

## SAFE HARBOR



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### **CURRENT SITUATION**



- Heidelberg Pharma monetized the potential royalty streams from TLX250-CDx (out-licensed to Telix Pharmaceuticals) - and built its financing strategy around this
- USD 70 m milestone payment due upon FDA approval of TLX250-CDx and monies planned to be used to finance the ADC pipeline
- Positive FDA decision on TLX250-CDx was expected in late August (PDUFA: 27 August 2025)
  - Clear, positive Phase III data in area of high unmet medical need
  - First BLA application in summer 2024 was rejected by FDA due to questions about Chemistry, Manufacturing and Controls (CMC); these were addressed by Telix
  - Second BLA submission accepted by FDA in February 2025: Priority Review granted and PDUFA date scheduled
- Telix receives Complete Response Letter on 27 August 2025
- Cash as of 31 August 2025: EUR 22.9 m cash reach until Q1 2026

Strategic decision to refocus R&D efforts and to significantly reduce operating expenses to extend cash reach

## AGREEMENT WITH HEALTHCARE ROYALTY



Partial monetization of royalty stream for TLX250-CDx - an imaging agent for kidney cancer out-licensed to Telix

Key terms of the agreement between Heidelberg Pharma and HealthCare Royalty:

- USD 45 m upfront payments already received, not refundable
- Maximum of USD 70 m payment upon FDA approval of TLX250-CDx, with further reductions if FDA approval occurs after the end of 2025
- Cumulative royalties sold are capped at an undisclosed maximum value, royalty payments then revert to Heidelberg Pharma, and HealthCare Royalty will then receive a low single-digit royalty tail percentage

Cap for royalty stream secures participation in mid- and long-term upside

Heidelberg Pharma benefits over the short- and long-term from global product sales of TLX250-CDx



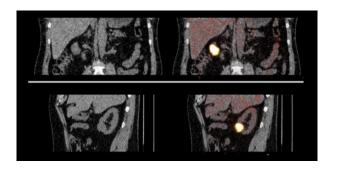
#### **Complete Response Letter received from FDA on 27 August 2025**

- CRL does not relate to clinical study results or the safety/efficacy of the product, but is focused on technical and regulatory aspects of manufacturing and supply chain
  - Deficiencies related to Chemistry, Manufacturing and Controls (CMC), particularly the complexity of commercial manufacturing
  - Insufficient demonstration of comparability between the product used in the successful Phase 3 ZIRCON trial and the intended commercial-scale product
  - Form 483s issued to two third-party manufacturing partners, which must be remedied before resubmission
- Telix will request Type A meeting with FDA as soon as possible
- Telix believes issues are readily addressable; submission remediation to begin immediately
- Telix to provide timing update
- Breakthrough Therapy designation status remains unchanged





Imaging of kidney cancer to better distinguish benign or malignant lesions



# STRATEGIC AND OPERATIONAL FOCUSING HEIDELBERG PHARMA



#### **COST-SAVING MEASURES**

- Focus on lead program: Clinical Phase I/IIa trial with HDP-101 in Multiple Myeloma will continue as planned
- Recently initiated Phase I trial with ADC candidate HDP-102 in Non-Hodgkin Lymphoma will be temporarily put on hold
- Preparations for Clinical Trial Application for ADC candidate HDP-103 will continue as planned
- Early research activities will be significantly scaled back
- Significant reduction in the workforce by approx. 75% by mid-2026
- Cost-saving measures expected to extend cash reach until mid-2026

### HDP-101 PRELIMINARY EFFICACY DATA



#### **OBJECTIVE RESPONSE RATES (ORR)**



#### PRELIMINARY EFFICACY

- Multiple responses were seen (from 90  $\mu g/kg$ ) across different dosing arms
- In Cohort 6 (90 µg/kg), 2 of 10 patients showed PR
  (1 patient is still ongoing with PR after 18 treatment cycles)
- In Cohort 5 (100  $\mu$ g/kg), 2 patients had partial responses (PR) and 1 a stringent complete response (sCR lasting 22 months to date) out of 6 patients
- In Cohort 7 (112.5 μg/kg), 2 patients out of 6 had PR
- In Cohort 8 (140  $\mu g/kg$ ) preliminary data shows 2 patients with PR and 1 patient with VGPR from 6 evaluable patients
- Partial response (PR)
- Very good partial response (VGPR)
- Stringent complete response (sCR)

<sup>\*</sup> Response data from Cohort 8 remain immature. Current follow-up is too limited to draw definitive conclusions on efficacy in Cohort 8 and additional data collection is ongoing.

# HDP-102 STARTED ENROLLMENT OF PATIENTS IN SPRING 2025





Multicenter, multinational open-label Phase Ia/Ib trial for relapsed/refractory B-cell malignancies



#### **General information**

- Broad potential application in B-cell malignancies
- Cohort 1 is completed (40 μg/kg)
- 3 patients enrolled: 1 DLBCL, 1 MZL, 1 SLL
- Clinical sites: Moldova, Romania, Poland



#### **Preliminary Outcome**

- Well tolerated treatment
- Preliminary signs of biological activity have been already observed at the very low dose of Cohort 1:
  - stable disease for 2 patients
  - regression of lymph nodes
  - decrease of lymphocytes
  - observed in different indications
- SRC recommended to dose escalate in the next cohort (65 μg/kg)

## ADC PIPELINE IN LIQUID & SOLID TUMOR INDICATIONS



#### **HDP-101**

# BCMA-ATAC for r/r Multiple Myeloma

- Phase I/IIa study dose escalation Cohort 8 completed
- Cohort 9 already opened with 175 μg/kg
- Recommended Phase II dose (RP2D) expected in 2026
- Phase IIa expected to start in 2026
- Huadong: HDP-101 IND in China approved; starting Phase II in China in 2026

#### **Continue as planned**

#### **HDP-102**

# CD37-ATAC for Non-Hodgkin Lymphoma

- CTA approval Q4 2024
- Phase I dose escalation study in NHL initiated Q2 2025

Temporarily on hold; available for partnering

#### **HDP-103**

# PSMA-ATAC for mCR Prostate Cancer

- First-in-human enabling and GLP tox studies completed
- Preparation for CTA to continue

Continue CTA prep as planned; available for partnering

#### **HDP-104**

## GCC-ATAC for colorectal cancer

 IND-enabling and GLP tox studies conducted in 2025

Available for partnering; no further internal development planned

