### ADVANCING TO GLOBAL LAUNCHES & CONTINUED PIPELINE PROGRESS

#### FY2023 RESULTS & BUSINESS UPDATES

February 28, 2024

HKEX:13 | Nasdaq/AIM:HCM





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### FY2023: strong execution on strategic direction





### STRATEGIC DELIVERY

- Executed our global vision of bringing our innovative medicines worldwide
- On track to be self-sustaining with a disciplined approach to leveraging R&D expertise and creating value through licensing and commercialization

PRODUCTS & PIPELINE PROGRESS

### LATE STAGE

- ✓ Fruq US FDA approval for 3L+ CRC
- ✓ Fruq under review in EU and JP (CRC)
- ✓ Fruq China sNDA accepted (GC)
- ✓ Savo China to file (add 1L METex14 NSCLC)
- ✓ Savo completed US enrollment (2L NSCLC)

### **2ND WAVE**

- ✓ Sovle China NDA filed with priority rev granted (ITP) & wAIHA Phase III initiated
- ✓ Taz bridging study fully enrolled (FL)
- To initiate IDH1/2 inhibitor HMPL-306 in Phase III

GLOBAL COMMERCIAL DELIVERY 200 (

- ✓ Speedy FRUZAQLA<sup>™</sup> US
   launch with strong early
   patient uptake
- ✓ Record

**Oncology/Immunology rev.** aided by the upfront payment from Takeda

 Strong commercial execution, combined inmarket sales grew +28% (+35% CER)





### On path to sustainable business

### **Condensed Consolidated Balance Sheets**

(in US\$ millions)	Dec 31, 2023	Dec 31, 2022
Assets		
Cash, cash equivalents & short-term investments	886.3	631.0
Accounts receivable	116.9	98.0
Other current assets	93.6	110.9
Property, plant and equipment	99.7	75.9
Investments in equity investees	48.4	73.8
Other non-current assets	34.9	39.8
Total assets	1,279.8	1,029.4
Liabilities and shareholders' equity		
Accounts payable	36.3	71.1
Other payables, accruals and advance receipts	271.4	264.6
Deferred revenue	127.1	13.5
Bank borrowings <sup>[1]</sup>	79.3	18.1
Other liabilities	22.3	25.2
Total liabilities	536.4	392.5
Company's shareholders' equity	730.6	610.4
Non-controlling interests	12.8	26.5
Total liabilities and shareholders' equity	1,279.8	1,029.4

### As of December 31, 2023

#### **Cash Resources**

- **\$886m** cash / cash eq. / ST inv.<sup>[2]</sup>
- \$68m unutilized banking facilities

#### Borrowing

**\$79m** in bank borrowings (Favorable interest rates lower than deposit rates)

#### Others

• \$19m additional cash at SHPL JV

### Impact of Takeda transaction

- **\$400m** non-refundable upfront payment was received on closing
- **\$280m** recognized on *Consolidated Statement of Operations* as *Revenue*, and the remainder was recorded in *Deferred revenue* as of December 31, 2023

1



### Higher revenue and net income due to Takeda upfront/milestone and reduction in R&D spending

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

(In US\$ million)		2023	2022
Revenue:			
Oncology/Immunology – Marketed Products	1	164.2	124.6
Oncology/Immunology – R&D	2	364.4	39.2
Oncology/Immunology consolidated revenue	3	528.6	163.8
Other Ventures		309.4	262.6
Total revenue		838.0	426.4
Operating expenses:			
Cost of revenue		(384.4)	(311.1)
R&D expenses	4	(302.0)	(386.9)
Selling & general admin. expenses	5	(133.2)	(136.1)
Total operating expenses		(819.6)	(834.1)
		18.4	(407.7)
Other income/(expense), net		39.9	(2.7)
Income/(loss) before income taxes & equity investees		58.3	(410.4)
Income tax (expense)/benefit		(4.5)	0.3
Equity investees, net of tax (SHPL)		47.3	49.7
Net income/(loss)		101.1	(360.4)
Less: Net income attrib. to non-controlling interests		(0.3)	(0.4)
Net income/(loss) attributable to HUTCHMED		100.8	(360.8)

### Total Consolidated Revenue up 97% (102% CER) to \$838m

#### 1. Oncology product revenue up 32% (39% CER) to \$164m

- 2. **R&D revenue of \$364m**, majority of which is revenue recognition of \$280m in Takeda upfront (of \$400m received), \$32m in Takeda milestone (of \$35m received) and \$34m in Takeda cost reimbursements
- 3. O/I consolidated revenue **met high end of guidance**

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

- 4. **R&D: supporting 15+ registration enabling programs,** primarily due to completion of major registration enabling trials and the ongoing strategic prioritization of pipeline
  - Ex-China decreased to \$107m (2022: \$171m)
  - China decreased to \$195m (2022: \$216m)
- 5. Selling & general admin. expenses decreased primarily due to restructuring of U.S. commercial operations in 2022, while China commercial operations increased to support revenue growth

### 1 2024 O/I consolidated revenue guidance of \$300-\$400m, driven by 30-50% growth target in O/I marketed product revenue



(in US\$ millions)	2023	2022	%Δ (CER)	2023	2022	%Δ (CER
		ncology M n-market	ledicines Sales <sup>[1]</sup>	Cons	olidated	Revenue <sup>[2]</sup>
ELUNATE <sup>®</sup> (fruquintinib)	\$107.5	\$93.5	+15% (+22%)	\$83.2	\$69.9	+19% (+26%
FRUZAQLA™ (fruquintinib)	\$15.1	-	-	\$7.2	-	-
SULANDA <sup>®</sup> (surufatinib)	\$43.9	\$32.3	+36% (+43%)	\$43.9	\$32.3	+36% (+43%
ORPATHYS <sup>®</sup> (savolitinib)	\$46.1	\$41.2	+12% (+19%)	\$28.9	\$22.3	+30% (+37%
TAZVERIK <sup>®</sup> (tazemetostat)	\$1.0	\$0.1	>700%	\$1.0	\$0.1	>700%
Product Revenue	\$213.6	\$167.1	+28% (+35%)	\$164.2	\$124.6	+32% (+39%)
Other R&D Services Income				\$52.4	\$24.2	+116% (+119%
Upfront & Milestone Income				\$312.0	\$15.0	
Total				\$528.6	\$163.8	+223% (+228%

[1] For ELUNATE®, FRUZAQLA<sup>™</sup> and ORPATHYS<sup>®</sup>, mainly represents total sales to third parties as provided by Lilly, Takeda and AstraZeneca, respectively.

