

Strategic Partnership: Heidelberg Pharma and Huadong

27/28 February 2022

## **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.

Given these uncertainties, prospective investors and partners are cautioned not to place undue reliance on such forward-looking statements. We disclaim any obligation to update any such forward-looking statements to reflect future events or developments.

This material is not intended as an offer or solicitation for the purchase or sale of shares of Heidelberg Pharma AG. This material may not be distributed within countries where it may violate applicable law.

# Welcome to our Call on the Strategic Partnership with Huadong



## **Speaker:**



**Dr. Jan Schmidt-Brand** CEO / CFO

## Q&A:



**Dr. George Badescu** CBO



**Prof. Dr. Andreas Pahl** CSO



Prof. Dr. Christof Hettich Chairman Managing Partner of dievini

## **Our Mission**

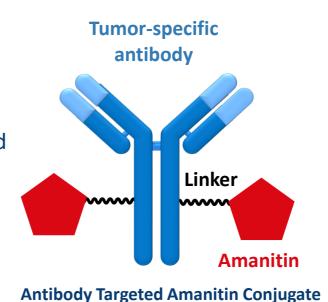


#### New option in cancer therapy with a unique mode of action

- Overcome resistance mechanisms
- Kill dormant tumor cells

#### Heidelberg Pharma's ADC approach – ATACs®

- Amanitin from the death cap mushroom as toxic payload
- Inhibition of RNA Polymerase II kills cancer cells
- Mode of action enables use of biomarker
- Optimized linker design
- Specifically engineered antibodies
- Development for hematological and solid tumor indications



## **ADC technology**

- Antibodies that specifically target a tumor-associated antigen
- Loaded with a highly effective toxin that they deliver to tumor cells
- Enable targeted therapy in oncology
- Improved therapeutic window and fewer side effects

ADCs bring toxins specifically to cancer cells, HDP's ADCs with amanitin as payload – ATACs®

# **Growing Pipeline**



Product	Target	Indication	Research	Preclinic	Clinic			Partner
Proprietary ATAC pi	peline					Ш	III	
HDP-101	ВСМА	Multiple myeloma (DLBCL/CLL)			<b>→</b>			Huadong (Asia)
HDP-102	CD37	NHL		<del></del>				Huadong (Asia)
HDP-103	PSMA	Prostate cancer		<del></del>				Huadong (Asia)
HDP-104	n/a	Undisclosed tumor indication	<del></del>					Huadong (Asia)
HDP-XX	n/a	Solid / Hematological tumors						
ATAC collaborations	5							
MGTA-ATACs	CD117, CD45	HSCs, Conditioning programs for blood cancers and genetic diseases						Magenta
TAK-ATACs	n/a	Oncology						Takeda/Millenium
Licensed legacy assets (non-ATACs)								
TLX250-CDx, TLX250, RHB-107, LH011		Different oncological indications; COVID-19			In clinical F	Phase I-III dev	velopment	Telix, RedHill, Link Health

## Rationale for the Strategic Partnership







Exclusive License agreement for the development and commercialization of ATAC® product candidates in Asia, including China, Hong Kong, South Korea and others, deal value USD 930 million

Huadong will also invest up to EUR 105 million in equity in Heidelberg Pharma

- Deal is providing a strong partner in Asia
- Funding will support advancing development of current product candidates and broadening the pipeline

- Support Heidelberg Pharma's global product development strategy in Asia
- Build a robust ADC product pipeline with best-in-class potential

# Partner Huadong Medicine – China Grand Enterprise: A Major Pharma Player in China and Beyond





- China Grand Enterprise (CGE) is a leading private conglomerate in China active in different sectors
- Healthcare is the key business of CGE, including chemical pharmaceuticals, biopharmaceuticals, herbal medicines and medical devices, CGE has 50 + pharmaceutical subsidiaries
- Consolidated revenue: ~USD30 bn (2020)



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Sales & Marketing

# **Huadong Medicine at a Glance**





**Headquartered in Hangzhou China** 



3 Major Businesses: Pharmaceutical, Distribution and Aesthetics



Founded in 1993



2020 Revenue USD5.2 bn Pharmaceutical USD1.7 bn



IPO in 1999 Ticker: SZ.000963 42% owned by CGE



**11,000 + Employees** 

Patient Centered. Science Driven.

