### ADVANCING TO GLOBAL LAUNCHES & CONTINUED PIPELINE PROGRESS

#### **CORPORATE PRESENTATION**

November 2023

Nasdaq/AIM:HCM | HKEX:13





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### A global science-focused biopharma



Fully integrated R&D and commercialization platform

#### Global novel drug discovery & manufacturing operations

20+ years novel drug discovery – 13 clinical-stage innovative NMEs<sup>[1]</sup> discovered in-house New flagship factory expected to come online in 2023/4 to expand capacity by 5x Listed on the LSE (HCM), NASDAQ (HCM), and HKEX (13)

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

- China, U.S., EU & Japan clinical capabilities
- First 3 novel oncology medicines approved in China
- 1 FDA approved

#### **Commercial teams in China**

- Oncology commercial team covering >3,000 hospitals in China
- Commercial partnering outside of China



### The path to a sustainable business...

HUTCHMED medium-term & long-term strategy

AMBITION to mature into a Target 2025 to be profitable biopharma self-sustaining from an emerging growth co 6-7 products potentially launched in China **VISION UNCHANGED:** discovering, developing & bringing new innovative medicines to patients worldwide 2022

> 1<sup>st</sup> global MRCT delivered 2<sup>nd</sup> sNDA-enabling Phase III



Peak year for cash burn

### **Growth & operating** leverage

HUTCHME

Blockbuster in-market sales Accelerating China growth Royalties from ex-China sales

2023 - 2024

Reduction in R&D costs

**Continued revenue growth** from new indications / regions

**Global commercialization** through partnerships

### H1 2023: strong execution on strategic direction



STRATEGIC DELIVERY

- ✓ Delivering revenue growth & executing long-term growth strategy
- Delivering global partnerships, to reach more patients than ever: Takeda licensing closed
- ✓ Delivering cash conservation & cost optimization: \$856m cash & 20% lower R&D costs vs H1'22

PRODUCTS & PIPELINE PROGRESS

#### LATE STAGE

- ✓ Fruq FDA approved (CRC)
- ✓ Fruq under review in EU and JP (CRC)
- ✓ Fruq China sNDA accepted (GC)
- ✓ Savo & '453 initiated new registration studies (GC, IHCC)
- Savo SAVANNAH enrollment to finish H2 2023 (2L NSCLC)

#### **2ND WAVE**

- ✓ Sovle ESLIM Ph III readout Aug 2023 (ITP)
- ✓ Taz bridging study to fully enroll H2'23 (FL)
- Amdiz reg Ph II H2'23 readout (FL)

CHINA COMMERCIAL DELIVERY 2000

### ✓ All 3 medicines on NRDL

Oncology/Immunology prod.
 rev. +26% (+35% CER)
 on track to meet guidance

 ✓ Combined in-market sales +16% (+25% CER) for ELUNATE<sup>®</sup>, SULANDA<sup>®</sup> & ORPATHYS<sup>®</sup>

CER = at constant exchange rate.

#### HUTCHME

### Agenda

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### **Financial review & outlook**

*Underpinned by strong financial & strategic fundamentals* 

### **Commercial delivery**

Novel oncology products continue to bring growth

### Manufacturing update

*New facility to enable more control and cost savings* 

### Late-stage pipeline

15+ potential NDAs & sNDAs in the next 3 years

### **Our strategy**

*Revenue growth & strategic actions on path to profitability* 



# **1** Well-financed position

#### On path to sustainable business

#### **Condensed Consolidated Balance Sheets**

(in US\$ millions)	Jun 30, 2023	Dec 31, 2022
Assets		
Cash, cash equivalents & short-term investments	856.2	631.0
Accounts receivable	129.2	98.0
Other current assets	105.1	110.9
Property, plant and equipment	96.8	75.9
Investments in equity investees	37.7	73.8
Other non-current assets	72.5	39.8
Total assets	1,297.5	1,029.4
Liabilities and shareholders' equity		
Accounts payable	54.6	71.1
Other payables, accruals and advance receipts	227.2	264.6
Deferred revenue	149.5	13.5
Bank borrowings <sup>[1]</sup>	40.1	18.1
Other liabilities	26.1	25.2
Total liabilities	497.5	392.5
Company's shareholders' equity	782.0	610.4
Non-controlling interests	18.0	26.5
Total liabilities and shareholders' equity	1,297.5	1,029.4

Cas	sh Resources
•	\$856m cash / cash eq. / ST inv. <sup>[2]</sup>
•	\$65m unutilized banking facilities
Βοι	rrowing
•	<b>\$40m</b> in bank borrowings
Otł	ners
•	\$44m additional cash at SHPL JV
Im	pact of Takeda transaction
•	\$400m non-refundable upfront payment was received in April 2023
•	<b>\$259m</b> recognized on <i>Consolidated Statement of Operations</i> as <i>Revenue</i> , and the remainder was recorded in <i>Deferred revenue</i> as of



# Oncology sales growth & Other Ventures income



#### Oncology consolidated revenues FY2023 guidance unchanged: \$450-\$550 million

(including recognizing ~\$280m of the Takeda upfront payment)

#### **Condensed Consolidated Statements of Operations**

(Unaudited, in US\$ millions, except share and per share data)	Six months end 2023	ed June 30, 2022
Revenues:		
Oncology/Immunology – Marketed Products	80.1	63.5
Oncology/Immunology – R&D	279.1	27.6
Oncology/Immunology consolidated revenues	359.2	91.1
Other Ventures	173.7	110.9
Total revenues	532.9	202.0
Operating expenses:		
Costs of revenues	(208.3)	(137.3)
R&D expenses	(144.6)	(181.7)
Selling & general admin. expenses	(68.3)	(79.8)
Total operating expenses	(421.2)	(398.8)
	111.7	(196.8)
Other income/(expense), net	25.4	(3.8)
Income/(loss) before income taxes & equity in earnings		
of equity investees	137.1	(200.6)
Income tax (expense)/benefit	(2.7)	4.2
Equity in earnings of equity investees, net of tax	35.1	33.5
Net income/(loss)	169.5	(162.9)
Less: Net (income)/loss attrib. to non-controlling interests	(0.9)	0.0
Net income/(loss) attributable to HUTCHMED	168.6	(162.9)
Per ordinary share (basic)	0.20	(0.19)
Per ordinary share (diluted)	0.19	(0.19)
Per ADS share (basic)	1.00	(0.96)
Per ADS share (diluted)	0.97	(0.96)

#### Total Consolidated Revenues up 164% (173% CER) to \$533m

- **Oncology product rev. up 26% (35% CER)** to \$80m (H1'22: \$64m)
- R&D revenues of \$279m included recognition of \$259m in Takeda upfront payment (out of \$400m)

#### **Control over operating expenses**

- R&D: supporting 15+ registration enabling programs
  - As a result of strategic prioritization of our pipeline
  - Ex-China decreased to \$56m (H1'22: \$84m)
- SG&A expenses decline primarily reflected the restructuring of the ex-China commercial infrastructure in late 2022

#### Benefitting from our 50% share of SHPL JV's growth

- Net revenues up 11% (19% CER) to \$235m (H1'22: \$212m)
- Net income attributable to HUTCHMED from equity investees up 5% (12% CER) to \$35m (H1'22: \$34m)

RMB declined 7% in H1 2023 vs USD

# Continuing growth of oncology product sales



Fruquintinib Capsules ELUNATE <sup>®</sup> 5 <sub>mg</sub>
Surufatinib Capsules suLANDA® 50mg
Калоники
Savolitinib Tablets Orpathys®
Huchus MediParro

