## **CORPORATE UPDATE**

MAY 2022







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# A global science-focused biopharma



 $(\theta)$ 

Fully integrated R&D and commercialization platform built over **22 years** 

>4,600 personnel<sup>[1]</sup> across HUTCHMED group ~1,700 person team in Oncology/Immunology

### Global novel drug discovery & manufacturing operations

20+ years novel drug discovery – 12 innovative NMEs<sup>[2]</sup> discovered in-house

~900 integrated R&D staff focused on oncology & immunological diseases

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# **Clinical development** & regulatory operations **in all major markets**

- China, U.S., EU & Japan clinical infrastructure
- >45 clinical studies underway world-wide
- First 3 novel oncology drugs approved

# **Commercial teams in China & U.S.** ~50% of the global pharma market

- ~700 person China oncology commercial team
- Covering over 2,500 China oncology hospitals

>4,600 personnel includes non-consolidated joint venture.
 [2] 13<sup>th</sup> oncology NME (TAZVERIK®) China rights licensed-in from Epizyme.

# 2021 Highlights



### An exceptional year for HUTCHMED, with momentum continuing into 2022

1	Commercial results China oncology	<ul> <li>2021 up 296% to \$119.6m from ELUNATE<sup>®</sup> and 2 new product launches</li> <li>Combined Jan-Feb 2022 in-market sales of 3 oncology drugs up 81%</li> </ul>
2	Broad development program	<ul> <li>20+ trial initiations, incl. 13 reg. studies on 6 assets, 5+ in planning</li> <li>4 new in-house NMEs into clinical development</li> </ul>
3	Late-stage assets	<ul> <li>7 registration studies for savolitinib in lung, kidney &amp; gastric cancer</li> <li>Fruquintinib FRESCO-2 global MRCT fully enrolled with 2022 readout</li> </ul>
4	Hematology progress	<ul> <li>2 Breakthrough Therapy Designations for amdizalisib and sovleplenib</li> <li>Tazemetostat aimed for accelerated approval &amp; availability in China</li> </ul>
5	Flourishing oncology organization	<ul> <li>At YE, 650+ commercial &amp; 800+ R&amp;D personnel – ~130 in U.S. &amp; Europe</li> <li>&gt;\$1bn in cash and further divestment opportunities of non-core assets</li> </ul>

# 1 Oncology commercial: 2021 as expected & momentum continues



Oncology consolidated revenues 2022 guidance: **\$160-\$190 million** (China only)



[1] Includes	s manufacturing fe	es commercia	l services and	rovalties
[I] metaace	s manaractaring ic	co, conniciciu	i services una	royunces.

US\$ (Growth vs. Prior Period)	2021	Jan-Feb 2022 Unaudited
In-market Sales		
<b>ELUNATE</b> <sup>®</sup>	\$71.0m <i>(111%)</i>	\$21.6m <i>(51%)</i>
SULANDA®	\$11.6m –	\$6.0m <i>(21%)</i>
ORPATHYS <sup>®</sup>	\$15.9m –	\$7.4m –
Total	\$98.5m <i>(192%)</i>	\$35.0m <i>(81%)</i>

#### **Consolidated Revenues**

Product Sales <sup>[1]</sup>	\$76.4m (2	282%)	\$24.3m <i>(61%)</i>
Other R&D Service income	\$18.2m (7	77%)	\$3.7m <i>(80%)</i>
Milestone payments	\$25.0m –		\$15.0m -
Total	\$119.6m (2	296%)	<b>\$43.0m</b> (151%)
2021 guidand <b>\$110-\$130 mill</b>			mentum continues in <b>Jan-Feb 2022</b>