Fru

TAZV

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Fruquintinib Capsules

Surufatinib Capsules

Savolitinib Tablets

ELUNATE

litetje Hacison Med Pharme Liller

SULANDA®

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**Orpathys**<sup>®</sup>

litelje

[2] For ELUNATE<sup>®</sup>, represents drug product supply, commercial service fees and royalties paid by Lilly, to HUTCHMED, and sales to other third parties invoiced by HUTCHMED; for FRUZAQLA<sup>™</sup>, represents drug product supply and royalties paid by Takeda; for ORPATHYS<sup>®</sup>, represents drug product supply 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.

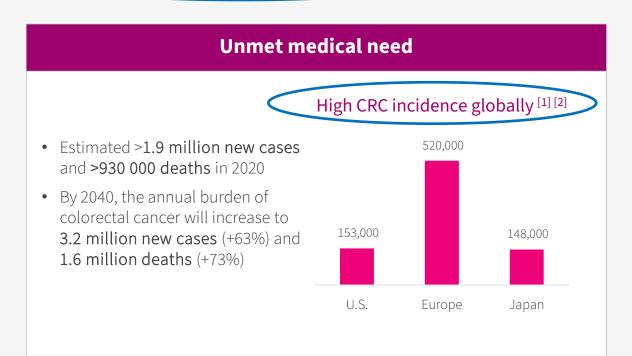
## <sup>1</sup> FRUZAQLA<sup>™</sup> : rapid patient uptake after launch in the U.S.

Colon cancer is the 3<sup>rd</sup> most common cancer and 2<sup>nd</sup> leading cause of cancer-related deaths worldwide <sup>[1]</sup>

### FRUZAQLA<sup>™</sup> in- market sales \$15.1m in 2023

- First prescription written 48 hours after US approval on 8<sup>th</sup> Nov 2023
- NCCN inclusion one-week after launch

**EU and JP submissions** for CRC made



Fruzaqla™ (fruquintinib) capsules

The first and only novel targeted therapy approved for mCRC, regardless of mutation status, in more than a decade



✓ A manageable safety profile in previously treated patients with CRC

HUTCHMF

NOW

APPROVED

An innovation

in mCRC

#### 8

# <sup>2</sup> China Commercial environment

Policies benefitting innovative medicines access + commercial organization at scale

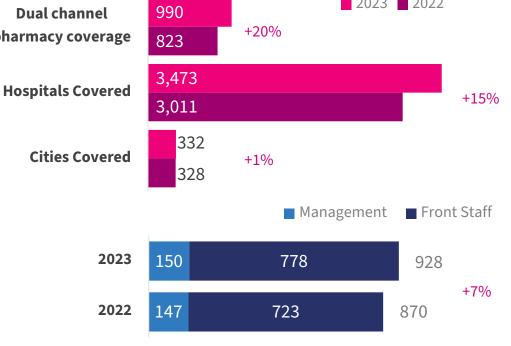
### Favorable operating environment

- Policies promoting access to innovative medicines
  - NMPA to accelerate review of innovative drug approval with breakthrough designations (Apr 2023)
  - Simplification of NRDL renewals (Jul 2023)
  - Shanghai hospitals formulary should cover drugs soon after NRDL inclusion, not taking up the NRDL budget first three years (Dec 2023)
  - Innovative drug pricing in Shanghai Pudong to be referenced to overseas comparables (Jan 2024)
  - NHSA to explore a more flexible and market-driven pricing mechanism for innovative chemical drugs (Feb 2024)

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

## Dual channel 990 2023 2022 pharmacy coverage 823 +20%

>39,000 oncology physicians covered



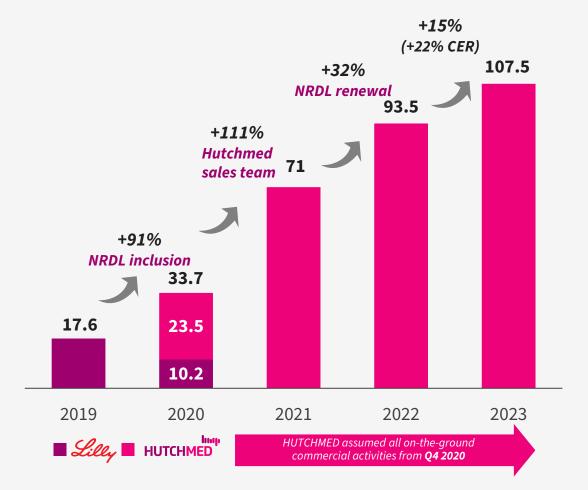


# <sup>2</sup> ELUNATE<sup>®</sup> (fruquintinib) remains market leader in 3L CRC





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



### Continued to be the leader in 3L CRC market in 2023

- HK 3L CRC approval in 2024
- China NRDL 2<sup>nd</sup> round successfully renewed at current terms
- ~105,000 est. 3L CRC new patients in 2023

#### Strong competitive position

- Inclusion in *CSCO, CACA CRC Guidelines*, Pan-Asian mCRC Clinical Practice and NCCN Guidelines<sup>[1]</sup>
- Maintaining leadership in patient share in 3L CRC (IQVIA<sup>[2]</sup>) in China

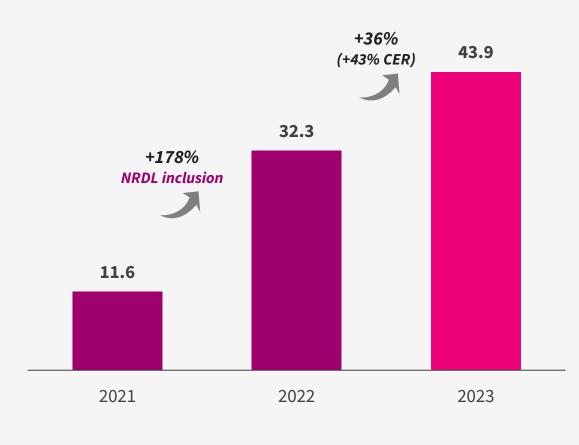
	Q4-18	Q4-19	Q4-20	Q4-21	Q4-22	Q2-23
<b>ELUNATE</b> ®	2%	25%	33%	39%	44%	47%
<b>STIVARGA</b> ®	29%	32%	35%	34%	29%	26%

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

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



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



### **Prescriptions increased significantly in 2023**

- NRDL successfully renewed at current terms
- ~34,000 est. new NET/NEN patients in 2023
- Increasing patient access after inclusion on the NRDL and long duration of treatment

