

## **Safe Harbor**



### **Forward looking statements**

This communication contains certain forward-looking statements, relating to the Company's business, which can be identified by the use of forward-looking terminology such as "estimates", "believes", "expects", "may", "will" "should" "future", "potential" or similar expressions or by general discussion of strategy, plans or intentions of the Company. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results of operations, financial condition, performance, or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

Such factors include, among others, the following: uncertainties related to results of our clinical trials, the uncertainty of regulatory approval and commercial uncertainty, reimbursement and drug price uncertainty, the absence of sales and marketing experience and limited manufacturing capabilities, attraction and retention of technologically skilled employees, dependence on licenses, patents and proprietary technology, dependence upon collaborators, future capital needs and the uncertainty of additional funding, risks of product liability and limitations of insurance, limitations of supplies, competition from other biopharmaceutical, chemical and pharmaceutical companies, environmental, health and safety matters, availability of licensing arrangements, currency fluctuations, adverse changes in governmental rules and fiscal policies, civil unrest, acts of God, acts of war, and other factors referenced in this communication.

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# **Heidelberg Pharma – a Clinical Stage Company**



# Our **Company**



113 employees



Headquarters in **Heidelberg** area, Germany

Listed on Frankfurt Stock Exchange: HPHA



Clinical stage biotech

Complete in-house research capabilities



Cash reach until mid-2025

(as of July 2023)



# Our **Approach**

**Inhibition of RNA Polymerase II** 

Targeted delivery via antibodies (ADC technology)

Use Amanitin as toxic payload (ATAC technology)

# Our **Mission**



**Provide new options** in cancer therapy

Overcome resistance mechanisms

Kill dormant tumor cells

**Develop biomarker** for patient stratification

# **Growing Pipeline of Proprietary and Partnered Programs**



	Product	Target	Indication	Research	Preclinic	Phase I	Phase II	Phase III	Partner
ATAC pipeline	HDP-101	BCMA	Multiple Myeloma						Huadong (China+)
	HDP-102	CD37	NHL (DLBCL/CLL)						Huadong (option China+)
	HDP-103	PSMA	Prostate cancer						Huadong (China+)
	HDP-104	GCC	Gastrointestinal (e.g., CRC)						Huadong (option China+)
	HDP-XX	n/a	Solid & hematological malignancies						Proprietary
ATAC partners	TAK-ATAC	n/a	Oncology						Takeda
	CHIOME-ATAC	CDCP1	Oncology						Chiome
Legacy assets	TLX250-CDx	CA-IX	Renal and urothelial carcinoma, TNBC						Telix
	TLX250	CA-IX	Renal carcinoma						Telix
ega	RHB-107		Oncology/GI, Covid-19						RedHill
	LH011		Pancreatic						Link Health

## **Important Events H1 2023**



#### Clinical trial with ATAC candidate HDP-101

- Adaptations to study protocol; continuation of patient recruitment
- Initiation of additional, new study sites in Europe
- Patient from 3<sup>rd</sup> cohort continues to be dosed and shows stable disease