# <sup>2</sup> Deep & increasingly broad portfolio



Most discovered in-house, & designed for global differentiation

### **20+ trial initiations, including 13 registration studies** & > 5 more are planned for 2022

PRODUCT	MOA	DISCOVERY <sup>[1]</sup>	INDICATIONS	PARTNER	RIGHTS	CHINA <sup>[2]</sup>	GLOBAL <sup>[2]</sup>
Surufatinib (SULANDA®)	VEGFR 1/2/3, FGFR1 & CSF-1R	In-house (est. LOE ~2035)	NET, NEC, multiple I/O combos	None	HCM holds all WW rights	Marketed (non-pNET) Marketed (pNET)	E.U. MAA accepted
Fruquintinib (ELUNATE®)	VEGFR 1/2/3	In-house (est. LOE ~2033)	Colorectal, gastric, NSCLC, EMC, (multiple I/O & TKI combos)	Lilly	HCM has WW rights ex- China; 70%-80% of sales in China <sup>[4]</sup>	Marketed (Colorectal); Ph.III (Gastric)	<b>Ph.III U.S., E.U., Japan</b> (Colorectal)
Savolitinib (ORPATHYS®)	MET	In-house (est. LOE ~2035)	NSCLC, kidney, gastric, colorectal <sup>[3]</sup> (multiple I/O & TKI combos)		AZ has WW rights; China (30% royalty); ex-China (9-18% tiered royalty)	Marketed (NSCLC mono) Ph.III (NSCLC combo) Ph.II reg-intent (GC)	Ph.II/III global (multiple NSCLC) Ph.III global (PRCC)
Amdizalisib (HMPL-689)	ΡΙ3Κδ	In-house (est. LOE ~2040)	B-cell malignancies – indolent NHL	None	HCM holds all WW rights	Ph.II reg-intent (FL & MZL)	<b>Ph.I</b> U.S., E.U., Aus (NHL)
Sovleplenib (HMPL-523)	Syk	In-house (est. LOE ~2037)	ITP, B-cell malignancies – indolent non-Hodgkin's lymphoma (NHL)	None	HCM holds all WW rights	<b>Ph.Ib/II</b> (>200 NHL pts.) <b>Ph. III</b> (ITP)	<b>Ph.I</b> U.S., E.U., Aus (NHL)
TAZVERIK®	EZH2	Epizyme	Solid tumors, hematological malignancies	(Epizyme <sup>-</sup>	HCM has commercial rights in Greater China	IND Cleared (China)	Marketed by Epizyme
HMPL-453	FGFR 1/2/3	In-house (est. LOE ~2039)	Cholangiocarcinoma	None	HCM holds all WW rights	Ph.II (Solid Tumors )	-
HMPL-306	IDH 1/2	In-house (est. LOE ~2043)	Hematological malignancies, solid tumors	None	HCM holds all WW rights	Ph.I (Hem. malignancies)	<b>Ph.I</b> (solid tumor & hem. malignances)
HMPL-295	ERK (MAPK pathway)	In-house	Solid tumors	None	HCM holds all WW rights	Ph.I (Solid tumors)	-
HMPL-760	3G BTK	In-house	Hematological malignancies	None	HCM holds all WW rights	Ph.I (B-Cell NHL)	IND cleared
HMPL-653	CSF-1R	In-house	Solid tumors	None	HCM holds all WW rights	<b>Ph. I</b> (Advanced Malignant Solid Tumors & TGCT)	4 New clinica
HMPL-A83	CD47	In-house	mAb – solid tumors, hematological malignancies	None	HCM holds all WW rights	IND cleared	assets in 2021

[1] Approximate estimated Loss of Exclusivity (LOE) in key markets considering multiple patent families, extension, and regulatory protection;
 [2] Represents the most advanced clinical trial stage and indication;
 [3] Investigator initiated trials (IITs);
 [4] Subject to meeting pre-agreed sales targets, Lilly will pay HUTCHMED an estimated total of 70%-80% of ELUNATE<sup>®</sup> sales in the form of royalties, manufacturing costs and service payments.