### Maintaining market share position

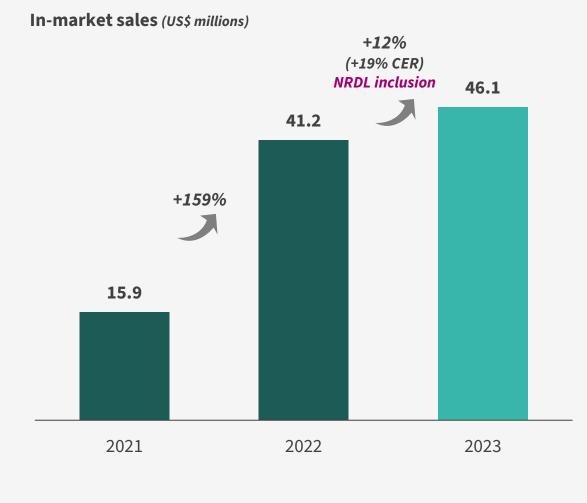
- Included in CSCO & CACA NENs Guidelines, China GEP NETs Expert Consensus and CMA NENs Consensus<sup>[1]</sup>
- Ranked the 2<sup>nd</sup> brand in NET market since Q3 2022, surpassed Sutent<sup>®</sup> & Afinitor<sup>®</sup> (IQVIA<sup>[2]</sup>)

	Q3-21	Q1-22	Q3-22	Q1-23	Q4-23
SULANDA®	7%	14%	16%	17%	21%
Somatostatin analogues	53%	47%	42%	36%	38%
Sutent®	14%	14%	14%	13%	10%
Afinitor®	10%	9%	10%	11%	9%

## <sup>2</sup> ORPATHYS<sup>®</sup> (savolitinib) first-in-class MET inhibitor

NRDL inclusion has expanded patient access significantly





### NRDL inclusion from March 1, 2023

• Sales +19% at CER, despite a ~38% price reduction for NRDL

### Potential expansion into 1L MET Exon 14 in 2024

• Strong 1L clinical results

### **Publications**

- WCLC<sup>[1]</sup> 2023 (PFS 13.8mo; ORR 61%)
- ELCC <sup>[2]</sup> March 2023

### Inclusion in key treatment guidelines

- NHC, CSCO, CACA, CMA, CTONG [3]
- MET testing now recommended as SOC for late-stage NSCLC

### AZ a strong China commercial partner

- Top lung cancer franchise synergies
- Increasing METex14 testing rate
- Improving brand differentiation amidst rising competition
- Potential NSCLC indications in combination with TAGRISSO®

[1] World Conference on Lung Cancer; [2] European Lung Cancer Congress;

## <sup>3</sup> Strengthened manufacturing capability



Expanding capacity for China and global markets

### Shanghai facility completed

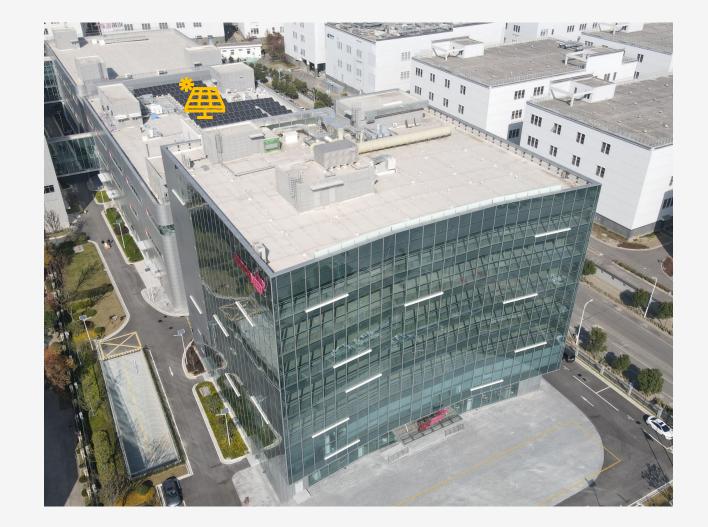
- Expanding capacity >5x
- Qualification of facility & equipment
- Clinical supplies in 2023
- Commercial supplies in 2025

### **Global supply chain established**

- API CMO in China qualified
- Suzhou facility passed pre-approval inspection (PAI) by the FDA
- Second site in Switzerland ready

### Solar panels installed

- Contributing renewable energy directly, particularly in cooling indoor areas, significantly reducing electricity usage and greenhouse gas emissions
- Progress made in fulfilling our commitment to reduce emissions





### **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)	•	tatus	Est. (s)NDA filing if positive
FRUQ	FRESCO-2	3L+ colorectal cancer	Global	~690, treatment vs. BSC, OS	EN	US FDA approved MA validated; Japan NDA filed	FDA approved EU, JP pending
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	NDA in t	China accepted January 2024	Review ongoing
SAVO*	Confirmatory	NSCLC, MET Exon 14 alteration	China	~160, 1 arm, ORR		Positive P3b	Early 2024
FRUQ	FRUSICA-1	2L EMC, combo with PD-1	China	~140, 1 arm, ORR	LPI July '23, China BTD		Early 2024
TAZ^	Bridging	3L follicular lymphoma	China	~40, 2 arms (EZH2+ or wt), ORR	LPI Sep'23		Mid 2024
SAVO*	SAVANNAH	2/3L TAGRISSO <sup>®</sup> refractory NSCLC, MET+	Global	New cohort for potential AA	LPI Feb '24		Late 2024
FRUQ	FRUSICA-2	2L RCC, combo with PD-1	China	~260, 2 arms, PFS	LPI Dec'23		2025
SURU	SURTORI-01	2L NEC, combo with PD-1	China	~190, combo vs. chemo, OS	Enrolling		2025
SAVO*	SACHI	2L EGFR TKI refractory NSCLC, MET+	China	~250, combo vs. chemo, PFS	Enrolling		2025
SAVO*	GASTRIC	3L GC, MET amplified	China	~60, 1 arm, ORR	Enrolling	Reg. cohort opened Mar 2023	2025
SOVLE	ESLIM-02	2L wAIHA	China	~110, 2 arms (placebo), Hb response	FPI 1Q '24		2026
SAVO*	SANOVO	1L EGFRm+ NSCLC, MET+	China	~320, combo vs. Tagrisso, PFS	Enrolling		2026
SAVO*	SAMETA	MET driven PRCC, combo with PD-L1	Global	~200, 3 arms combo vs. monos, PFS	Enrolling		2026
SAVO*	SAFFRON	2/3L TAGRISSO <sup>®</sup> refractory NSCLC, MET+	Global	~320, combo vs. chemo, PFS	Enrolling		2026
HMPL-453	IHCC, FGFR2	IHCC, FGFR2 fusion	China	~90, 1 arm, ORR	Enrolling	Reg. cohort opened Mar 2023	2026
AMDIZ <sup>#</sup>	3L FL	3L follicular lymphoma	China	~100, 1 arm, ORR	LPI Feb '23		TBC
AMDIZ#	2L MZL	2L marginal zone lymphoma	China	~80, 1 arm, ORR	FPI Apr '21		TBC

\*In collaboration with AstraZeneca ^ In collaboration with Ipsen.

