Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/heidelberg-pharma-granted-orphan-drug-designation-fda-its-proprietary-atac-candidate-hdp-101

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

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.

Press release

27-Mar-2024
Source: Heidelberg Pharma AG

Further information

- Heidelberg Pharma AG
- American Association for Cancer Research - Annual Meeting 2024