# Savolitinib – major late-stage expansion

7 registrational studies – 3 global & 4 in China

### **GLOBAL** – led by AstraZeneca

### **MET-driven Papillary Renal Cell Carcinoma (PRCC)**

- Savolitinib + IMFINZI<sup>®</sup> vs. SUTENT<sup>®</sup> Phase III registration study
- FPI in October 2021 **SAMETA Study**

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#### 2L TAGRISSO® refractory NSCLC w/ MET aberration

- **SAVANNAH study** continue evaluation for potential accelerated approval; plan to present data in H2 2022
- Savolitinib + TAGRISSO<sup>®</sup> Phase III registration study \$15 million milestone from AstraZeneca triggered by initiation of start-up activities in Feb 2022 – FPI targeted mid-2022 – SAFFRON Study

### **CHINA** – *led by* HUTCHMED

HUTCH

Astra7ene

#### MET Exon14 skipping NSCLC

- NDA conditional approval in June 2021
- **Confirmatory Phase III study** FPI September 2021

### 2L EGFR TKI refractory NSCLC w/ MET amplification

- Savolitinib + TAGRISSO<sup>®</sup> Phase III registration study
- FPI in November 2021 **SACHI Study**

#### 1L EGFRm+ NSCLC w/ MET overexpression

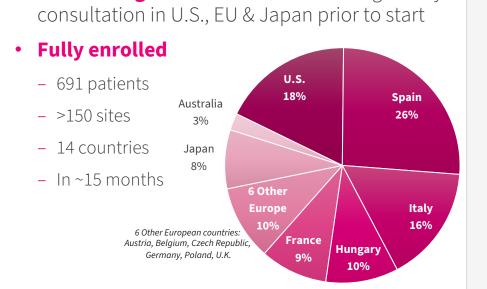
- Savolitinib + TAGRISSO<sup>®</sup> Phase III registration study
  - FPI in September 2021 **SANOVO Study**

#### Gastric cancer w/ MET amplification

- Single arm study with potential for registration
- FPI in July 2021

# <sup>3</sup> Fruquintinib – FRESCO-2 to readout in H2 2022 HUTCHMED

### If positive, plan U.S. filing at year end in ≥3L mCRC, with EU & Japan soon after

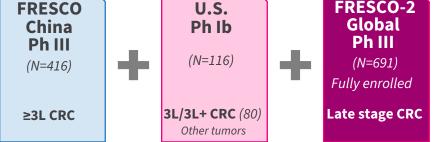


**FRESCO-2 global MRCT Phase III** – regulatory

•

- **Potential to fill an unmet medical need** if FRESCO-2 is positive the package will support filing for third-line & above metastatic CRC
- **U.S. Fast Track Designation** for ≥3L mCRC & potential for U.S. rolling submission
- Extensive list of **supporting studies**

# FRUQUINTINIB – Basis for global filings<br/>Aggregation of China, U.S. & global studiesFRESCOU.S.FRESCO-2



### Consistency in tumor control

despite additional prior lines of therapy in U.S. study

ASCO-GI	U.S. Phase 1b <sup>[1]</sup>		FRESCO <sup>[2]</sup>	
2022	<b>Cohort B</b> (n=41+)	<b>Cohort C</b> (n=40)	Fruquintinib (n=278)	<b>Placebo</b> (n=138)
Prior VEGF/R Tx	93%	100%	30%	30%
<b>mOS,</b> mo. [95% CI]	<b>10.7</b> [6.7-11.7]	<b>9.3</b> [5.2-NR]	<b>9.3</b> [8.2-10.5]	<b>6.6</b> [5.9-8.1]
	was conducte	imor assessment d in 3 patients. mber 3, 2021	DCO: January	/ 17, 2017

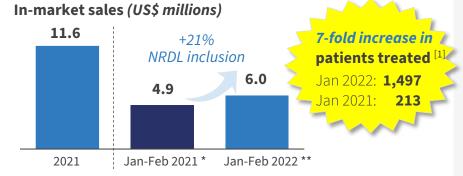
ORR., objective response rate; DCR, disease control rate;; mPFS, median progression free survival; mOS, median overall survival; TEAE, treatment emergent adverse event; CI, confidence interval; NR, not reached; Tx, treatment; [1] Dasari, et al. Phase 1/1b trial of fruquintinib in patients with advanced solid tumors: preliminary results of the dose expansion cohorts in refractory metastatic colorectal cancer. ASCO-GI 2022 #93. doi: 10.1200/JCO.2022.40.4\_suppl.093; [2] Li J, et al. Effect of Fruquintinib vs Placebo on Overall Survival in Patients With Previously Treated Metastatic Colorectal Cancer: The FRESCO Randomized Clinical Trial. JAMA. 2018;319(24):2486-2496. doi:10.1001/jama.2018.7855.