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# in view of the changing regulatory landscape, we are currently evaluating the clinical development plan and regulatory guidance before deciding the regulatory strategy for this indication.

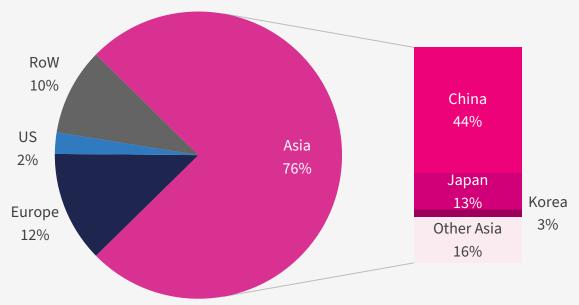
### 4 Fruquintinib 2L gastric cancer: China sNDA accepted for review April 2023

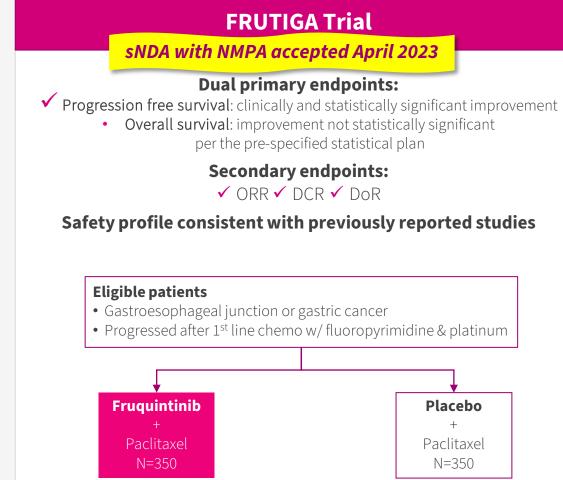
FRUTIGA combo study with paclitaxel in 2L gastric cancer to expand patients served

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

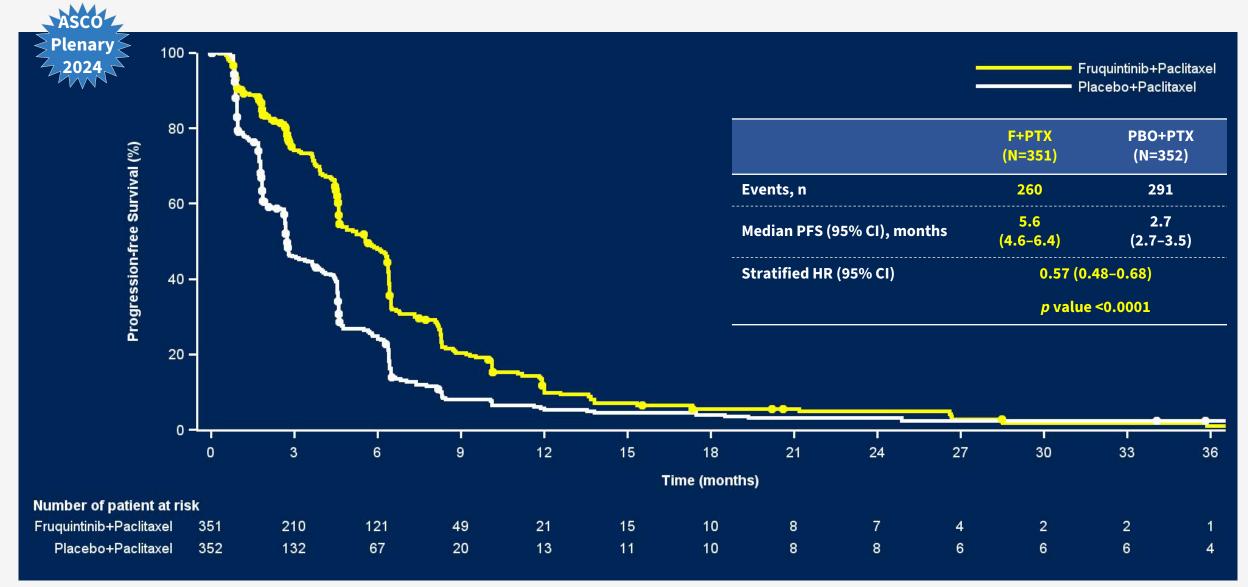
- 1.09 million new patients globally
- China, Japan & Korea account for ~60% of newly diagnosed