# **Huadong Manufacturing Sites**





#### Hangzhou, Headquarter

Center of management, marketing, R&D, and manufacture



#### Jiangdong, Hangzhou

Microbial, Macromolecular API, Oral Solid Preparations, Powder Injection Preparations, etc



#### Yancheng, Jiangsu

Synthetic, Microbial Fermentative API, Preparations for Topical Use Drugs



Xi'an, Shanxi

Synthetic API, Innovative Narcotic Drugs R&D and manufacture





API certified by FDA





**2** Formulations certified by EMA



# **Huadong Sales Network in China**





6,000+ Medical Reps

2,400+ Tier 3 Hospitals

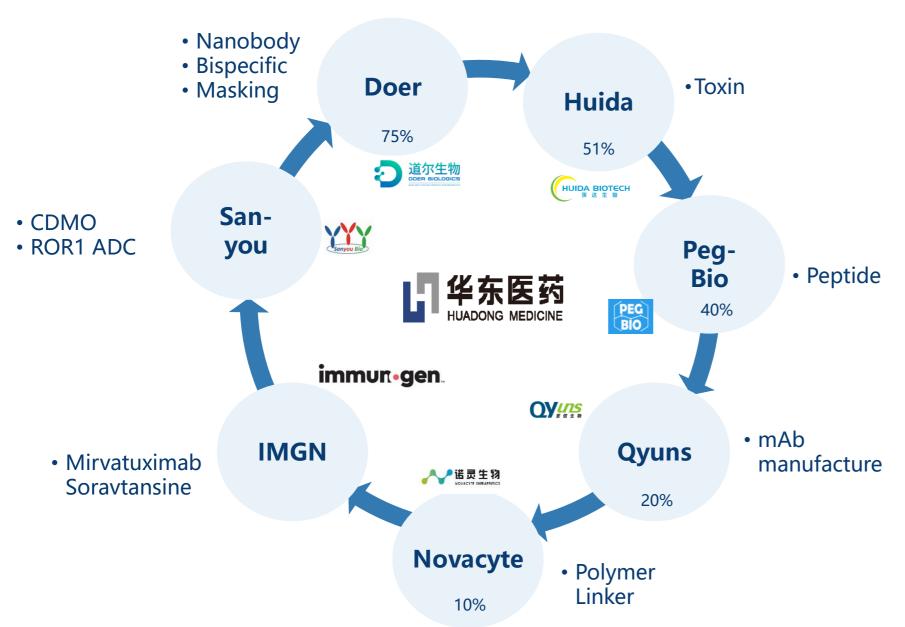
16,000+ Tier 2 and Tier 1 Hospitals

52,000+ Clinics

260,000+ Retail Pharmacies

## **Huadong is Building an ADC Ecosystem**





### Huadong's ADC capabilities

- Development
- Manufacturing
- Marketing & sales in China and APAC



Feeding Huadong's pipeline and supporting its ADC infrastructure in Europe and beyond

# **ATAC®** Multi-Program Exclusive Licensing Agreement



## HDP-101 (BCMA ATAC) HDP-103 (PSMA ATAC)

 Exclusive development and commercialization rights HDP-102 (CD-37 ATAC) HDP-104 (undisclosed)

• Exclusive option

#### Next 2 ATAC candidates

Right of first negotiation (ROFN)

#### For select countries in Asia<sup>1</sup>, excludes Japan

#### **Terms**

- Upfront payment of USD 20 m
- Milestone payments of up to USD 449 m
- Royalties on sales, single to low doubledigit percentage for each candidate

- Undisclosed option exercise fee
- Total of up to USD 461 m
- Royalties on sales, single to low doubledigit percentage for each candidate
- Terms to be negotiated at the time of triggering ROFN

<sup>&</sup>lt;sup>1</sup> People's Republic of China, Hong Kong, Macao, Taiwan, South Korea, Indonesia, Singapore, The Philippines, Thailand, Bangladesh, Bhutan, Brunei, Myanmar, Cambodia, Laos, Malaysia, Maldives, Mongolia, Nepal and Vietnam; excludes Japan, India, Pakistan, Sri Lanka