### **Technology**

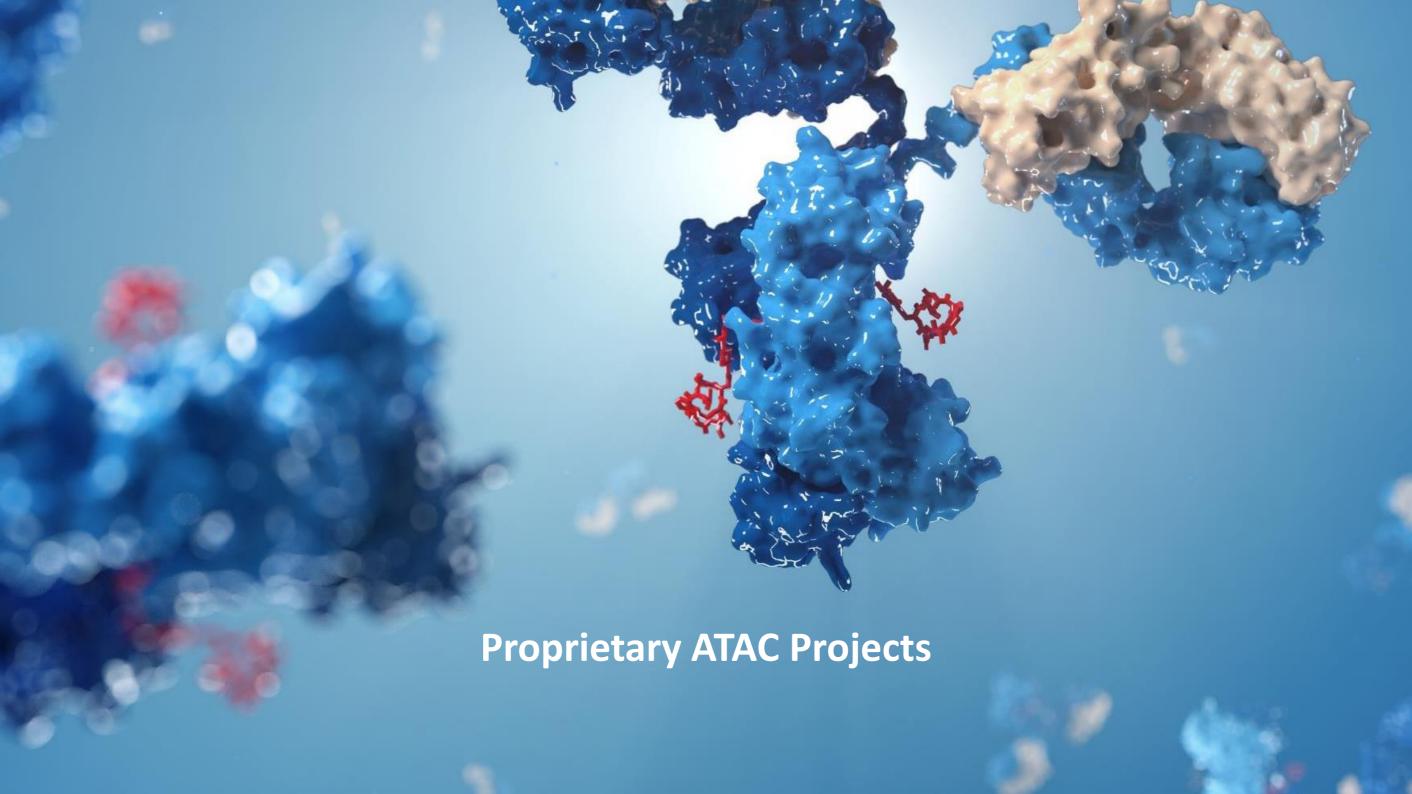
New preclinical data of the ATAC technology platform presented at the AACR 2023 Annual Meeting

#### **Corporate events**

- Walter Miller appointed Chief Financial Officer
- Divestment of minority stake in Emergence leads to higher cash inflows and earnings

#### **Partnerships**

- Research and exclusive option agreement with Binghamton University related to a novel and proprietary immunostimulatory technology platform
- Partnership with Magenta terminated due to strategy change at Magenta

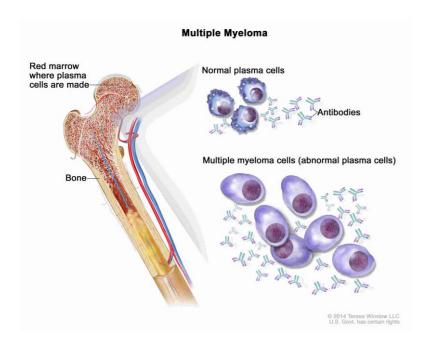


## Lead Program: HDP-101 in Multiple Myeloma



## Multiple Myeloma (MM)

- 70,000 deaths annually
- Median survival ~47-110 months
- Characterized by the proliferation of single clone of plasma cells derived from B-cells
- BCMA (B-cell maturation antigen) overexpression and activation are associated with MM





Source: healthcare-ineurope.com



Source: Heidelberg Pharma

## **HDP-101: Anti-BCMA-ATAC**

- Targeted elimination of BCMA-containing cells with favorable preclinical toxicity profile
- Higher potency in cells with 17p deletions, which are associated with aggressive disease
- Clinical trial started in Feb 2022