Annual incidence of gastric cancer by geography



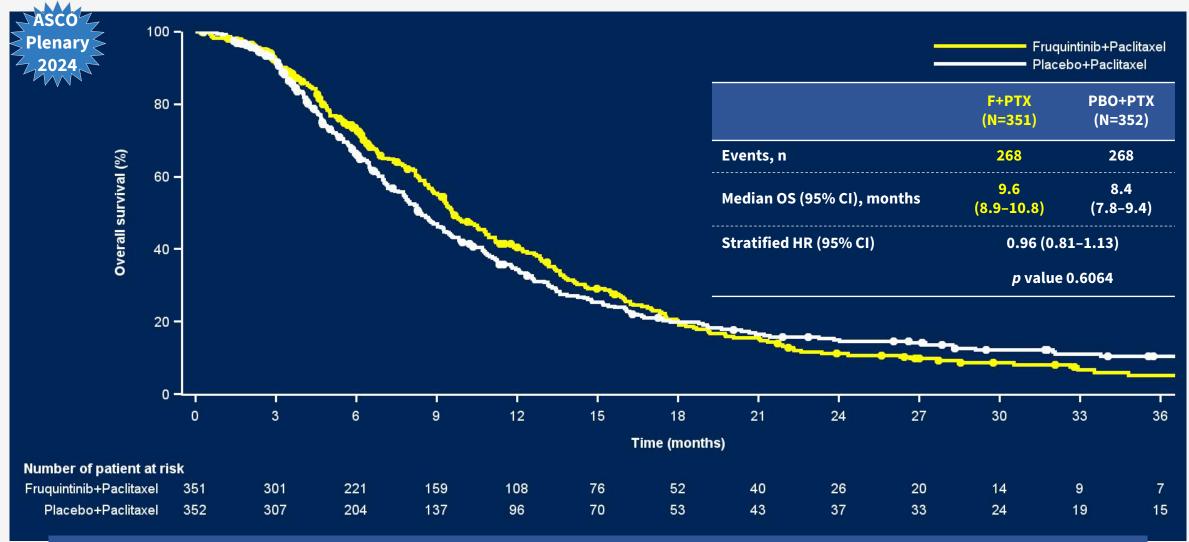


### FRUTIGA: dual-primary endpoint: progression-free survival (ITT set)



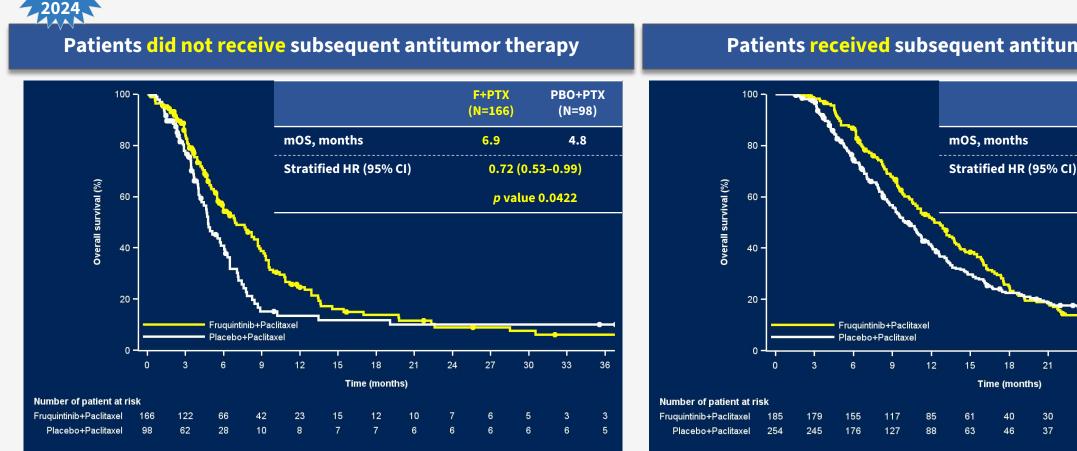
HUTCHME

## FRUTIGA: dual-primary endpoint: overall survival (ITT set) HUTCHME



Subsequent antitumor therapy imbalanced between the 2 groups: 52.7% in F+PTX vs 72.2% in PBO+PTX

#### 4 **FRUTIGA: OS with or without subsequent antitumor therapy** HUTCHME



ASCO

Plenary

Patients received subsequent antitumor therapy

18

40

46

21

30

37

24

31

27

F+PTX

(N=185)

12.2

0.90(0.73 - 1.11)

p value 0.3262

13

18

**PBO+PTX** 

(N=254)

10.0

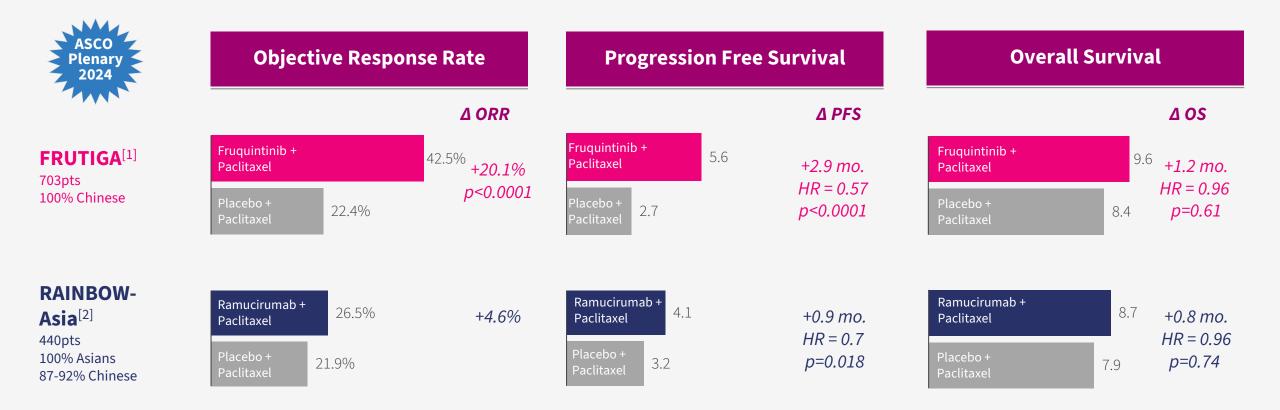
F+PTX demonstrated the trend for OS benefit regardless of receiving subsequent antitumor therapy

10

## <sup>4</sup> Fruquintinib 2L gastric cancer: phase III data highlights



Promising 2L treatment option for patients with advanced G/GEJ adenocarcinoma



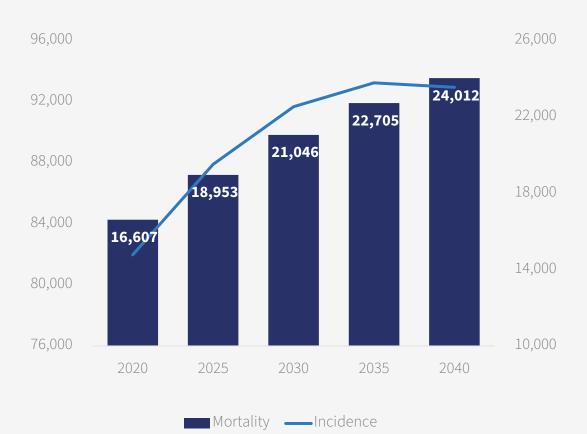
Note: Illustrative comparison only. No head-to-head studies have been conducted. Study parameters differ

[1] Feng W, et al. Fruquintinib plus paclitaxel versus placebo plus paclitaxel as second-line therapy for advanced gastric or gastro-oesophageal junction adenocarcinoma (FRUTIGA): a randomised, multicentre, double-blind, placebo-controlled, phase 3 study. ASCO Plenary Session. 2024; Abstract 438780; [2] Rui-Hua X, et al. Efficacy and safety of weekly paclitaxel with or without ramucirumab as second-line therapy for the treatment of advanced gastric or gastroesophageal junction adenocarcinoma (RAINBOW-Asia): a randomised, multicentre, double-blind, phase 3 trial. *Lancet.* 2021;6: 1015-24.doi:10.1016

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

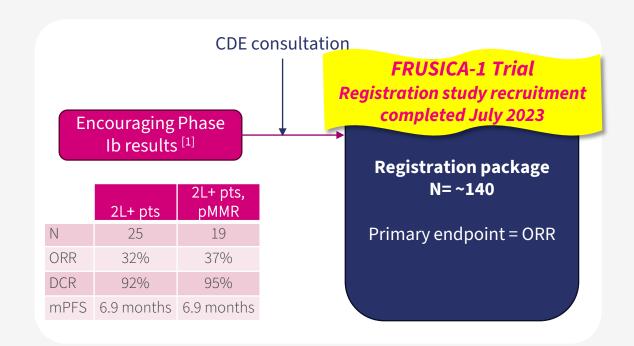
Breakthrough Therapy Designation in China for pMMR subtype