(US\$ in millions)	H1 2023	H1 2022	%Δ (CER)	H1 2023	H1 2022	%∆ (CER)
	In-	market Sa	ales <sup>[1]</sup>	Consoli	idated Re	venues <sup>[2]</sup>
ELUNATE <sup>®</sup> (fruquintinib)	\$56.3	\$50.4	+12% (+20%)	\$42.0	\$36.0	+16% (+25%)
SULANDA <sup>®</sup> (surufatinib)	\$22.6	\$13.6	+66% (+79%)	\$22.6	\$13.6	+66% (+79%)
ORPATHYS <sup>®</sup> (savolitinib)	\$22.0	\$23.3	-5% (+2%)	\$15.1	\$13.8	+10% (+17%)
TAZVERIK <sup>®</sup> (tazemetostat)	\$0.4	\$0.1	+560% (+583%)	\$0.4	\$0.1	+560% (+583%)
Product Sales <sup>[2]</sup>	\$101.3	\$87.4	+16% (+25%)	\$80.1	\$63.5	+26% (+35%)
Other R&D Service income				\$20.4	\$12.6	+62% (+66%)
Upfront & Milestone payment				\$258.7	\$15.0	
Total				\$359.2	\$91.1	+294%(+301%)

[1] For ELUNATE® and ORPATHYS®, represents total sales to third parties as provided by Lilly and AstraZeneca, respectively; and their sales to other third parties as invoiced by HUTCHMED.

[2] For ELUNATE<sup>®</sup>, represents manufacturing fees, commercial service fees and royalties paid by Lilly, to HUTCHMED, and sales to other third parties invoiced by HUTCHMED; for ORPATHYS<sup>®</sup> represents manufacturing fees and royalties paid by AstraZeneca and sales to other third parties invoiced by HUTCHMED; for ORPATHYS<sup>®</sup> represents manufacturing fees and royalties paid by AstraZeneca and sales to other third parties invoiced by HUTCHMED; for SULANDA<sup>®</sup> and TAZVERIK<sup>®</sup>, represents the Company's sales of the products to third parties.

# Commercial environment



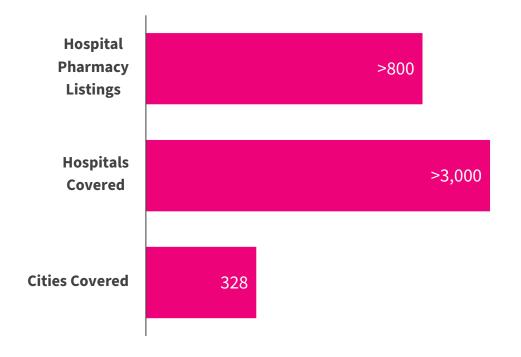
Policies benefitting innovative medicines access + commercial organization at scale

#### **Favorable operating environment**

- China is the second largest country by pharmaceutical spending <sup>[1]</sup>
- Policies promoting access to innovative medicines
  - Life sciences is one of the key strategic priority sectors to provide a better quality of life
  - Simplification of NRDL renewals (Jul 2023)
  - CDE guideline to accelerate review of innovative marketing applications with breakthrough designations (Apr 2023)
  - Guidance on development of oncology medicines, encouraging innovations that have real clinical value (Dec 2021)
- Emergence of commercial health insurance

#### **Robust on-the-ground presence**

- 900+ oncology commercial team
- >33,000 oncology physicians covered



# <sup>2</sup> ELUNATE<sup>®</sup> (fruquintinib) remains market leader in 3L CRC





#### In-market sales (US\$ millions)



#### **Underlying demand remains strong**

- ~17,000 est. new patients treated, up ~20% vs H1 2022
- COVID-related impact early in the year has resolved
- Improving access to diagnosis & treatment in Tier 3 & 4 cities

#### Strong competitive position

29%

**STIVARGA®** 

- Inclusion in CSCO & CACA CRC Guidelines<sup>[1]</sup>
- Inclusion in Pan-Asian mCRC Clinical Practice Guidelines
- Maintaining leadership in patient share in 3L CRC

   (IQVIA<sup>[2]</sup>)
   Q4-18
   Q4-20
   Q4-21
   Q4-22
   Q2-23

   ELUNATE®
   2%
   25%
   33%
   39%
   44%
   47%

35%

34%

29%

26%

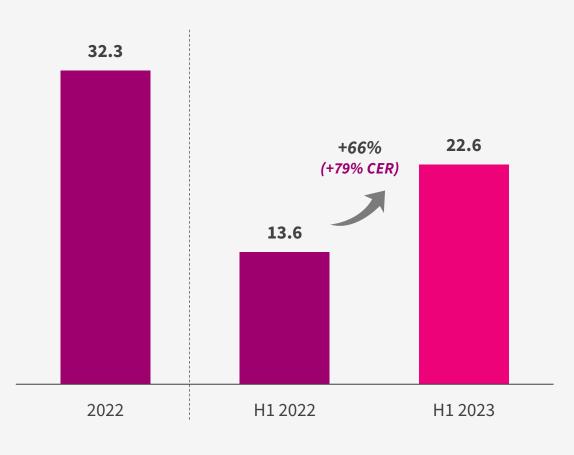
32%

[1] New treatment guidelines with Chinese Society of Clinical Oncology (CSCO) and Chinese Anti-Cancer Association (CACA). [2] IQVIA audit data in proprietary post-launch research panel of mainly Class 3 hospitals in Top 30 cities in China.

# <sup>2</sup> SULANDA (surufatinib) increasing patient access & duration of treatment



#### In-market sales (US\$ millions)



#### **Continued benefit of NRDL inclusion**

- ~12,000 est. new patients treated, vs ~7,500 in H1 2022
- Increase in duration of treatment
- Additional hospital listings (+19%)

#### Maintaining market share position

- Included in CSCO & CACA NENs Guidelines<sup>[1]</sup> and China GEP NETs Expert Consensus
- Inclusion in guidelines outside of NENs/NETs
- Ranked the 2<sup>nd</sup> brand in NET market since Q3 2022, surpassed Sutent<sup>®</sup> & Afinitor<sup>®</sup> (IQVIA<sup>[2]</sup>)

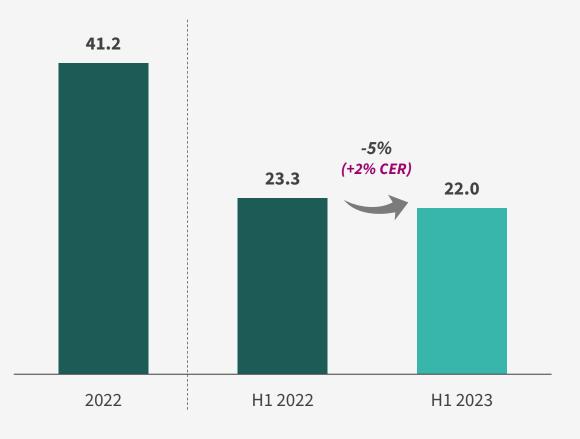
Q1 2023	SANDOSTATIN®	SULANDA®	SUTENT®	AFINITOR®	Other
Pt share	36%	17%	13%	11%	23%

