Ad hoc announcement

Disclosure of inside information under Article 17 of Regulation (EU) No 596/2014

Heidelberg Pharma's Partner Telix Pharmaceuticals Gives Regulatory Update for its Imaging Agent TLX250-CDx

- FDA has requested additional data relating to the Chemistry, Manufacturing, and Controls (CMC) package
- Expected payment of USD 70 million from HealthCare Royalty to Heidelberg Pharma will be delayed
- Current cash reach until Q1 2026

Ladenburg, Germany, 28 August 2025 – Heidelberg Pharma AG (FSE: HPHA), a clinical stage biotech company developing innovative Antibody Drug Conjugates (ADCs), today announced that its licensing partner Telix Pharmaceuticals Limited, headquartered in Melbourne, Australia, (ASX: TLX, NASDAQ: TLX; Telix) was informed by the US Food and Drug Administration (FDA) that deficiencies relating to the Chemistry, Manufacturing, and Controls (CMC) package have been identified.

At the end of December 2024, a Biologic License Application (BLA) had been submitted to the agency by Telix. On 26 February 2025, Telix announced that the FDA had accepted the BLA for TLX250-CDx, granted a Priority Review, and set 27 August 2025 as aimed end of the review period (Prescription Drug User Fee Act [PDUFA] date). Today, Telix published that it has received a Complete Response Letter (CRL) from the FDA for the BLA for TLX250-CDx (Telix ASX Announcement).

The CRL identifies deficiencies relating to the Chemistry, Manufacturing, and Controls (CMC) package. The FDA has requested additional data to establish comparability between the drug product used in the ZIRCON Phase 3 clinical trial and the scaled-up manufacturing process intended for commercial use. Additionally, the FDA has documented notices of deficiency issued to two third-party manufacturing and supply chain partners that will require remediation prior to resubmission.

Based on current information, Telix believes these concerns are readily addressable and submission remediation will begin immediately. New timelines will be communicated as soon as they are available.

Under the licensing agreement with Telix, Heidelberg Pharma is entitled to milestone payments and double-digit royalties if the product receives market approval. Heidelberg Pharma sold a portion of the future royalties to HealthCare Royalty (HCRx). Based on this agreement, the Company is eligible to receive USD 70 million from HCRx upon FDA approval of TLX250-CDx. Now, the payment condition has not been met. As a result, the current cash reach remains unchanged until Q1 2026.

The Executive Management Board, together with the Supervisory Board, are in discussions about alternative financing as well as cost-saving measures.

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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

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

ITAC™, ETAC™ are pending trademark applications of Heidelberg Pharma Research GmbH.

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