# 3 Surufatinib – China expanding; ex-China approval delays

### **CHINA** – momentum building

#### 2022 NRDL & access rapidly growing in China

• NRDL inclusion Jan 2022 allowing wider patient access



#### PD-1 combo studies entering registration stage

• Following SURTORI-01 (NEC) multiple new Phase IIIs expected in 2022 for Surufatinib + Toripalimab combo

	NEC (2L)	ESCC (2L)	GEJ/GC (2L)	SCLC (2L)
Status	SURTORI-01 Phase III Initiated Sep-2021	<b>SURTORI-02</b> Phase III to initiate	Reg design under discussion	Phase II Ongoing

• International exploratory studies with tislelizumab (PD-1) also ongoing

# **GLOBAL** – CRL a setback, but committed to bringing it to patients through additional trial

HUTCHM

#### FDA – NDA Complete Response Letter (CRL)

- China SANET trials not applicable to U.S.;
- Importance of multi-region clinical trials (MRCTs)
- No questions on safety/efficacy in Chinese patients
- HUTCHMED will collaborate with FDA to bring surufatinib to patients in need

#### EMA – MAA Status

- MAA validated & accepted for review in July 2021
- Reached 180-day assessment
- Site inspections required timing will be subject to access by inspectors from Europe

#### Japan - Bridging Study Ongoing

- Bridging study initiated in Sept 2021
- Discussion with PMDA will follow study readout

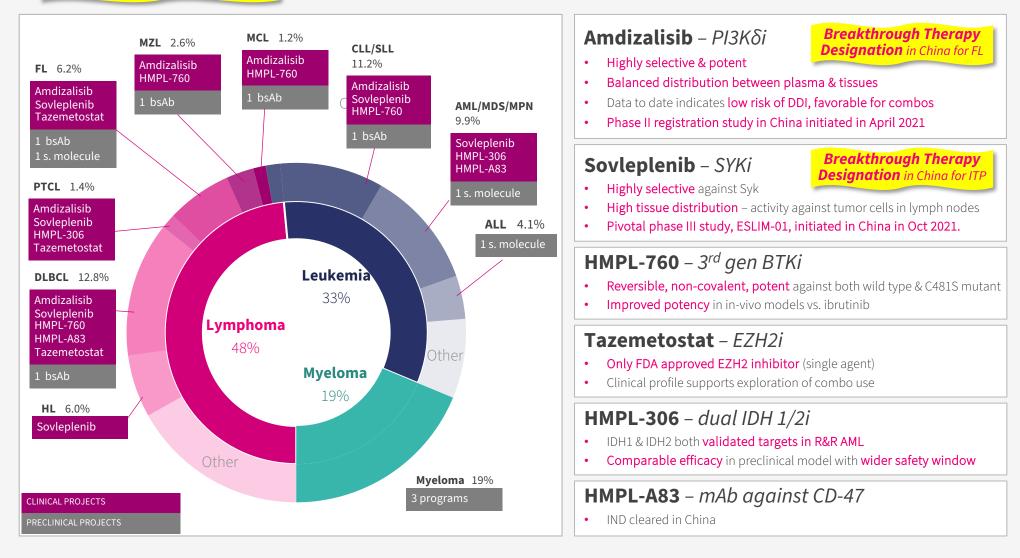
#### Conducting multi-regional registration trials has been our foundational approach

\* Normal launch distribution channel pipeline fill; \*\* Consumption sales; [1] New & continuing patients; NRDL = National Reimbursement Drug List; NEC= Neuroendocrine Carcinoma; ESCC = Esophageal Squamous Cell Carcinoma; GEJ = gastroesophageal junction cancer; GC= gastric cancer; SCLC = small cell lung cancer