# **ORPATHYS®** (savolitinib) first-in-class MET inhibitor

NRDL inclusion has expanded patient access significantly



#### In-market sales (US\$ millions)



#### NRDL inclusion from March 1, 2023

- Sales flat due to delayed start of NRDL plus a ~38% price reduction
- However, volume up +84% in Q2'23 vs. Q2'22 aided by NRDL inclusion
- Approved in Macau in March 2023

#### Inclusion in key treatment guidelines

- NHC, CSCO, CACA, CMA, CTONG<sup>[1]</sup>
- MET diagnostic testing is now recommended as SOC for late-stage NSCLC

#### AZ a strong China commercial partner

• Top lung cancer franchise synergies

# <sup>3</sup> New Shanghai manufacturing facility ready



### Shanghai facility construction is completed

- Expands capacity >5x
- Qualification of facility & equipment in 2023
- Clinical supplies manufacturing in 2023
- Commercial supplies manufacturing around 2025

#### Solar panels installation in 2023

• In line with sustainability initiatives



### <sup>4</sup> HUTCHMED registration/potential registration studies



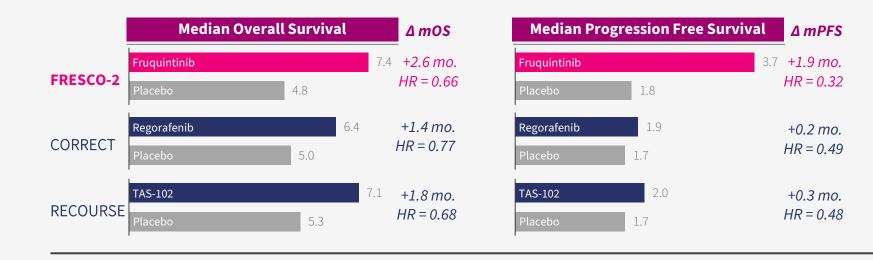
#### 15+ programs for seven drug candidates supporting potential near-term NDA filings

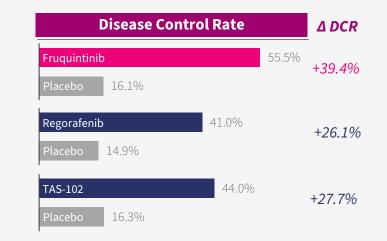
Drug	Study	Target Disease	Region	Design (N, arms, 1° endpoint)	Status	Est. (s)NDA filing if positive
FRUQ	FRESCO-2	3L+ colorectal cancer	Global	~690, treatment vs. BSC, OS	US FDA approved EMA validated, Japan NDA filed	FDA approved Nov 2023
FRUQ	FRUTIGA	2L GC, combo with chemo	China	~700, combo vs. chemo, OS & PFS	sNDA in China accepted April 2023	Review ongoing
SOVLE	ESLIM-01	2L immune thrombocytopenia	China	~180, 2 arms (placebo), DRR	Positive topline Aug '23	End of 2023
AMDIZ	3L FL	3L follicular lymphoma	China	~100, 1 arm, ORR	LPI Feb '23	End of 2023
SAVO*	Confirmatory	NSCLC, MET Exon 14 alteration	China	~160, 1 arm, ORR	LPI H1 '23	2024
FRUQ	2L EMC	2L EMC, combo with PD-1	China	~130, 1 arm, ORR	LPI July '23, China BTD	2024
TAZ^	Bridging	3L follicular lymphoma	China	~40, 2 arms (EZH2+ or wt), ORR	LPI summer '23	2024
AMDIZ	2L MZL	2L marginal zone lymphoma	China	~80, 1 arm, ORR	FPI Apr '21	2024
SAVO*	SACHI	2L EGFR TKI refractory NSCLC, MET+	China	~250, combo vs. chemo, PFS	FPI Nov '21	2024
SAVO*	SAVANNAH	2/3L Tagrisso® refractory NSCLC, MET+	Global	New cohort for pot. AA	FPI Jan '19Re-opened in Sept 2022	2024
SURU	SURTORI-01	2L NEC, combo with PD-1	China	~190, combo vs. chemo, OS	FPI Sep '21	2024
SAVO*	GASTRIC	Ref. GC, MET amplified	China	~60, 1 arm, ORR	FPI Jul '21         Reg. cohort opened Mar 2023	2025
FRUQ	2L RCC	2L RCC, combo with PD-1	China	~260, 2 arms, PFS	FPI Oct '22	2025
SOVLE	WAIHA	2L wAIHA	China	~110, 2 arms (placebo), Hb response	FPI Sep '22	2025
SAVO*	SANOVO	1L EGFRm+ NSCLC, MET+	China	~320, combo vs. Tagrisso, PFS	FPI Sep '21	2026
SAVO*	SAMETA	MET driven PRCC, combo with PD-L1	Global	~200, 3 arms combo vs. monos, PFS	FPI Oct '21	2026
SAVO*	SAFFRON	2/3L Tagrisso <sup>®</sup> refractory NSCLC, MET+	Global	~320, combo vs. chemo, PFS	FPI Aug '22	2026
453	IHCC, FGFR2	IHCC, FGFR2 fusion	China	~90, 1 arm, ORR	FPI Sept '20 Reg. cohort opened Mar 2023	2026

# Fruquintinib US FDA approved Nov 2023



#### Competitive profile demonstrated in multi-regional clinical trial





		FRESC	<b>0-2</b> <sup>[1] [4]</sup>	CORRE	<b>CT</b> [2] [4]	RECOUI	<b>RSE</b> <sup>[3]</sup> <sup>[4]</sup>
	Tolerability	Fruquintinib	Placebo	Regorafenib	Placebo	TAS-102	Placebo
Fruquintinib is well	Discontinuation due to AE	20%	21%	17%	12%	4%	2%
tolerated with a	TEAE Grade≥3	63%	50%	54%	14%	69%	52%
	Major TEAE Grade≥3						
safety profile	Hypertension	14%	1%	7%	1%	n/a	n/a
consistent with the	Hand-foot syndrome	6%	0%	17%	<1%	n/a	n/a
previously	Asthenia / fatigue	8%	4%	15%	9%	7%	9%
established monotherapy profile	Other AEs of note	<ul> <li>No black box war</li> <li>Monitor blood pr the first month a thereafter as clin</li> </ul>	essure weekly for nd at least monthly	<ul> <li>Blackbox warning on hepatoxicity</li> <li>Monitor liver function prior to and monthly or more frequently during treatment</li> </ul>		<ul> <li>Severe myelosuppression</li> <li>Obtain complete blood counts prior to and on day 15 of each cycle</li> </ul>	

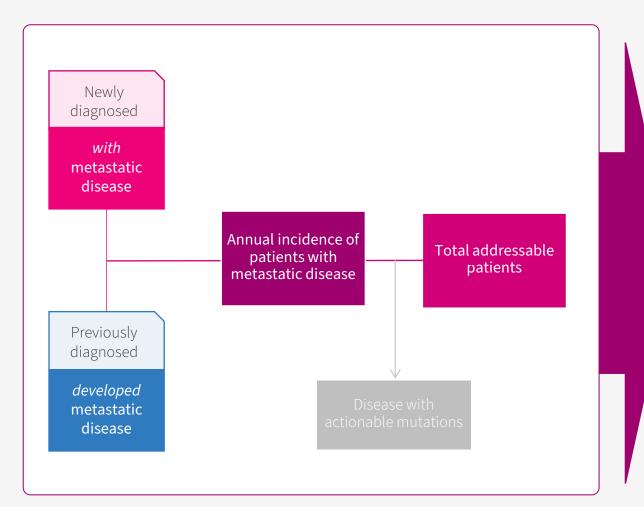
Note: Illustrative comparison only. No head-to-head studies have been conducted. Study parameters differ.