Medical need: Mortality from EMC projected to grow in China<sup>[2]</sup>



### Chemotherapy remains as SOC in 1L and 2L EMC treatment in China with high unmet need in 2L setting

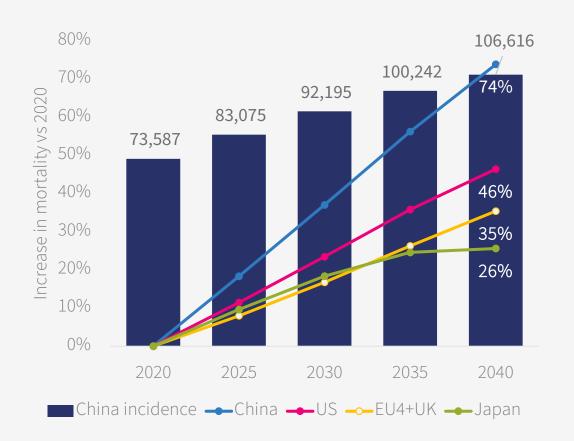
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## <sup>4</sup> Fruquintinib with sintilimab 2L RCC: Phase II/III in China



### Increase in mortality rate vs 2020 in China to outpace that of the US, EU4+UK, and Japan <sup>[1]</sup>



### FRUSICA-2 Trial Phase II/III study

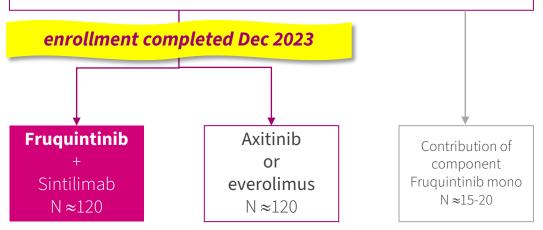
**Primary endpoint:** Progression free survival (IRC)

### Secondary endpoints:

Tumor response (ORR, DCR, DoR) • Overall Survival • Safety

#### **Eligible patients**

- Histologically, cytologically confirmed RCC
- Progressed on, after or were intolerant to received 1L VEGFR-TKIs



# Fruquintinib with sintilimab 2L RCC: PD-1 antibody combinations CHMED

No PD-1/VEGFi combo approved in 1L or 2L RCC in China

### Robust and durable responses seen in previously treated advanced RCC

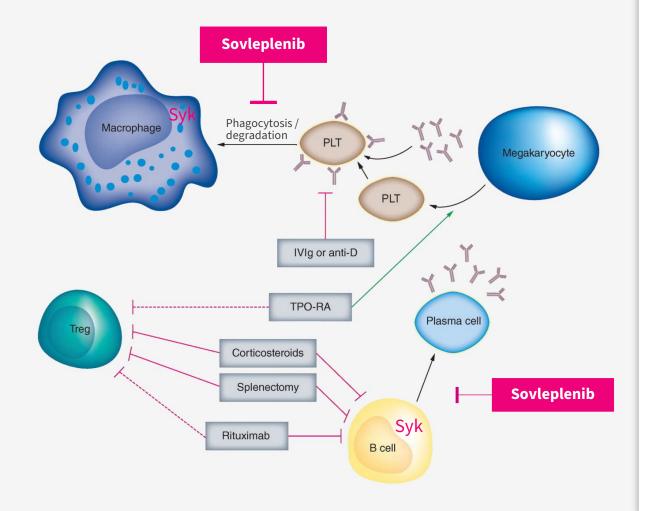
ASCO 2023	Fruquintinib + Sintilimab P2 POC			KEYMAKER-U03 <sup>[3]</sup> Belzutifan + lenvatinib	-	embrolizumab FE-146) <sup>[4]</sup>
- Thur	Study <sup>[1]</sup>	Cabozantinib	Atezolizumab + cabozantinib	Arm 5	ICI naïve	ICI pretreated
TKI dose	5mg QD 2 weeks on / 1 week off	60mg QD		20 mg QD	20 m	g QD
Data cut-off date	Nov 30, 2022	January	/ 3, 2023	Sept 29, 2022	August	18, 2020
Median f/u duration	23.3 months	15.2 months		6.9 months	19.8 months	
Ν	20	259	263	24	17	104
<b>ORR</b> [95% CI]	60.0%	40.9% [34.8 to 47.3]	40.5% [34.5 to 46.8]	50% [29 to 71]	52.9% [27.8 to 77.0]	62.5% [52.5 to 71.8]
DCR [95% CI]	85.0%	88.5%	91.1%	88%	94.1% [71.3 to 99.9]	92.3% [85.4 to 96.6]
mDoR, months [95% Cl]	n/a	14.8 [11.3 to 20.0]	12.7 [9.8 to 12.3]	NR	9.0 [3.5 to NR]	12.5 [9.1 to 17.5]
mPFS, months [95% Cl]	15.9	<b>10.8</b> [10.0 to 12.5]	<b>10.6</b> [9.8 to 12.3]	<b>11.2</b> [4.2 to NR]	<b>11.8</b> [5.5 to 21.9]	<b>12.2</b> [9.5 to 17.7]

[1] ASCO 2023 J Clin Oncol 41, 2023 (suppl 16; abstr e16514), DOI: 10.1200/JCO.2023.41.16\_suppl.e16514; [2] ASCO 2023 J Clin Oncol 41, 2023 (suppl 17; abstr LBA4500), DOI: 10.1200/JCO.2023.41.17\_suppl.LBA4500; [3] ASCO 2023 J Clin Oncol 41, 2023 (suppl 16; abstr 4553), DOI: 10.1200/JCO.2023.41.16\_suppl.4553; [4] Lee CH, et al. Lenvatinib plus pembrolizumab in patients with either treatment-naive or previously treated metastatic renal cell carcinoma (Study 111/KEYNOTE-146): a phase 1b/2 study. Lancet Oncol. 2021;22(7):946-958. doi:10.1016/S1470-2045(21)00241-2.

