

# ADVANCING TO GLOBAL LAUNCHES & CONTINUED PIPELINE PROGRESS

CORPORATE PRESENTATION

May 2024

HKEX:13 | Nasdaq/AIM:HCM





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# FY2023 and YTD: 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 EU CHMP positive opinion, and under review in JP (CRC)
- ✓ Fruq China sNDA accepted (GC)
- ✓ Fruq China NDA accepted (EMC)
- ✓ Savo China sNDA accepted (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



- ✓ **Speedy FRUZAQLA® US launch** with strong early patient uptake
- ✓ **Record Oncology/Immunology rev.** aided by the upfront payment from Takeda
- ✓ **Strong commercial execution**, combined in-market sales grew +28% (+35% CER)

# Strengthened Cash Position

On path to sustainable business

## Condensed Consolidated Balance Sheets

(in US\$ millions)

	Dec 31, 2023	Dec 31, 2022
<b>Assets</b>		
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
<b>Total assets</b>	<b>1,279.8</b>	<b>1,029.4</b>
<b>Liabilities and shareholders' equity</b>		
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
<b>Total liabilities</b>	<b>536.4</b>	<b>392.5</b>
<b>Company's shareholders' equity</b>	<b>730.6</b>	<b>610.4</b>
Non-controlling interests	12.8	26.5
<b>Total liabilities and shareholders' equity</b>	<b>1,279.8</b>	<b>1,029.4</b>

## 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] Bank borrowings of US\$31.1m under current liabilities and US\$48.2m under non-current liabilities; [2] Short-term investments: deposits over 3 months.

# 1 2023 Financial Overview

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
<b>Total revenue</b>		<b>838.0</b>	<b>426.4</b>
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)
<b>Total operating expenses</b>		<b>(819.6)</b>	<b>(834.1)</b>
		<b>18.4</b>	<b>(407.7)</b>
Other income/(expense), net		39.9	(2.7)
<b>Income/(loss) before income taxes &amp; equity investees</b>		<b>58.3</b>	<b>(410.4)</b>
Income tax (expense)/benefit		(4.5)	0.3
Equity investees, net of tax (SHPL)		47.3	49.7
<b>Net income/(loss)</b>		<b>101.1</b>	<b>(360.4)</b>
Less: Net income attrib. to non-controlling interests		(0.3)	(0.4)
<b>Net income/(loss) attributable to HUTCHMED</b>		<b>100.8</b>	<b>(360.8)</b>

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

- Oncology product revenue up 32% (39% CER) to \$164m**
- 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
- O/I consolidated revenue **met high end of guidance**

### Control over operating expenses

- 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)
- 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)
	Oncology Medicines In-market Sales <sup>[1]</sup>			Consolidated Revenue <sup>[2]</sup>		
ELUNATE® (fruquintinib)	\$107.5	\$93.5	+15% (+22%)	\$83.2	\$69.9	+19% (+26%)
FRUZAQLA® (fruquintinib)	\$15.1	-	-	\$7.2	-	-
SULANDA® (surufatinib)	\$43.9	\$32.3	+36% (+43%)	\$43.9	\$32.3	+36% (+43%)
ORPATHYS® (savolitinib)	\$46.1	\$41.2	+12% (+19%)	\$28.9	\$22.3	+30% (+37%)
TAZVERIK® (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® and ORPATHYS®, mainly represents total sales to third parties as provided by Lilly, Takeda and AstraZeneca, respectively.

[2] For ELUNATE®, 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®, represents drug product supply and royalties paid by Takeda; for ORPATHYS®, represents drug product supply and royalties paid by AstraZeneca and sales to other third parties invoiced by HUTCHMED; for SULANDA® and TAZVERIK®, represents the Company's sales of the products to third parties.

# FRUZAQLA® : 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 [1]

## FRUZAQLA® 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



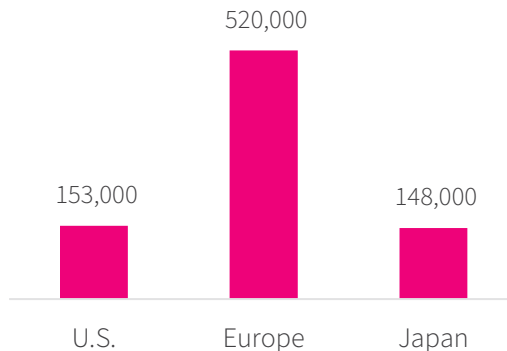
**The first and only novel targeted therapy approved for mCRC, regardless of mutation status, in more than a decade**



## Unmet medical need

**High CRC incidence globally [1] [2]**

- Estimated >1.9 million new cases and >930 000 deaths in 2020
- By 2040, the annual burden of colorectal cancer will increase to 3.2 million new cases (+63%) and 1.6 million deaths (+73%)



- ✓ Significant improvements in OS, with corresponding improvements in PFS
- ✓ A manageable safety profile in previously treated patients with CRC