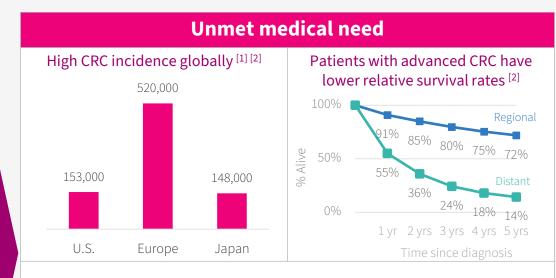
[1] Dasari A, et al. Fruquintinib versus placebo in patients with refractory metastatic colorectal cancer (FRESCO-2): an international, multicentre, randomised, double-blind, phase 3 study. *Lancet*. 2023;402(10395):41-53. doi:10.1016/S0140-6736(23)00772-9; [2] Grothey A, et al. Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet*. 2013;381(9863):303-312. doi:10.1016/S0140-6736(12)61900-X; [3] Mayer RJ, et al. Randomized trial of TAS-102 for refractory metastatic colorectal cancer. *N Engl J Med*. 2015;372(20):1909-1919. doi:10.1056/NEJMoa1414325; [4] USPI.

# <sup>4</sup> Colorectal cancer a significant burden...



#### ...but treatment options limited for most patients





#### • Limited use of approved 3L treatments

- Regorafenib (approved Q3 2012)
- TAS-102 (approved Q3 2015) +/- bevacizumab
- Chemotherapy, anti-VEGF & anti-EGFR agents used across all lines
- Newer treatment options focus on discrete actionable mutations
  - ~10% BRAF mutation <sup>[3] [4]</sup>
  - ~15% MSI-H or dMMR <sup>[5] [6]</sup>
  - 3-5% HER2 alterations [7]

[1] International Agency for Research on Cancer; [2] SEER; [3] D'Haene N, et al. Clinical application of targeted next-generation sequencing for colorectal cancer patients: a multicentric Belgian experience. *Oncotarget*. 2018;9(29):20761-20768. Published 2018 Apr 17. doi:10.18632/oncotarget.25099; [4] Venderbosch S, et al. Mismatch repair status and BRAF mutation status in metastatic colorectal cancer patients: a pooled analysis of the CAIRO, CAIRO2, COIN, and FOCUS studies. Clin Cancer Res. 2014;20(20):5322-5330. doi:10.1158/1078-0432.CCR-14-0332; [5] André T, et al. Pembrolizumab in Microsatellite-Instability-High Advanced Colorectal Cancer. *N Engl J Med*. 2020;383(23):2207-2218. doi:10.1056/NEJMoa2017699; [6] Koopman, M., et al. Deficient mismatch repair system in patients with sporadic advanced colorectal cancer. *Br J Cancer*. 2009;100(2):266–273. doi:10.1038/sj.bjc.6604867; [7] Ahcene Djaballah S, et al. HER2 in Colorectal Cancer: The Long and Winding Road From Negative Predictive Factor to Positive Actionable Target. *Am Soc Clin Oncol Educ Book*. 2022;42:1-14. doi:10.1200/EDBK\_351354.

# <sup>4</sup> Fruquintinib partnership with Takeda progressing well



Working closely together and preparing to transfer regulatory sponsorship

Financials & governance	<ul> <li>US\$400m upfront received</li> <li>Joint team established and started collaboration</li> </ul>	And I
<b>Regulatory Filings</b>	<ul> <li>Completed U.S. NDA rolling submission in March 2023; PDUFA Nov 30, 2023</li> <li>MAA submission in Europe validated June 2023</li> <li>Submitted JNDA to the Japan PMDA in Sept 2023</li> </ul>	
<b>Commercial Launch</b>	<ul> <li>Takeda initiating launch readiness in advance of PDUFA date</li> </ul>	90
Further Clinical Development (LCM)	<ul> <li>Joint team discussions and advisory boards held to discuss LCM strategy</li> <li>HUTCHMED ongoing programs in China may inform decisions</li> </ul>	

### <sup>4</sup> Fruquintinib 2L gastric: sNDA accepted April 2023



FRUTIGA combo study with paclitaxel in 2L gastric cancer to expand patients served

#### **FRUTIGA Trial**

sNDA with NMPA accepted April 2023

#### **Dual primary endpoints:**

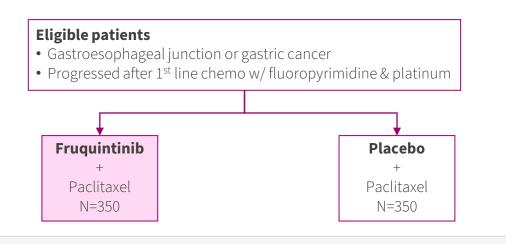
✓ **Progression free survival**: clinically and statistically sign. improvement

**Overall survival**: improvement not statistically significant per the pre-specified statistical plan

#### Secondary endpoints:

✓ ORR ✓ DCR ✓ DoR

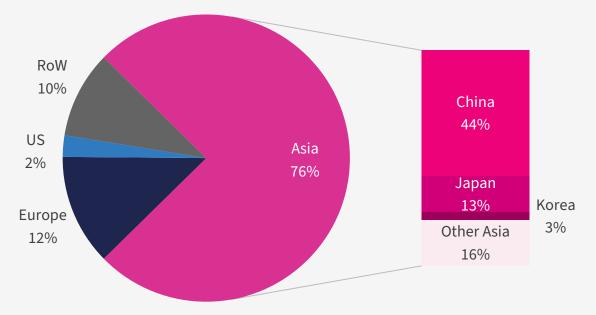
#### Safety profile consistent with previously reported studies



#### 5<sup>th</sup> MOST COMMONLY DIAGNOSED CANCER WORLDWIDE DISPROPORTIONATELY AFFECTS ASIA

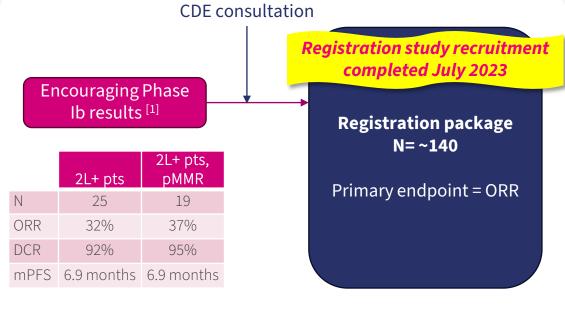
- **1.09 million** new patients globally
- China, Japan & Korea account for ~60% of newly diagnosed
- 478,500 diagnosed in China every year

Annual incidence of gastric cancer by geography



### <sup>4</sup> Fruquintinib endometrial cancer: Lead ICI combo in China

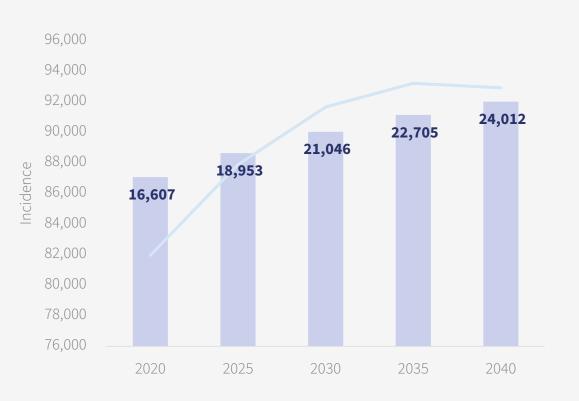
Breakthrough Therapy Designation in China for pMMR subtype