## Immune thrombocytopenia (ITP)



Unmet medical needs to be addressed with next-gen Syk inhibitor Sovleplenib (HMPL-523)



### Current treatments target Treg, megakaryocyte and B cells

- ✓ Long-term efficacy tapers off
- ✓ All patients become refractory and run out of options

### Syk is a validated target for ITP

- Syk offers a different mechanism by targets both B cells & macrophages
- ✓ Fostamatinib approved in the US, EU and JP moderate efficacy, dose limited by tox

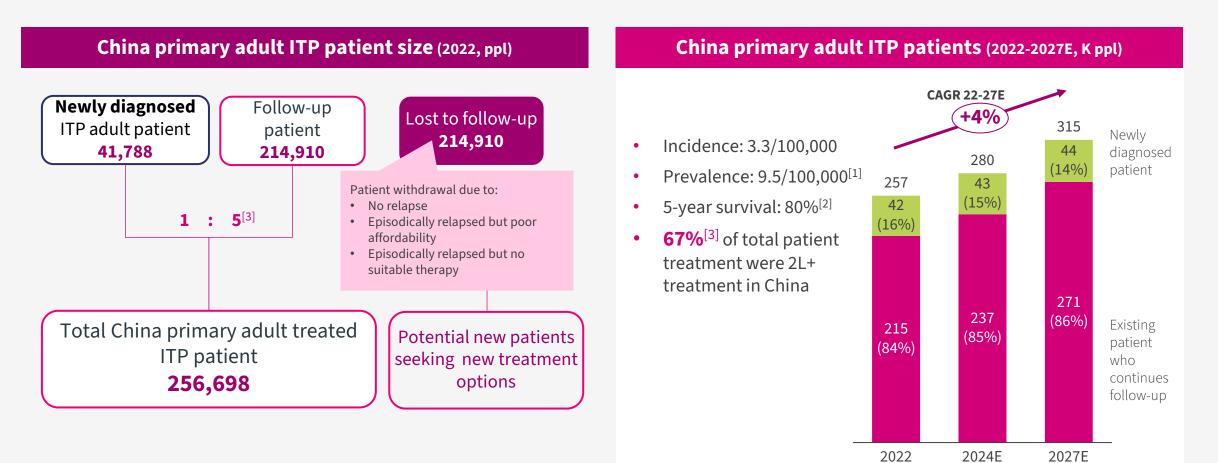
### Sovleplenib (HMPL-523)

- China Phase III completed met all primary and secondary endpoints, NDA accepted by China NMPA in Jan 2024 with priority review status
- ✓ BTD granted by China NMPA in Jan 2022 for ITP
- ✓ US IND cleared, Phase Ib/II for ITP patients in start-up

# China adult ITP patients

Significant burden of disease remains





[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] IQVIA analysis

### 4 Sovleplenib shows high response rate in heavily pre-treated ITP patients

Durable response rate for sovleplenib and TPO-RAs were similar, even 75% patients were prior treated with TPO/TPO-RA The efficacy of sovleplenib is better than fostamatinib

#### **Durable response**<sup>[1]</sup> **Overall response**<sup>[2]</sup> Treated Treated Placebo Placebo 49.0% Romiplostim 2.0% Romiplostim 7.1 83.1% Eltrombopag 38.0% Eltrombopag 28.0% 79.0% 2.0% 18.0% Fostamatinib 43.0% Fostamatinib 14.0% Sovleplenib Sovleplenib 0.0% 40.0% 9.1% 80.0% (Phase I)<sup>[3]</sup> (Phase I)<sup>[3]</sup> 0% 20% 60% 40% 0% 20% 40% 60% 80% 100%

Efficacy comparison of Sovleplenib vs launched products

[1]Definition of durable response:

Fostamatinib: same with HMPL-523

Eltrombopag/Hetrombopag: platelets≥50 x 109/L at ≥75% of their platelet count assessments

Romiplostim/Avatrombopag: platelets  $\geq$  50 x 109/L for any 6 of the last 8 weeks of the 24-week, without rescue medication

[2]Overall response: not reported in Avatrombopag [3] Only 8-weeks blind treatment

### 4 Sovleplenib 2L ITP: NDA filing accepted for priority review in January 2024

Highly differentiated oral Syk inhibitor with breakthrough therapy designation in China

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

### **ESLIM-01 Trial**

#### 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

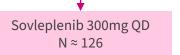
### Safety profile consistent with previously reported studies

Placebo QD

N ≈ 62

#### **Eligible patients**

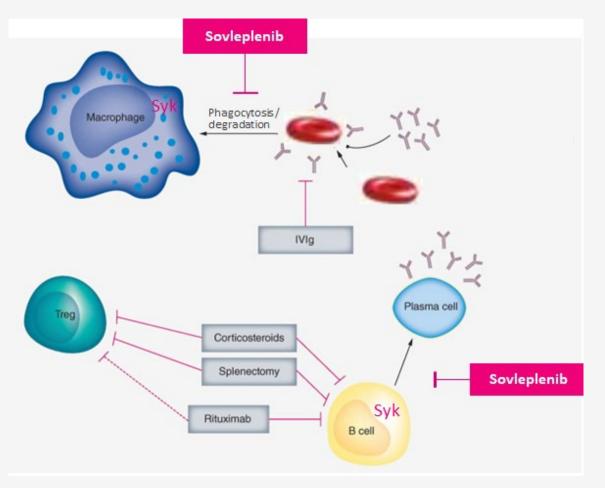
- ECOG PS score of 0~1
- Duration of disease is > 6 months
- Intolerance or insufficient response, or recurrence after at least one standard drug therapy
- A history of response to previous ITP therapy



## Warm autoimmune hemolytic anemia (wAIHA)



No FDA-approved therapy for wAIHA yet, significant unmet medical needs exist



# wAIHA is an autoimmune disorder characterized by increased destruction of red blood cell (RBC) by autoantibodies at body temperature, leading to hemolysis and anemia

- It is the most prevalent form of AIHA, accounting for -80% cases of AIHA in adults
- It is associated with significant morbidity and mortality

### No FDA approved therapy yet, high unmet medical needs exist

- Corticosteroids are the standard 1L treatment, but majority patients are refractory or experience relapses
- Off-label use of rituximab for 2L wAIHA has been recommended in many countries as an alternative to splenectomy; however, there is no universal consensus on the recommended dose (375 mg/m2 vs 100mg fixed dose), and it has a late onset of effects (4-6 weeks). In addition, relapses are common

### Syk is a potential target for wAIHA

- RBC phagocytosis is dependent on Syk signaling through Fc receptors in macrophages
- Syk is also involved in B-cell receptor signaling pathway that lead to the development of antibody-secreting plasma cells
- Positive Phase II sovleplenib in wAIHA leading to launch of Phase III in China

### Sovleplenib is a selective, potent, oral Syk inhibitor, increased RBC counts dose dependently in an anti-Ly76 induced anemia mouse model

## Savolitinib – major late-stage expansion



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

### **GLOBAL** – led by AstraZeneca

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



**SAVANNAH study** – completed enrollment in Feb 2024, NDA filing end of 2024, basis of potential accelerated approval by the FDA

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

Savolitinib + TAGRISSO<sup>®</sup> Phase III registration study – **SAFFRON Study** ongoing enrollment

### 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
  - SAMETA Study ongoing enrollment

### **CHINA** – *led by HUTCHMED*

### MET Exon14 skipping NSCLC



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

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

- Savolitinib + TAGRISSO<sup>®</sup> Phase III registration study
- **SACHI Study** to complete enrollment in late 2024