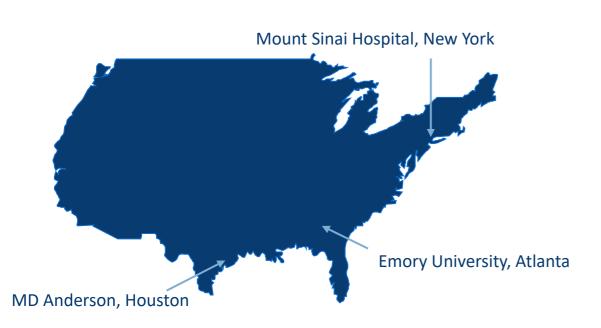


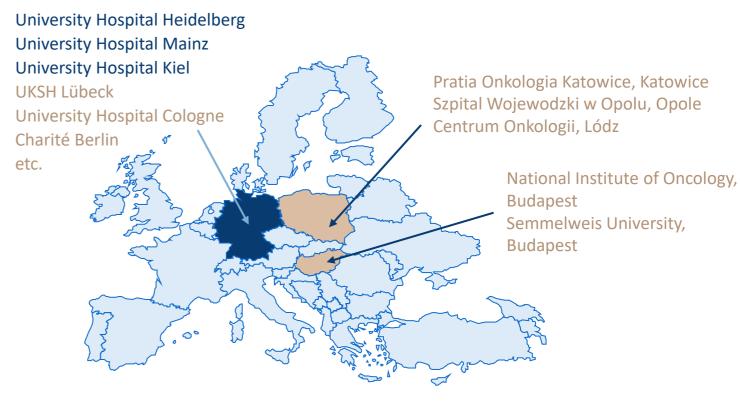
# **HDP-101: Phase I/IIa Study Status**



#### Status of the Phase I dose escalation study

- Three patient cohorts (20, 30, and 60 µg/kg) completed so far, 8 patients in total
- Latest review by Safety Review Committee in March:
  - Treatment is safe and well-tolerated in these three cohorts
  - Discussion of Magenta events: no indication that they were related to the ATAC platform
    - Voluntary implementation of additional precautionary safety measures to maximize the safety of the patients
- Dose escalation to be continued with 80  $\mu$ g/kg in the fourth cohort
- US and Polish centers are currently recruiting patients

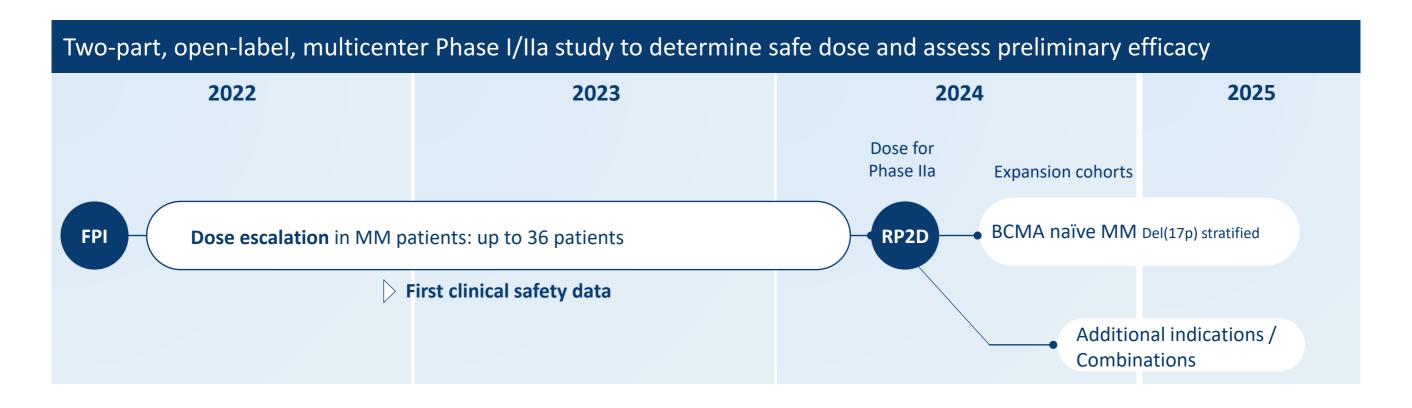




→ Further centers in Germany as well as Poland and Hungary are being initiated

# **HDP-101: Clinical Development Plan for Multiple Myeloma**





## **Further ATAC Candidates: HDP-102 and HDP-103**



#### HDP-102: anti-CD37-ATAC

- CD37 is expressed on B-cell lymphoma cells
- Specific indication of non-Hodgkin lymphoma (NHL), relevant prevalence of 17p deletion in NHL
- Publication of scientific data in the journal Blood
  - Strong efficacy of a CD37-ATAC on tumor cells, leading to high tumor regression
  - Possible additional indication Richter syndrome, an aggressive form of non-Hodgkin's lymphoma
- Production of material for preclinical and clinical studies on track
- Submission of study application planned for 2024

#### **HDP-103: anti-PSMA-ATAC**

- PSMA is overexpressed in nearly all cases of prostate cancer; limited expression in normal tissue
- Target indication is Metastatic Castration-Resistant Prostate Cancer (mCRPC)
- Prevalence of 17p deletion in mCRPC is 60%
- Production of material for preclinical and clinical studies on track
- Preclinical development completed

# **Important Technology Data Presented at AACR Annual Meeting 2023**



#### **Poster title:** Subcutaneous dosing increases the therapeutic index of Amatoxin-based ADC

Comparison of subcutaneous versus intravenous routes of administration in preclinical models

