to its lead candidate HDP-101. Heidelberg Pharma is investigating the candidate in a clinical Phase I/IIa study for the treatment of relapsed/refractory multiple myeloma (RRMM).

HDP-101 is an antibody-drug conjugate, that consists of an anti-BCMA antibody, a specific linker and the Amanitin toxin. BCMA (B-cell maturation antigen) is a surface protein that is highly expressed in multiple myeloma cells and to which BCMA antibodies specifically bind.

**Prof. Dr. Andreas Pahl, Chief Executive Officer at Heidelberg Pharma**, commented: “We are delighted that our proprietary ATAC candidate, HDP-101, has been granted Orphan Drug Designation by the FDA, providing further validation of its potential benefit as a therapeutic for patients with multiple myeloma. This indication represents a major unmet medical need where new, more effective therapies are urgently required. Orphan Drug Designation will provide us with several important benefits, including a potential seven-year marketing exclusivity upon HDP-101 receiving approval from the FDA.”

Orphan Drug Designation is granted for a drug or biological product that is intended for the prevention, diagnosis, or treatment of rare diseases or disorders that affect fewer than 200,000 people in the US. The designation provides significant incentives to promote the development of the drug including tax credits for qualified clinical trials, prescription drug user-fee exemptions, and potential seven-year marketing exclusivity upon FDA approval.

The team at Heidelberg Pharma will be presenting early safety and preliminary efficacy data at the upcoming [American Association for Cancer Research \(AACR\) Annual Meeting](#), being held in San Diego, California on the 5 - 10 April 2024.

HDP-101 is an investigational product that has not yet been approved by any regulatory authority, including the FDA. The safety and efficacy of this investigational compound is being evaluated and is not yet established.

#### **About Heidelberg Pharma**

Heidelberg Pharma develops novel drugs based on its ADC technologies for the targeted and highly effective treatment of cancer. ADCs are antibody-drug conjugates that combine the high affinity and specificity of antibodies with the efficacy of toxins to fight cancer. Selected antibodies are loaded with various toxins, the so-called payloads, that are transported into diseased cells. Inside the cells, the toxins then unleash their effect and kills the diseased cells.

Heidelberg Pharma is the first company to use the mushroom toxin Amanitin in cancer therapies by exploiting the toxin's biological mechanism of action with its innovative ATAC technology as a new therapeutic modality. It offers the opportunity to not only overcome resistance of cancer cells against therapeutic agents currently used, but also has the ability to eliminate dormant tumor cells. This could lead to significant advances in cancer therapy - even for patients who no longer respond to any other treatment. The most advanced product candidate HDP-101 is a BCMA-ATAC for the indication multiple myeloma, which is currently in clinical development.

In addition to Amanitin, alternative payloads also expand the ADC platform technologies of Heidelberg Pharma to develop targeted and highly effective ADCs for the treatment of a variety of malignant hematologic and solid tumors.

Heidelberg Pharma AG is a biopharmaceutical company 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](http://www.heidelberg-pharma.com).

ATAC® is a registered trademark of Heidelberg Pharma Research GmbH.

### **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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