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

- Savolitinib + TAGRISSO<sup>®</sup> Phase III registration study
- SANOVO Study to complete enrollment in late 2024



# Gastric cancer w/ MET amplification Single arm study with potential for registration

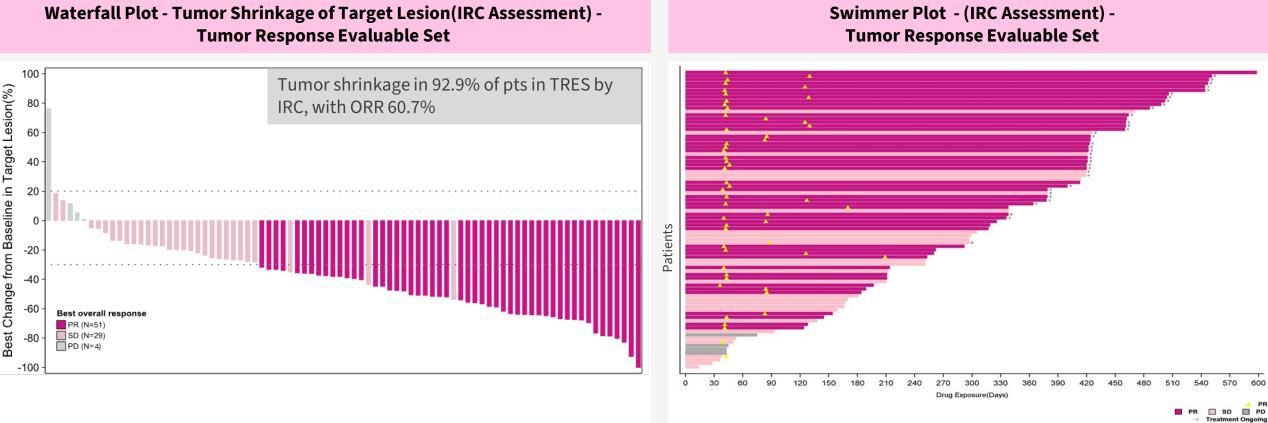
Registration cohort FPI March 2023





## <sup>4</sup> Savolitinib: 1L MetEx14+ NSCLC Patients, WCLC 2023

Deep and Durable Response (IRC assessment)



## <sup>4</sup> Savolitinib: 2L EGFRm+ NSCLC w/ MET aberration



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

	MET	specific		
vel biomarker a		t enrichm ANNAH <sup>[1]</sup>	ient strato	egy drive
N=185* 300mg QD		<b>-high</b> d/or FISH10+		<b>'-low</b> d/or FISH 5-10
Prevalence among patients screened	34	%	28	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>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]

\*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.

	All comers; not MET specific					
	MARIPO	<b>)SA-2</b> <sup>[2]</sup>	<b>TL05</b> <sup>[3]</sup>	<b>ORIENT-31</b> <sup>[4] [5]</sup>		
Patient Screening	EGFR-mutant advanced NSCLC after disease progression on osimertinib		Previously treated NSCLC with AGAs	EGFR-mutated non-squamo NSCLC after progression on EG TKI Therapy		
	Amivantamab + chemo	chemo	Dato-DXd	Sintilimab+ bevacizumab+ chemo	Sintilimab+ chemo	
Number of Patients	n=131	n=263	n=78 (EGFRm)	n=158	n=158	
ORR	64%	36%	<b>44%</b>	48%	35%	
mDoR	6.9 mo.	5.6 mo.	7.0 mo.	8.5 mo.	7.4 mo.	
mPFS	6.3 mo.	4.2 mo.	5.8 mo.	7.2 mo.	5.5 mo.	

### Investing in new launches, near and mid-term pipeline



### 3 medicines commercialized

5

First US approval achieved

# 4 regulatory approvals in major markets

- Accelerate ongoing registration trials and initiate new registration trials
- Invest in novel NME with BIC/FIC potentials: MAP kinase pathway inhibitors, menin inhibitor, novel ADCs

<ul> <li>Fruzaqla™ (fruquintinib) capsules</li> <li>ELUNATE® Fruquintinib Capsules</li> </ul>	<ul> <li>EU and JP approval for CRC</li> <li>China 3 indications (GC, EMC, RCC) filed or to be filed</li> <li>Ex-China: combination strategy</li> </ul>
<b>沃瑞沙®</b> Orpathys® ★★₩ ₽ #	<ul><li>U.S. filing for 2L NSCLC</li><li>Expanding to 1L NSCLC, 3L GC and 2L PRCC</li></ul>
Sovleplenib	<ul><li>China ITP approval</li><li>International dose-finding study to commence</li></ul>
	<ul><li>China 2L NEC Phase III ongoing</li><li>Potential for new LCM indications</li></ul>
TAZVERIK (tazemetostat) tablets	<ul> <li>China 3L+ follicular lymphoma filing mid 2024</li> <li>Global 2L follicular lymphoma Phase III ongoing</li> </ul>
HMPL-453 (FGFR1/2/3)	<ul><li> 2L FGFR2 fusion IHCC</li><li> China Phase II (registration phase) FPI Mar 2023</li></ul>
HMPL-306 (IDH1/2)	<ul><li>IDH1 or 2+ relapsed/refractory myeloid leukemia</li><li>China Phase III planned for 2024</li></ul>

Growing US sales, indication expansion in China



### Thank you



www.hutch-med.com

### **References & Abbreviations**



ADS = American depositary share. AIHA = autoimmune hemolytic anemia. ALK = anaplastic lymphoma kinase. 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. CBCL= cutaneous B-cell lymphoma. CER = constant exchange rate. CI = confidence interval. 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 ≥ 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 = gastric cancer. GEJ = gastroesophageal junction 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 (Shanghai) Company Limited. *IDH* = *Isocitrate dehydrogenase.* In-market sales = total sales to third parties provided by Eli Lilly (ELUNATE<sup>®</sup>), AstraZeneca (ORPATHYS<sup>®</sup>) and HUTCHMED (SULANDA<sup>®</sup> and TAZVERIK<sup>®</sup>). *HCPs* = *healthcare professionals* ICI = immune checkpoint inhibitor IHC = immunohistochemistry. IHC50+ = MET overexpression as detected by IHC with 3+ in  $\geq$  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. NETs = 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.* QD = 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*. ROS-1 = c-ros oncogene 1. SHPL = Shanghai Hutchison Pharmaceuticals Limited. SOC = standard of care. Syk = spleen tyrosine kinase. TNBC = triple negative breast cancer. TGCT = tenosynovial giant cell tumor. 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.