# Next wave: strong heme onc portfolio



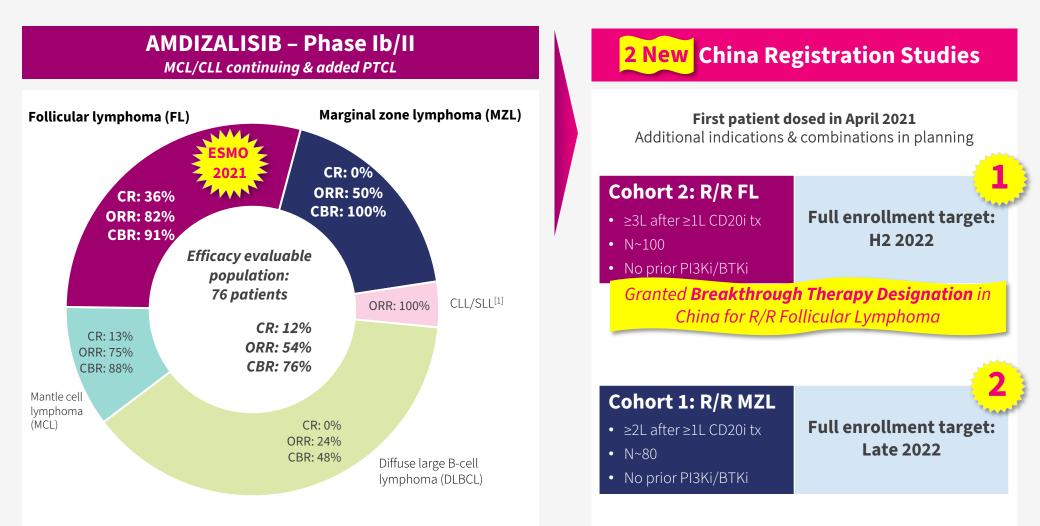
### 6 clinical-stage assets designed to cover virtually the entire heme onc spectrum



# Amdizalisib – China Breakthrough Therapy



China registration trials initiated, supported by differentiated POC data



As of June 15, 2021. ESMO 2021: Cao J, et al. #8330 - A phase Ib study result of HMPL-689, a PI3K inhibitor, in Chinese patients with relapsed/refractory lymphoma. Annals of Oncology (2021) 32 (suppl\_5): S773-S785. doi: 10.1016/annonc/annonc676. [1] Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL); POC = Proof-of-concept – Phase Ib/II expansion data

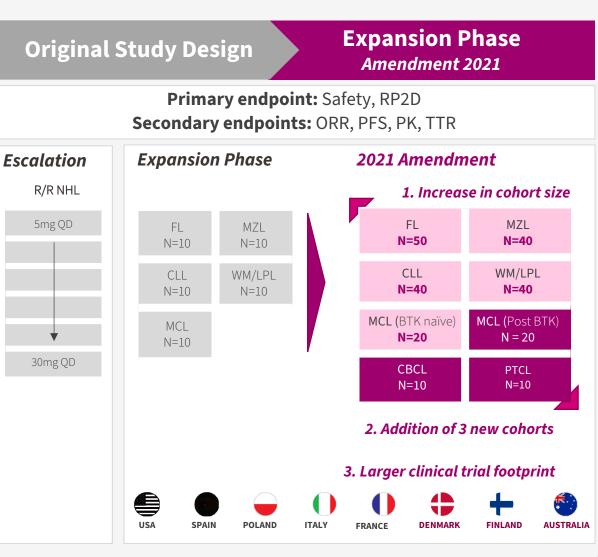
# Amdizalisib – Global development



Large scale expansion (N=210) - accumulating global evidence of clinical differentiation

### Amdizalisib Global Strategy

- Continue generating robust & differentiated monotherapy data
- Amended global study to:
  - 1. Increase in cohort size for select lymphoma indications based on proof of activity
  - 2. Addition of newer cohorts in high unmet need lymphoma indications
  - **3. Larger clinical trial footprint** with additional countries to support expansion
- Explore combination opportunities with both approved & novel agents
- Continue to work with Regulatory agencies to define a data-driven path to NDA



# Sovleplenib – immune thrombocytopenia (ITP) HUTCHMED

Syk inhibitor promising data for treatment of ITP, a condition with high unmet medical need

### **Results from China Phase I/II in R/R primary ITP**

- Oral, fast onset of efficacy **ORR 80% & Durable ORR 40%**
- Robust efficacy in heavily pre-treated patients
- Similar efficacy level with or without prior TPO/TPO-RA therapies