# China Commercial environment

## Policies benefitting innovative medicines access + commercial organization at scale

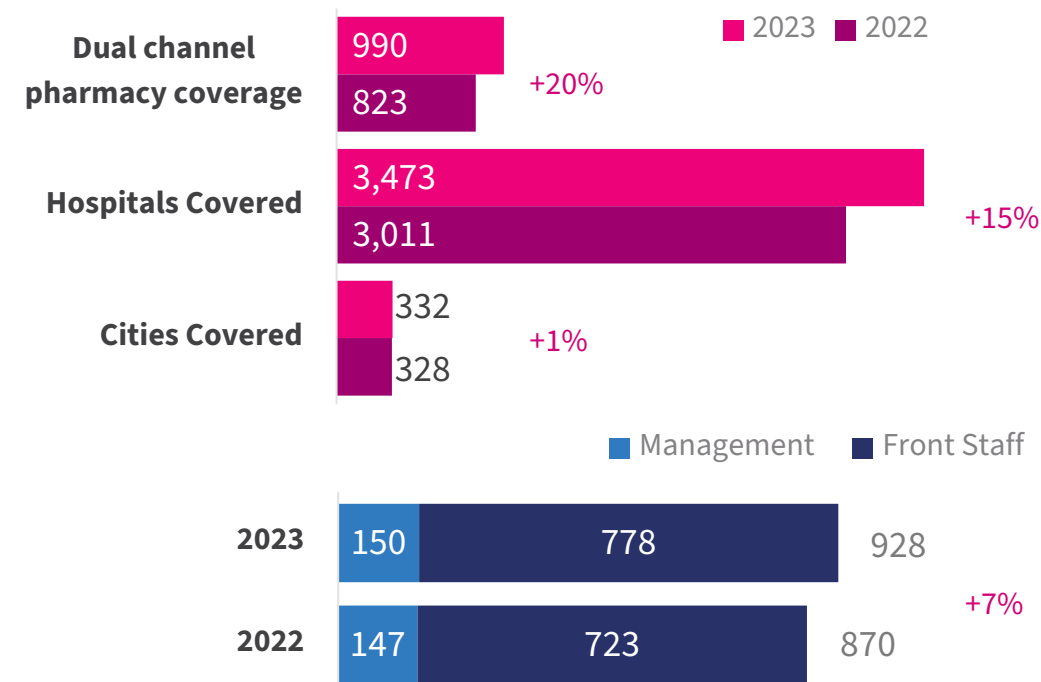
### Favorable operating environment

#### Policies promoting access to innovative medicines

- Beijing released a draft to implement the carve out of innovative drugs from the conventional cost control regime (Apr 2024)
- Guangzhou and Zhuhai introduced regional policies to encourage innovative drug usage (Apr 2024)
- NDRC's plan for "full-scale support" for innovative drug development (Mar 2024)
- NHSA to explore a more flexible and market-driven pricing mechanism for innovative chemical drugs (Feb 2024)
- Innovative drug pricing in Shanghai Pudong to be referenced to overseas comparables (Jan 2024)
- Shanghai hospitals formulary should cover drugs soon after NRDL inclusion, not taking up the NRDL budget first three years (Dec 2023)
- Simplification of NRDL renewals (Jul 2023)

### Robust on-the-ground presence

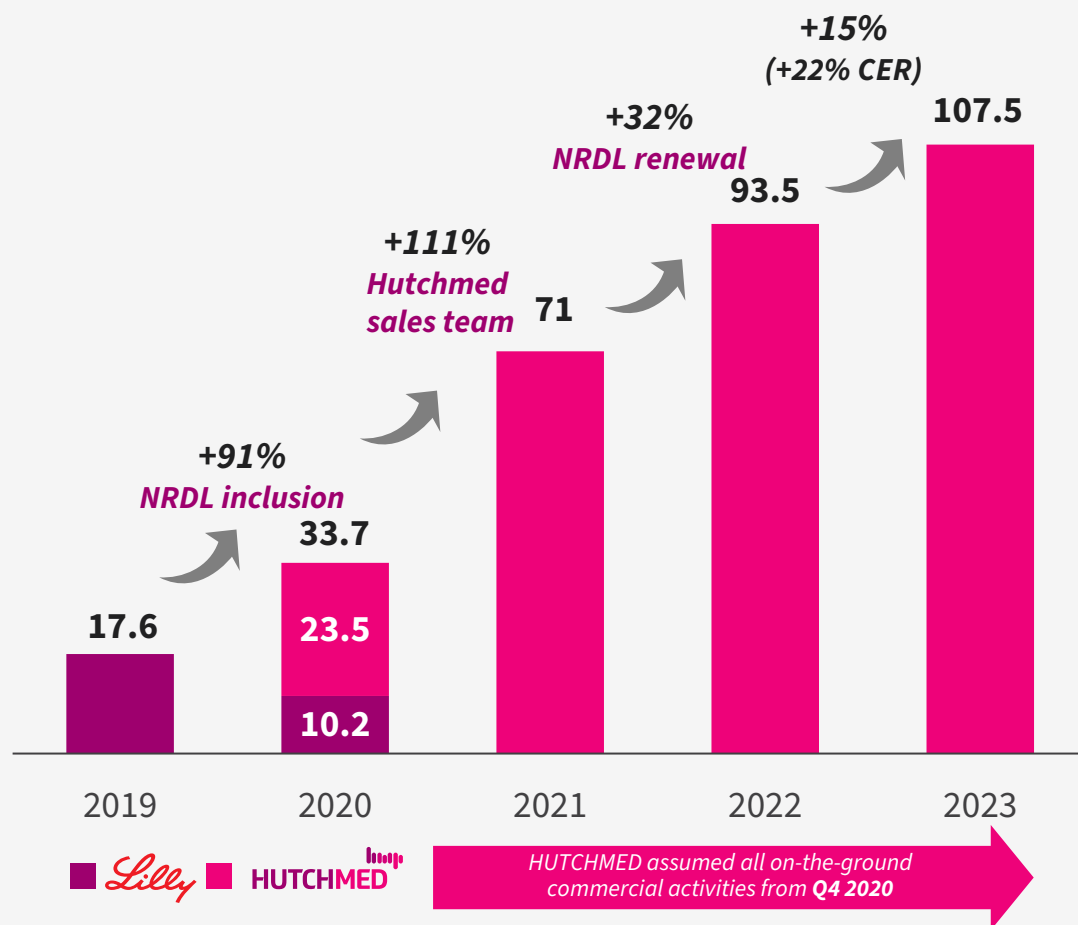
#### • >39,000 oncology physicians covered