~70% of patients have tumors of pMMR subtype <sup>[2]</sup>

#### Medical need: Mortality from EMC projected to grow in China <sup>[3]</sup>

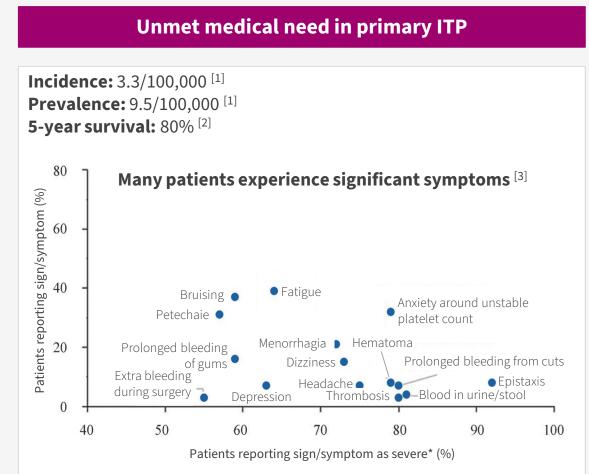
HUTCHN



Mortality — Incidence



Significant burden of disease remains



\*Patients reported symptom severity on a 7-point Likert scale where 1 = not severe at all and 7 = worst imaginable. The data presented are for "severe" based on scores ≥5.



#### Treatments for chronic ITP<sup>[4]</sup>

Agent	<b>Response</b> (1x PLT ≥50×10 <sup>9</sup> /L)	Durable response	Use of rescue medication	2022 Revenues for all indications <sup>[5]</sup>		
TPO-RA treatmen	nt increases plate	let production				
PROMACTA® (eltrombopag) <sup>[6]</sup>	59-70% (6 weeks) <sup>[7]</sup>	60% (6/8 visits, 18% weeks 18-26) <sup>[8]</sup> (vs 40%) <sup>[8]</sup>				\$2.1 billion (ITP + SAA)
NPLATE® (romiplostim) <sup>[6]</sup>	79-88% (24 weeks)	38-61% 20-26% (6/8 visits, (vs 57-62%) weeks 16-24)		\$1.3 billion (ITP + radiation sickness)		
TPIAO <sup>® [9]</sup>	60.3% (14 days)	Treatment period	US\$465 million (ITP + CIT)			
DOPTELET <sup>®</sup> (avatrombopag) <sup>[6]</sup>	66% at day 8	Median cumulative nu response without res 12 wee	scue medication:	\$245 million / \$107 million to China distributor Fosun (ITP + CLD)		
Hetrombopag <sup>[10]</sup>	59-64% (8 weeks)	Median maximum continuous durations of response: 64 days		n/a (ITP + SAA)		
Treatments to de	ecrease platelet d	estruction				
RITUXAN <sup>®</sup> (rituximab) <sup>[4]</sup>	~60% (4 weeks of tx)	20-25% n/a		Not FDA approved for ITP		
TAVALISSE <sup>®</sup> (fostamatinib) <sup>[6]</sup>	43% (12 weeks)	16-18% (4/6 visits, weeks 14-24)	30% (vs 45%)	\$76 million (ITP)		

[1] Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. *Blood.* 2017 May 25;129(21):2829-2835; [2] Mannering N, et al. Survival in adult patients with chronic primary and secondary immune thrombocytopenia: A population-based study. *Transfusion.* 2023;63(2):415-426. doi:10.1111/trf.17212; [3] Adapted from Wang RT, et al. [A physician-patient survey for primary immune thrombocytopenia: Chinese subgroup analysis of I-WISh International Survey]. *Zhonghua Xue Ye Xue Za Zhi.* 2021;42(5):369-375. doi:10.3760/cma.j.issn.0253-2727.2021.05.004 ; [4] Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv.* 2019;3(22):3780-3817. doi:10.1182/bloodadvances.2019000812; [5] company reports; [6] USPI; [7] Study 773A and B from US PI; [8] RAISE study from US PI; [9] Mei H, et al. A multicenter, randomized phase III trial of hetrombopage: a novel thrombopoietin receptor agonist for the treatment of immune thrombocytopenia. *J Hematol Oncol.* 2021;14(1):37. Published 2021 Feb 25. doi:10.1186/s13045-021-01047-9; [10] Company report.

# Sovleplenib 2L ITP: NDA filing around YE2023



Highly differentiated oral Syk inhibitor with breakthrough therapy designation in China

#### ESLIM-01 Trial

NDA filing with NMPA planned around YE2023

#### Primary endpoint: durable response rate

✓ Platelet count  $\geq$ 50×10<sup>9</sup>/L on at least 4 of 6 scheduled visits during week 14 to 24

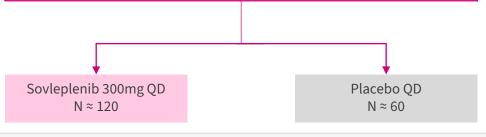
#### Secondary endpoints:

✓ ORR ✓ Safety

#### Safety profile consistent with previously reported studies

#### **Eligible patients**

- ECOG PS score of 0~1
- Duration of disease is > 6 months
- Intolerance or insufficient response, or recurrence after at least one standard drug therapy
- A history of response to previous ITP therapy



#### **Sovleplenib encouraging Phase I/II results**

#### **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 with or without prior TPO/TPO-RA therapies

#### **Breakthrough Therapy Designation in China**

	Sovleplenib – 300 mg, once daily					
	<b>Double-blinded Pts</b> 0-24 weeks	<b>Cross-over Pts</b> 9-24 weeks	Total			
ORR: n (%)	75.0% (12/16)	100.0% (4/4)	80.0% (16/20)			
Durable ORR: n (%)	31.3% (5/16)	75.0% (3/4)	40.0% (8/20)			
Use of rescue medication	6% (1/16)	0	5% (1/20)			

Liu X, et al. Sovleplenib (HMPL-523), a novel Syk inhibitor, for patients with primary immune thrombocytopenia in China: a randomised, doubleblind, placebo-controlled, phase 1b/2 study [published online ahead of print, 2023 Apr 4]. *Lancet Haematol.* 2023;S2352-3026(23)00034-0. doi:10.1016/S2352-3026(23)00034-0