- Subcutaneous dosing was shown to result in prolonged half-life and lower maximum serum levels
- Improved therapeutic index of HDP-103 (improved tolerability combined with consistent efficacy)
- Patent filed for use with all ATACs

# <u>Poster title</u>: Amanitin-based ADCs targeting Guanylyl cyclase C (GCC) as novel therapeutic modality for treatment of colorectal cancer

Preclinical data on ATACs targeting GCC (guanylyl cyclase C)

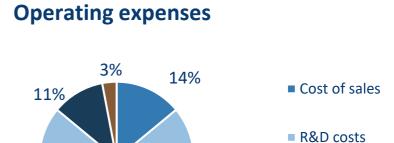
- GCC is overexpressed in many gastrointestinal tumors, most notably in colorectal cancer (>95%) and in ~ 65% of esophageal, gastric, and pancreatic tumors
- High antitumor activity and inhibition of tumor growth even at low concentrations after single or multiple dose treatment
- Favorable safety profile due to the good tolerability
- New early pipeline candidate HDP-104



## **Profit and Loss H1 2023**



in € m	H1 2023*	H1 2022*	Change
Sales revenue and other income	4.7	12.2	-61%
Operating expenses	20.7	18.5	12%
Cost of sales	2.9	3.5	-17%
R&D costs	14.8	11.8	25%
Administrative costs	2.3	2.8	-18%
Other expenses	0.7	0.3	133%
Net loss for the period	16.0	8.6	86%



72%



Other expenses

- Sales revenue decreased in line with planning; previous year was extraordinarily high due to the license payment of Huadong
- **R&D costs** increased as a result of the clinical trial with HDP-101 and extended manufacturing costs for the ATAC projects
- **Net loss** for the period significantly higher due to substantially lower income and higher expenses

<sup>\*</sup> Fiscal year starts 1st December; first half ends 31st May

# **Balance Sheet and Cash as of End of May 2023**



Assets (€ m)	31.05.2023	30.11.2022
Non-current assets	13.1	12.7
Other current assets	7.5	6.6
Cash	57.4	81.3
	78.0	100.6

Equity and liabilities (€ m)	31.05.2023	30.11.2022
Current liabilities	23.5	66.6
Non-current liabilities	3.6	6.0
Equity	50.9	28.0
	78.0	100.6

- Average cash usage per month €3.2 m (Guidance: €2.7 to €3.1 m) compared to average cash inflow of €1.2 m in H1 2022, excluding cash effects from financing activities
- Cash of €57.4 m below the year-end figure of €81.3 m due to ongoing operational costs and partial loan repayment
- Cash reach is unchanged expected until mid-2025 based on current planning

# **Guidance 2023**



in € m	6M 2023	FY 2022	Guidance 2023
Sales revenue and other income	4.7	19.9	7.0 to 10.0
Operating expenses	20.7	37.0	37.0 to 41.0
R&D expenses	14.8	26.4	
Operating result (EBIT)	(16.0)	(17.2)	(28.5) to (32.5)
Funds required for operations, capex	18.9	8.9	32.5 to 36.5
Funds required per month	3.2	0.7	2.7 to 3.1

# **Next Steps:** High Priority and Focus on HDP-101 on Clinical Progress



## HDP-101 (BCMA-ATAC for MM)

#### Phase I/IIa study in RRMM

- Patient recruitment for 4<sup>th</sup> cohort ongoing, further study centers to be initiated
- Phase I completion in early 2024 and dose finding for Phase IIa
- Start Phase IIa part in 2024

#### **Partnership with Huadong**

- Initial discussions to conduct clinical studies in China
- Preparation of clinical trial in China started



## HDP-102 (CD37-ATAC for NHL)

- Completion of preclinical and toxicological studies
- Clinical trial application 2024

## HDP-103 (PSMA-ATAC for prostate cancer)

- Completion of preclinical and toxicological studies
- Clinical trial application 2025

## Partner projects

#### Telix (TLX250-CDx)

- Filing for regulatory approval with the FDA and other agencies
- Planned approval in ccRCC and launch in 2024
- Indication expansion: Ongoing Ph II studies in bladder cancer and in triple-negative breast cancer

## **Investment Summary**



## A clinical-stage company with the goal of becoming a global ADC player

Disruptive first-in-humans
mode of action provides high
efficacy and potential for unique
clinical advantages



Validated by international **high-quality partnerships** 

Clinical lead program with best-in-class potential for indication with high medical need

**certain aggressive** tumors based on **biomarker** 

Strategic partnership for Asia, fastest growing pharmaceutical market

High value potential with growing ATAC pipeline and attractive ADC environment