# Four Key ATAC® Programs Part of Strategic Collaboration



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

- Lead indication: Multiple myeloma (MM)
- BCMA (B-cell maturation antigen) overexpression and activation are associated with MM
- Phase I/IIa clinical trial ongoing in USA and Germany

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

- Target indication: Metastatic castration-resistant prostate cancer (mCRPC)
- PSMA is overexpressed in nearly all cases of prostate cancer
- Potential IND application in 2023

#### **HDP-102: CD37-ATAC**

- Target indication: non-Hodgkin lymphoma (NHL)
- CD37 is overexpressed on B-cell lymphoma cells
- Potential IND application in 2023

#### **HDP-104: undisclosed target**

China is one of the major global and fastest growing markets

## **Clear Responsibilities in a Well-defined Process**



**Heidelberg Pharma** 

Huadong

Development and commercialization outside Asia

**Participation to global clinical trials** 

**Clinical trial and commercial supply of products** 

**Commercialization of products in Asia** 

Heidelberg Pharma to become a global ADC player

# Further Support via Equity Investment - Huadong to Become a Major Shareholder



Investment agreement between Heidelberg Pharma, Huadong Medicine Investment Holding (Huadong) and main shareholder dievini Hopp BioTech holding (dievini)

- Huadong will invest up to EUR 105 m in Heidelberg Pharma via a planned rights issue and purchase of shares from dievini:
  - Rights issue of up to EUR 80 m planned, based on prospectus and using authorized capital: Up to 12.4 m shares @ EUR 6.44, same as last financing round in April 2021
  - Huadong to participate in rights issue and acquire up to ~26% of Heidelberg Pharma shares outstanding, dievini to offer its subscription rights as needed
  - Huadong plans additional share purchase from dievini of up to 9% of shares outstanding to reach total shareholding of up to 35% of share capital post rights issue
- Huadong to become 2<sup>nd</sup> largest shareholder in Heidelberg Pharma, dievini to remain largest shareholder.

Rights issue	using authorized capital					
Volume	EUR 80 m					
Number of shares	12,408,649					
Share price	EUR 6.44					
Subscription ratio	11:4					
Planned new share capital	46,584,458					
Plan						
Planned, not yet approved						

## **Approval Process and Scenario Planning**



#### **Required approvals:**

- German Federal Ministry of Economic Affairs and Climate Action according to Foreign Trade and Payments Ordinance (Außenwirtschaftsverordnung)
- Chinese law for Overseas Direct Investment (ODI)
- BaFin (German Federal Financial Supervisory Authority) exemption from potential mandatory takeover offer for Huadong

#### **Scenario planning:**

- If no approval until 27th July 2022, Huadong can extend the Long Stop Date until 27th October 2022.
  - Huadong and dievini will grant 12-months loans of EUR 10 m each at same terms.
  - Loans will be repaid in cash.
- If the approvals are not granted until the Long Stop Date, no shares will be issued to and acquired by Huadong.
  - Then dievini might consider participating in the rights issue and exercise a part of its subscription rights to fulfil its financing commitment (17th February 2022).

# A Transformative Deal with a Strong Partner: Supporting our Strategy to Become a Global ADC Player



Significant immediate strengthening of cash position\*

Adds another dedicated, longterm investor to our strategic shareholder base Enables accelerated development and potentially shorter time to market and broadening of pipeline

Potential broadening of the collaboration to further exploit synergies

















Success-based milestones and royalties offer potential for ongoing cash infusion to support business for the long term

Resource sharing via joint clinical development means less use of our own resources

Secures market access in China, one of the major global and growing markets, and Asian markets

<sup>\*</sup>Financial guidance to be provided on 24th March with 2022 financial results

## **Contact Us**



## Heidelberg Pharma AG

Gregor-Mendel-Str. 22 68526 Ladenburg, Germany Website: www.heidelberg-pharma.com

George Badescu, CBO Tel.: +49 6203 10090 george.badescu@hdpharma.com

## IR/PR support

MC Services AG Katja Arnold (CIRO) Tel.: +49 89 210 28840

Email: katja.arnold@mc-services.eu

### Ticker data

ISIN: DE000A11QVV0

Symbol: HPHA

Reuters: HPHA.DE

Bloomberg: HPHA.GY