### Amdizalisib progressing towards NDA in 2023 in FL



China registration studies supported by differentiated proof-of-concept data

#### Encouraging single agent activity in indolent NHL [1]



#### Highly favorable safety profile



All AEs / ≥Gr3 AEs	Amdizalisib <sup>[1]</sup>	Aliqopa®	Copiktra®	Linperlisib <sup>[3]</sup>	Parsa	clisib
	30mg QD	(copanlisib) <sup>[2]</sup>	(duvelisib) <sup>[2]</sup>	80mg QD	CITADEL-203 (FL) <sup>[4]</sup>	China cohort <sup>[5]</sup>
Ν	153	244	442	84	103	61
Neutropenia*	37% / 12%	32% / <b>29%</b>	63% / <b>43%</b>	46% / 16%	48% / 16%	49% / 16%
Leukopenia	5% / 2%	36% / 27%	29% / 8%*	36% / 5% *	<10%	33% / 2%
Anemia	22% / 5%	na	20% / 11%	<10%	34% / 3%*	<20%
Thrombocytopenia	5% / 1%	22% / 8%	17% / 10%	16% / 4%	22% / 0%*	<20%
Diarrhea	16% / 4%	36% / 5%	50% / 23%	16% / 1%	44% / 14%	<20%
Rash	24% / 6%	15% / 2%	31% / 9%	12% / 1%	14% / 3%	<20%
ALT increased	32% / 1%	na / 2%	40% / 8%	23% / 1%	30% / 2%	23% / 0%
AST increased	29% / 1%	na / 2%	37% / 6%	18% / 1%	29% / 0%	<20%
Pyrexia	16% / 1%	na	26% / 2%	<10%	19% / 3%	<20%
Pneumonia	25% / 16%	21% / 14%**	21% / 15%	20% / 19%	<10%	<20%
Hypertension	7% / 1%	35% / 29%	na	na / <2%	<10%	<20%
Hyperglycemia	9% / 0%	54% / 34%	na	13% / 1%	<10%	<20%
Interstitial lung disease	4% / 1%	na	na	5% / 4%	<10%	<20%
Lipase increased*	15% / 8%	21% / 8%	36% / 16%	14% / 4%	<10%	<20%
AES leading to:						
Discontinuation	12%	24%	35%	18%	25%	na
Dose reduction	17%	24%	23%	na	20%	na
Dose interruption	46%	64%	64%	43%	48%	na
Current status in China	Ph. II reg study FL & MZL	Approved for 3L+ FL	Approved for 3L+ FL	Approved for 3L+ FL	NDA accepte	ed for 3L+ FL

Phase Ib data as of January 31, 2023

Note: Illustrative comparison only. No head-to-head studies have been conducted. Study parameters differ. \*Laboratory values; \*\*Lower respiratory tract infections.

[1] ICML 2023: Cao J, et al. #653 - Updated results from a phase 1b study of amdizalisib, a novel inhibitor of phosphoinositide 3-kinase-delta (PI3K\delta), in patients with relapsed or refractory lymphoma (with additional unpresented data at the same data cut-off date); [2] US FDA; [3] Wang T, et al. The oral PI3K\delta inhibitor linperlisib for the treatment of relapsed and/or refractory follicular lymphoma: A phase 2, single-arm, open-label clinical trial [published online ahead of print, 2023 Feb 3]. *Clin Cancer Res.* 2023; CCR-22-2939. doi:10.1158/1078-0432.CCR-22-2939; [4] ASH 2021 Abstract #338; [5] ASCO 2022 Abstract #7574.

# Savolitinib – major late-stage expansion

**7 registrational studies** – 3 global & 4 in China



#### **GLOBAL** – led by AstraZeneca

#### 2/3L TAGRISSO<sup>®</sup> refractory NSCLC w/ MET aberration



**SAVANNAH study** – continue evaluation for potential accelerated approval; first data presentation at WCLC

#### 2/3L TAGRISSO® refractory NSCLC w/ MET aberration

Savolitinib + TAGRISSO<sup>®</sup> Phase III registration study – **SAFFRON Study** initiated in 2022

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

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



#### MET Exon14 skipping NSCLC



- NDA conditional approval in June 2021
- **Confirmatory Phase IIIb study** 1L cohort results at WCLC

#### 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

Registration cohort FPI March 2023





# MET Exon 14 NSCLC (monotherapy)

#### Competitive landscape in China

Subgroups	Status in China	N/EE	<b>ORR (%)</b> <sup>[1]</sup>	DCR (%)	mDoR (months)	mPFS (months)	mOS (months)	Discontinuation due to TRAEs
Savolitinib	Approved							
Confirmatory (1L) <sup>[2]</sup>	WCLC 2023	87/84	61% [49.5 to 71.2]	95% [88.3 to 98.7]	NR [9.7 to NR]	13.8 [9.7 to NR]	NR [17.4 to NR]	8%
Phase II <sup>[3]</sup>	1	70/62	<b>49%</b> [36.1 to 62.3]	<b>93%</b> [84.1 to 98.2]	<b>9.6</b> [5.5 to NR]	<b>6.9</b> [4.2 to 19.3]	14.0 [9.7 to NR]	Any TEAE: 14.3% - 22.6%
Gumarontinib <sup>[4]</sup>	Approved	84/79	<b>66%</b> [54,76]	<b>84%</b> [74 to 91]	<b>8.3</b> [6.2 to NE]	<b>8.5</b> [7.6 to 9.7]	17.3 [12.1 to NE]	8%
1L		44	<b>71%</b> [55,83]	<b>89%</b> [74 to 91]	15.0 [6.3-NE]	7.6 [4.1 to 9.6]	NE [11.7 to NE]	
≥2L		35	<b>60%</b> [42,76]	<b>77%</b> [60 to 90]	<b>8.2</b> [5.1 to NE]	<b>11.7</b> [7.6 to 21.9]	16.2 [8.7 to 17.5]	
Tepotinib Asian cohort <sup>[5</sup>		79	<b>54%</b> [42.8 to 65.7]	<b>77%</b> [664 to 85.9]	18.5 [8.3 to NR]	12.1 [6.9 to NR]	<b>20.4</b> [19.1 to NR]	14.8%
1L	Filed March	27	<b>67%</b> [46.0 to 83.5]	<b>78%</b> [57.7 to 91.4]	<b>NR</b> [6.9 to NR]	<b>NR</b> [8.3 to NR]	NR [16.3 to NR]	
≥2L	2022	52	<b>48%</b> [34.0 to 62.4]	<b>77%</b> [63.2 to 87.5]	<b>9.7</b> [5.6 to NR]	<b>11.0</b> [5.6 to 19.9]	<b>20.4</b> [14.3 to NR]	

[1] If available to BICR = blinded independent central review; [2] WCLC 2023 #OA21.03 at DCO April 30, 2023; [3] BICR data for EE patients available in the initial presentation at ASCO 2020 to abstract #9519; [4] Yu Y to et al. Gumarontinib in patients with non-small-cell lung cancer harbouring MET exon 14 skipping mutations: a multicentre to single-arm to open-label to phase 1b/2 trial. EClinicalMedicine. 2023;59:101952. Published 2023 Apr 6. doi:10.1016/j.eclinm.2023.101952; [5] Kato T, et al. Tepotinib in Asian patients with advanced NSCLC with MET exon 14 (METex14) skipping. *J. Clin. Oncol.*. 2022; 40, no. 16\_suppl 20-9120. DOI: 10.1200/JCO.2022.40.16\_suppl.9120

### <sup>4</sup> Savolitinib: EGFRm+ NSCLC w/ MET aberration



#### An oral-only, chemo-free option for MET+ patients whose EGFRm+ NSCLC progressed on TAGRISSO®

	SAV	ANNAH		0,
N=185* 300mg QD		- <b>high</b> /or FISH10+	<b>MET-low</b> IHC50–90 and/or FISH 5-10	
Prevalence among patients screened	34			3%
Prior Chemo	20%	No prior chemo subset	18%	No prior chemo subset
Number of patients	n=108	n=87	n=77	n=63
<b>ORR,</b> [95% CI]	<b>49%</b> [39–59]	<b>52%</b> [41-63]	<b>9%</b> [4-18]	<b>10%</b> [4-20]
<b>mDoR,</b> [95% CI]	<b>9.3 mo.</b> [7.6–10.6]	<b>9.6 mo.</b> [7.6–14.9]	<b>6.9 mo.</b> [4.1–16.9]	<b>7.3 mo.</b> [4.1-NC]
<b>mPFS,</b> [95% CI]	<b>7.1 mo.</b> [5.3–8.0]	<b>7.2 mo.</b> [4.7–9.2]	<b>2.8 mo.</b> [2.6–4.3]	<b>2.8 mo.</b> [1.8–4.2]

Novel biomarker and patient enrichment strategy driven by

\*Evaluable for efficacy defined as dosed patients with measurable disease at baseline who had  $\geq 2$  on-treatment RECIST scans. Excludes eight patients with invalid or missing test results for IHC90+ and/or FISH10+ status, these patients were excluded from the subgroup analyses based on MET levels.