		Sovler	olenib – 300 mg, ol	nce daily
	ASH 2021	Double-blinded Patients	Cross-over Patients	Total
		8 + 16 weeks N=16	16 weeks N=4	N=20
ORR: n (%)	<b>PLT≥50×10<sup>9</sup>/L:≥1 time</b>	12 (75.0)	4 (100.0)	16 (80.0)
Durable ORR: n (%)	PLT≥50×10 <sup>9</sup> /L:≥4 times of the last 6 visits	5 (31.3)	3 (75.0)	8 (40.0)

New ESLIM-01 pivotal Phase III study initiated October 2021

# <sup>4</sup> Sovleplenib – Global development



Dose expansion ongoing into 9 indolent NHL patient populations

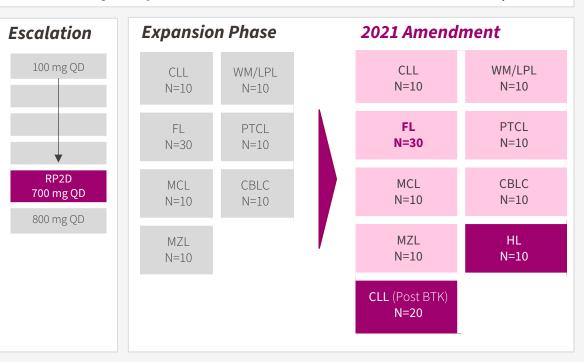
### Sovleplenib Global Strategy

- Continue generating monotherapy data in lymphoma indications of interest:
  - 1. Follicular lymphoma
  - 2. Hodgkin's lymphoma
  - 3. CLL (post BTKi)
- **Explore combination opportunities** in lymphoma
- Expand to non-malignant hematology conditions of relevance such as chronic immune thrombocytopenia Phase I in U.S. / EU

