

PRESS RELEASE

Heidelberg Pharma AG and Huadong Medicine Receive NMPA Approval for Clinical Trial of HDP-101 Combination Therapy in China

Ladenburg, Germany, 26 August 2026 – Heidelberg Pharma AG (FSE: HPHA), a clinical-stage biotech company developing innovative Antibody Drug Conjugates (ADCs), today announced that the China National Medical Products Administration (NMPA) has granted Clinical Trial Approval for a Phase Ib/II clinical trial evaluating pamlectabart tismanitin (HDP-101), the Company's novel BCMA-targeting ADC, in combination therapy for the treatment of patients with relapsed/refractory multiple myeloma.

The trial will evaluate the safety, tolerability, and preliminary efficacy of pamlectabart tismanitin in combination either with pomalidomide and dexamethasone, or with daratumumab and dexamethasone, in adult patients with relapsed/refractory multiple myeloma who have received at least one prior line of therapy. The trial will be conducted by Heidelberg Pharma's partner Huadong Medicine Co., Ltd. in China who will bear the development cost.

Pamlectabart tismanitin is being evaluated as a monotherapy in an ongoing Phase I/IIa clinical trial in the U.S. and Europe since 2022. Following dose-escalation in the Phase 1 part of the trial and the determination of the recommended Phase II dose (RP2D), a monotherapy bridging study with pamlectabart tismanitin has been initiated in China in March 2026. Pamlectabart tismanitin has received key regulatory designations from the U.S. FDA, including Orphan Drug Designation (ODD) in March 2024 and Fast Track Designation (FTD) in October 2025.

Combination therapies are an important part of Heidelberg Pharma's clinical development strategy for pamlectabart tismanitin, with the aim of evaluating the ADC in combination with established treatment regimens to potentially expand its use across earlier treatment lines and broader patient populations.

In February 2022, Heidelberg Pharma entered into a strategic partnership including equity investment with Huadong Medicine. Under the agreement, Huadong Medicine obtained exclusive development and commercialization rights to HDP-101 across 20 Asian markets. Huadong Medicine also became the second-largest shareholder of Heidelberg Pharma.

About Heidelberg Pharma

Heidelberg Pharma is the first company to develop cancer therapies using Amanitin, a compound derived from the green death cap mushroom. 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 (INN: pamlectabart tismanitin) is a BCMA ATAC in clinical development for multiple myeloma. The candidate has been granted Orphan Drug Designation and Fast Track Designation from the FDA. A second ATAC candidate, HDP-

102 is in clinical development stage 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. These programs are available 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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