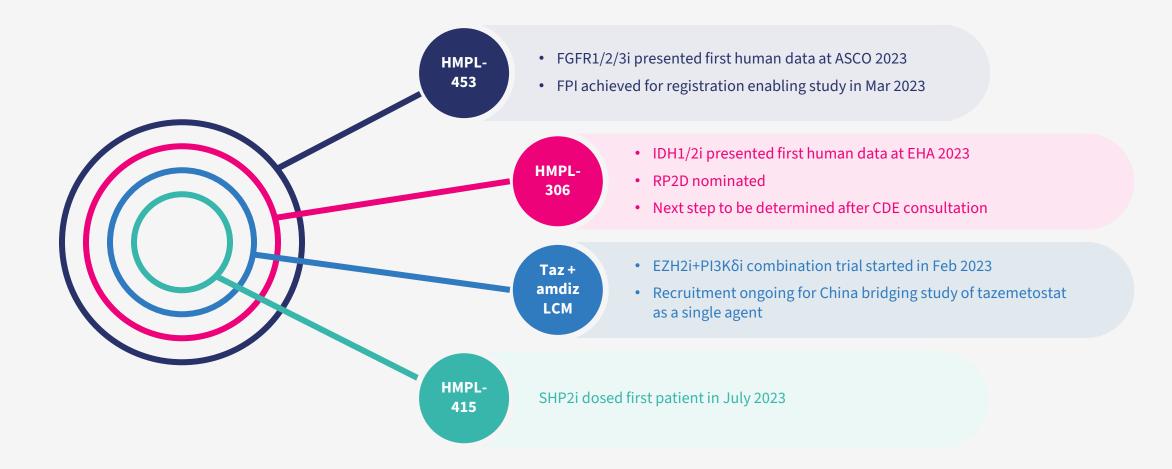
WCLC 2022 Abstract # EP08.02-140. DOI: <u>https://doi.org/10.1016/j.jtho.2022.07.823</u> ESMO 2023 Abstract #LBA15 <u>https://www.annalsofoncology.org/article/S0923-7534(23)04281-3/fulltext</u> ESMO 2023 Abstract #1314MO https://www.annalsofoncology.org/article/S0923-7534(23)03185-X/fulltext

	MAR	<b>TL05</b>		
	Ami+laz + chemo	Ami + chemo	Chemo	Dato-DXc
Number of patients	n=263	n=131	n=263	N=78 (EGFRm
<b>ORR,</b> [95% CI]	<b>63%</b> [57-69]	<b>64%</b> [55-72]	<b>36%</b> [30-42]	<b>44%</b> [32–55]
<b>mDoR,</b> [95% CI]	<b>9.4 mo.</b> [6.9-NE]	<b>6.9 mo.</b> [5.5-NE]	<b>5.6 mo.</b> [4.2-9.6]	<b>7.0 mo.</b> [4.2-10.2]
<b>mPFS,</b> [95% CI]	<b>8.3 mo.</b> [6.8-9.1]	<b>6.3 mo.</b> [5.6-8.4]	<b>4.2 mo.</b> [4.0-4.4]	<b>5.8 mo.</b> [5.4-8.3]

# <sup>4</sup> Our innovative engine remains productive



Progression of early-stage programs in 2023





# 4 Clinical deliverables in 2023-4

To make significant progress with multiple late-stage programs

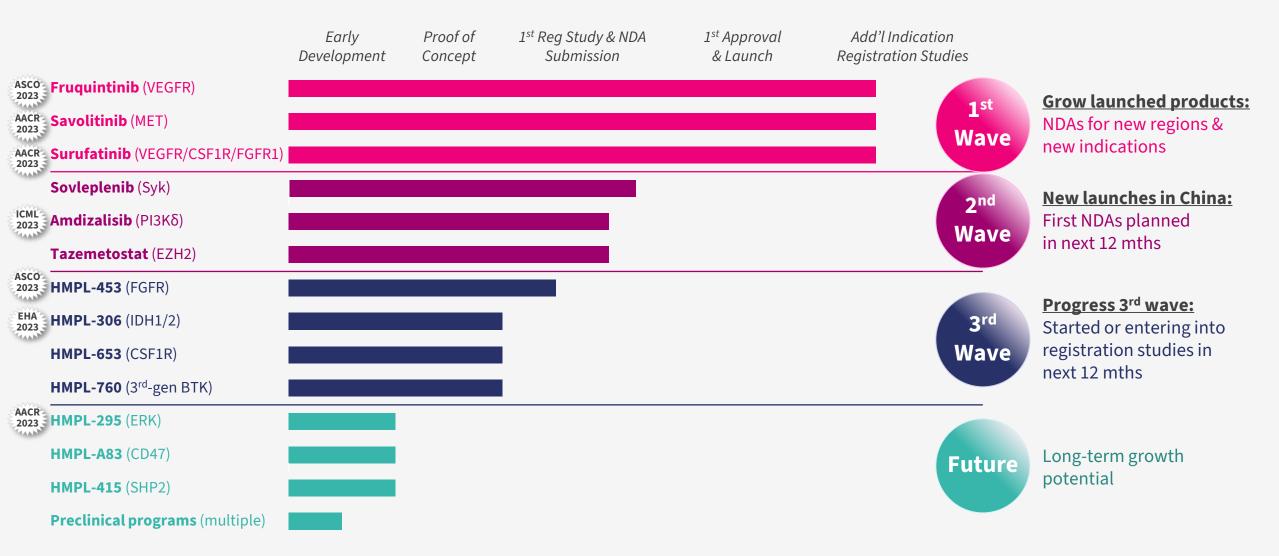
<b>Regulatory activities</b>		
<b>Fruquintinib</b> mono US, EU, Japan for 3L+ CRC	$\rightarrow$	<ul> <li>✓ US FDA approved Nov 2023</li> <li>✓ EMA MAA validated June 2023</li> <li>✓ Japan NDA filed Sept 2023</li> </ul>
<b>Fruquintinib</b> + chemo <i>China for 2L GC</i>		✓ China sNDA filing accepted April 2023
<b>Sovleplenib</b> mono China for 2L ITP	$\rightarrow$	China NDA filing around YE 2023 ✓ Readout August 2023
<b>Fruquintinib</b> + sintilimab China for 2L EMC*	$\rightarrow$	<ul> <li>China Breakthrough Designation in July 2023</li> </ul>
Readouts		
<b>Amdizalisib</b> mono China for 3L FL*	$\rightarrow$	Readout late 2023 Completed recruitment Feb 2023
<b>Savolitinib</b> mono China confirm. for NSCLC, MET ex14	$\rightarrow$	Cohort 2 readout YE 2023 Cohort 1 results at WCLC 2023 Completed recruitment H1 2023
<b>Fruquintinib</b> + sintilimab China for 2L EMC*	$\rightarrow$	H1 2024 Completed recruitment July 2023
<b>Tazemetostat</b> mono China for 3L FL*	$\rightarrow$	Mid 2024 Complete recruitment summer 2023