### Original Study Design

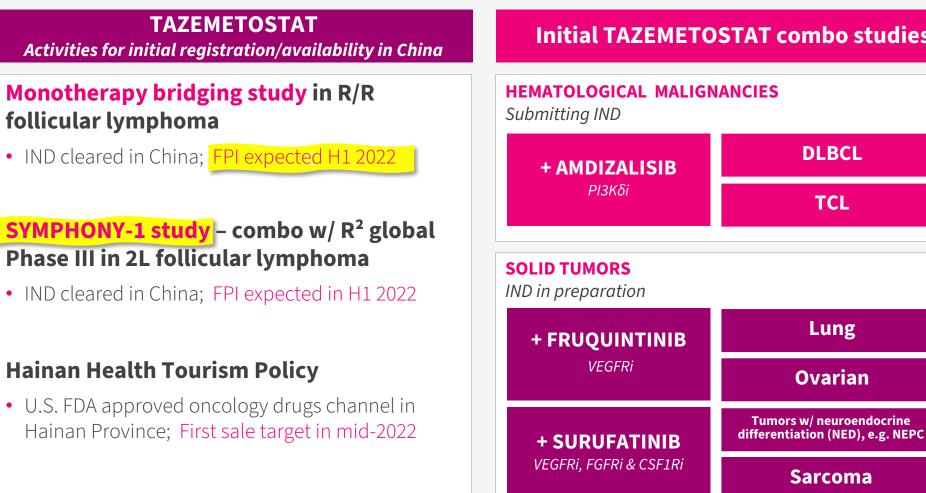
#### **Expansion Phase** Amendment 2021

**Primary endpoint:** Safety, RP2D **Secondary endpoints:** ORR, PFS, PK, Time on Treatment/Response



### Tazemetostat – a first-in-class EZH2 inhibitor HUTCHME

Aim for accelerated China approval & to assess major combination opportunities



### Initial TAZEMETOSTAT combo studies

# Strong oncology sales growth & cash position HUTCH

### Cash Resources: \$1,012m (As of Dec 31, 2021) [1]

#### **Condensed Consolidated Statement of Operations**

	YE Dec 31,		
(in US\$ millions)	2021	2020	
Revenues:			
Oncology/Immunology – Marketed Products	76.4	20.0	
Oncology/Immunology – R&D	43.2	10.2	
Oncology/Immunology consolidated revenues	119.6	30.2	
Other Ventures	236.5	197.8	
Total revenues	356.1	228.0	
Expenses:			
Costs of revenues	(258.2)	(188.5)	
R&D expenses	(299.1)	(174.8)	
Selling & general admin. Expenses	(127.1)	(61.3)	
Total expenses	(684.4)	(424.6)	
Loss from Operations	(328.3)	(196.6)	
Gain on divestment of an equity investee	121.3	_	
Other (expense)/income	(8.7)	6.9	
Loss before income taxes & equity in earnings of	(215.7)	(189.7)	
equity investees			
Income tax expense	(11.9)	(4.8)	
Equity in earnings of equity investees, net of tax	60.6	79.0	
Net loss	(167.0)	(115.5)	
Less: Net income attrib. to non-controlling interests	(27.6)	(10.2)	
Net loss attrib. to HUTCHMED	(194.6)	(125.7)	

#### Revenues up +56% to \$356m

- Oncology up ~4x to \$120m (2020: \$30m)
- Other Ventures distribution sales up 20%

### **Global pipeline & org. expansion**

### • R&D up +71% to \$299m

- U.S. & EU R&D up 121% to \$140m
- China R&D up 43% to \$159m
- Oncology team grew 50% to ~1,500 staff

# Other Ventures income partially offsetting investment in R&D

- **\$159m** cash from divesting non-core OTC<sup>[2]</sup>
- Other non-core business income up 33% (Mainly SHPL \$45m<sup>[3]</sup>)

[1] cash / cash equivalents / Short-term investments (deposits over 3 months);

[2] Non-core OTC contributed one-time gains of (a) \$5.6m of land compensation and (b) \$82.9m gain on divestment;

[3] Shanghai Hutchison Pharmaceuticals Limited income attributable to HUTCHMED.

# 2022-23 Outlook



### Strategy & ambition unchanged, with a rich pipeline and a strong commercial track record

China commercial progress	<ul> <li>Oncology revenue guidance \$160-\$190m (China only)</li> <li>Q1 2022 strong; subject to headwinds due to COVID-19 in China</li> </ul>
Late-stage solid tumor assets	<ul> <li>Savolitinib global SAFFRON Phase III start, SAVANNAH data in H2</li> <li>Fruquintinib FRESCO-2 global MRCT with H2 2022 readout         <ul> <li>if positive, US NDA YE 2022; EU &amp; Japan H1 2023</li> </ul> </li> <li>Surufatinib currently under review by EMA; U.S. pivotal trial in planning</li> </ul>
Late-stage heme assets	<ul> <li>Amdizalisib FL &amp; MZL China fully enrolled H2 2022</li> <li>Sovleplenib ITP China fully enrolled YE 2022</li> <li>Tazemetostat launching in Hainan and initiating China bridging study</li> </ul>
Flourishing oncology organization	<ul> <li>780+ commercial &amp; 900+ R&amp;D personnel – ~150 in U.S. &amp; Europe</li> <li>&gt;\$1bn in cash and further divestment opportunities of non-core assets</li> </ul>

# Scientific/medical partnership strategy



### Our BD strategy is focused on **four key activities**



#### **ORPATHYS® world-wide**

- Launched in China
- 7 registration studies in NSCLC, PRCC & gastric cancer

#### **ELUNATE® China**





#### **Epigenetics**

• Epizyme: TAZVERIK®

**Pipeline** 

Synergy

Collaborations

#### IO Combos

- Junshi: Suru + TUOYI®
- Innovent: Fruq + TYVYT®
- *BeiGene:* Suru / Fruq + tislelizumab



Innovent

Innovent Biologics

Junshi

Biosciences

### Immunology

 4 preclinical candidates for immunological diseases

**Bandwidth** 

**Partnerships** 

- Funded by Inmagene
- HUTCHMED right to cocommercialize in China

INMAGENE

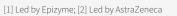
#### Strategic acquisitions

Capability

Enhancement

Deals

• Accelerate building new capability (e.g., biologics)



# Thank you



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