#### Continued progress on additional registration studies Savolitinib + osimertinib

<b>Savolitinib</b> + osimertinib Intl for 2L NSCLC, MET+*	$\rightarrow$	Complete recruitment H2 2023
<b>Fruquintinib</b> + sintilimab <i>China for 2L RCC</i>	$\rightarrow$	Complete recruitment YE 2023
<b>Amdizalisib</b> mono <i>China for 2L MZL</i> *	$\rightarrow$	Complete recruitment H1 2024
<b>Savolitinib</b> + osimertinib <i>China for 2L NSCLC, MET</i> +*	$\rightarrow$	Complete recruitment mid 2024
<b>Savolitinib</b> + osimertinib <i>China for 1L NSCLC, MET</i> +*	$\rightarrow$	Complete recruitment H2 2024
<b>Savolitinib</b> mono <i>China for Ref. GC, MET</i> +*	$\rightarrow$	<ul> <li>✓ Early readout at AACR 2023</li> <li>✓ China Breakthrough Designation Aug 2023</li> <li>Complete recruitment in H2 2024</li> </ul>
<b>Surufatinib</b> + toripalimab <i>China for 2L NEC</i>	$\rightarrow$	Complete recruitment H2 2024
✓ HMPL-453 mono China for IHCC, FGFR2 fusion*	$\rightarrow$	<ul> <li>✓ Ph Ib/II results at ASCO 2023</li> <li>✓ Reg. cohort FPI March 2023</li> </ul>
Sovleplenib mono		✓ Enrolled Phase II part H1 2023

# <sup>5</sup> Progressing the pipeline to maximize the value of each asset HUTCHME

#### Next potential new indications & medicines



### Thank you



www.hutch-med.com

### **References & Abbreviations**



ADS = American depositary share. AIHA = autoimmune hemolytic anemia. *ALL* = acute Lymphoblastic Leukemia AML = acute myeloid leukemia. API = active pharmaceutical ingredient. ASCO = American Society of Clinical Oncology. ASCO GI = ASCO (American Society of Clinical Oncology) Gastrointestinal Cancers Symposium ASH = American Society of Hematology *bsAb* = *bi-specific* antibody BID = twice daily. BRAF = B-Raf.BSC = best supportive care. BTK = bruton's tyrosine kinase. CER = constant exchange rate. CI = confidence interval. CIT = chemotherapy-induced thrombocytopenia. CLD = chronic liver disease. CLL/SLL = chronic lymphocytic leukemia and small lymphocytic lymphoma CRC = colorectal cancer. CRL = complete response letter. CSF-1R = colony-stimulating factor 1 receptor. DCO = data cutoff *DDI* = *drug-drug interactions*. Deutsche Bank AG = Deutsche Bank AG, Hong Kong Branch. DLBCL = diffuse large B-cell lymphoma *dMMR* = *deficient mismatch* DoR = duration of response. DRR = durable response rate. epNET = extra-pancreatic neuroendocrine tumor. *EGFR* = *epidermal growth factor receptor.* EGFRm+ = epidermal growth factor receptor mutated. EMA = European Medicines Agency. *EMC* = *endometrial cancer*. Epizyme = Epizyme Inc. ERK = extracellular signal-regulated kinase. ES = epithelioid sarcoma. EU = European Union. EZH2 = enhancer of zeste homolog 2. FISH = fluorescence in situ hybridization. FISH5+ = MET amplification as detected by FISH with MET copy number  $\geq 5$ 

and/or MET: CEP signal ratio  $\geq 2$ . FISH10+ = MET amplification as detected by FISH with MET copy number  $\geq 10$ . FDA = Food and Drug Administration. FGFR = fibroblast growth factor receptor. FL = follicular lymphoma. FPI = first patient in. GAAP = Generally Accepted Accounting Principles. *GC* = *qastric cancer*. GI = gastrointestinal. HBYS = Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited. HKEX = The Main Board of The Stock Exchange of Hong Kong Limited. HL = Hodgkin's lymphoma. HR = hazard ratio. HSBC = The Hongkong and Shanghai Banking Corporation Limited. Hutchison Sinopharm = Hutchison Whampoa Sinopharm Pharmaceuticals (Shanahai) Company Limited. IDH = Isocitrate dehydrogenase. In-market sales = total sales to third parties provided by Eli Lilly (ELUNATE<sup>®</sup>), AstraZeneca (ORPATHYS®) and HUTCHMED (SULANDA® and TAZVERIK®). *HCPs* = *healthcare professionals* ICI = immune checkpoint inhibitor IHC = immunohistochemistry. IHC50+ = MET overexpression as detected by IHC with 3+ in  $\ge$  50% tumor cells. IHC90+ = MET overexpression as detected by IHC with 3+ in  $\ge$  90% tumor cells. iNHL = indolent Non-Hodgkin's Lymphoma. I/O = Immuno-oncology. IND = Investigational New Drug (application). *IR* = *independent review*. IRC = independent review committee. ITP = Immune thrombocytopenia purpura. Lilly = Eli Lilly and Company. MAA = Marketing Authorization Application. MAPK pathway = RAS-RAF-MEK-ERK signaling cascade. Mab = monoclonal antibody. MCL = mantle cell lymphoma. *MDS/MPN = myelodysplastic/myeloproliferative neoplasms* MET = mesenchymal epithelial transition factor. MRCT = multi-regional clinical trial. MSI-H = high levels of microsatellite instability. MSS / pMMR = microsatellite stable / mismatch repair proficient.

MZL = marginal zone lymphoma. na = not available. NDA = New Drug Application. NEC = neuroendocrine carcinoma. NFTs = neuroendocrine tumors. NHL = Non-Hodgkin's Lymphoma. NME = new molecular entity. NR = not reached. NRDL = National Reimbursement Drug List. NSCLC = non-small cell lung cancer. ORR = objective response rate. OS = overall survival. OD = once daily. *PD* = *progressive disease*. PD-L1 = programmed cell death ligand 1. PFS = progression-free survival.  $PI3K\delta = phosphoinositide 3$ -kinase delta. PJP = pneumocystis jirovecii pneumonia. PMDA = Pharmaceuticals and Medical Devices Agency. pNET= pancreatic neuroendocrine tumor. ccRCC = clear cell renal cell carcinoma. PRCC = papillary renal cell carcinoma. PTCL = peripheral T-cell lymphomas. *R&D* = research and development. SAA = severe aplastic anemia. SHP2 = Src homology-2 domain-containing protein tyrosine phosphatase-2 SHPL = Shanghai Hutchison Pharmaceuticals Limited. SOC = standard of care. Syk = spleen tyrosine kinase. TKI = tyrosine kinase inhibitor. TPO-RA = thrombopoietin receptor agonists. Tx = treatment.VEGF = vascular endothelial growth factor. VEGFR = vascular endothelial growth factor receptor. wAIHA = warm antibody autoimmune hemolytic anemia. WM/LPL = Waldenström macroglobulinemia and lymphoplasmacytic lymphoma. WT = wild-type. WCLC = IASLC World Conference on Lung Cancer.