# ELUNATE® (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)

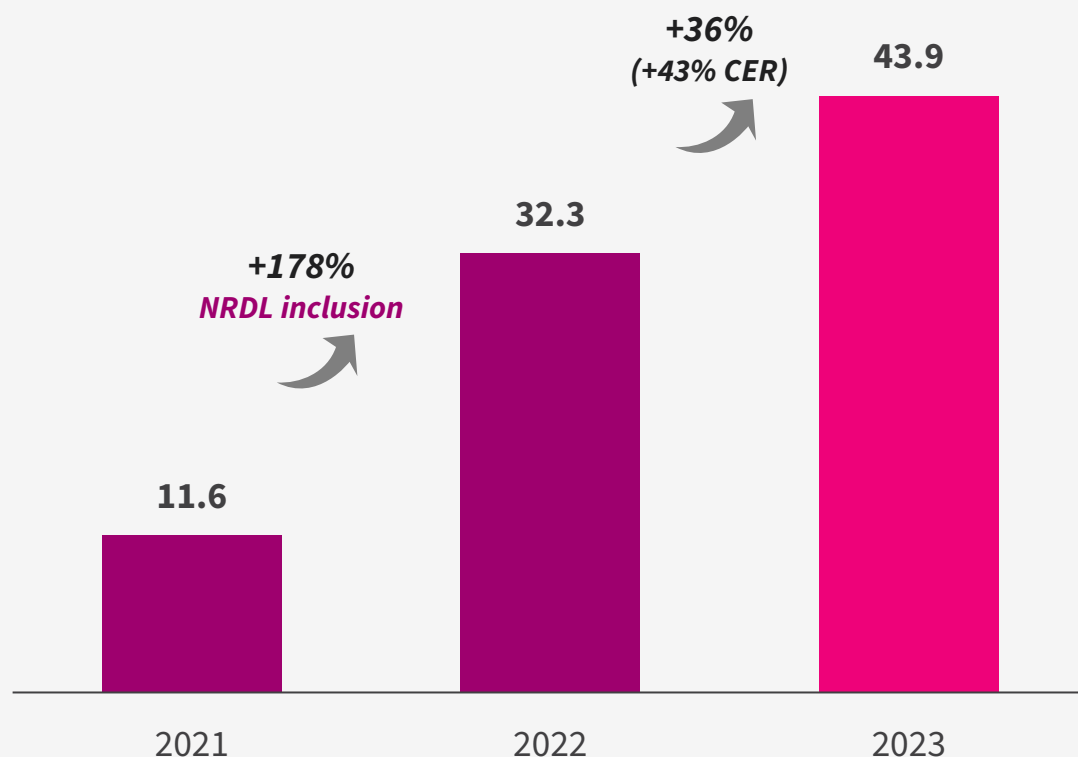
[2] IQVIA audit data in proprietary post-launch research panel of mainly Class 3 hospitals in Top 30 cities in China.

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

HUTCHMED



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
<b>SULANDA<sup>®</sup></b>	7%	14%	16%	17%	21%
<b>Somatostatin analogues</b>	53%	47%	42%	36%	38%
<b>Sutent<sup>®</sup></b>	14%	14%	14%	13%	10%
<b>Afinitor<sup>®</sup></b>	10%	9%	10%	11%	9%

[1] New treatment guidelines with Chinese Society of Clinical Oncology (CSCO), Chinese Anti-Cancer Association (CACA) and China Medical Association (CMA)

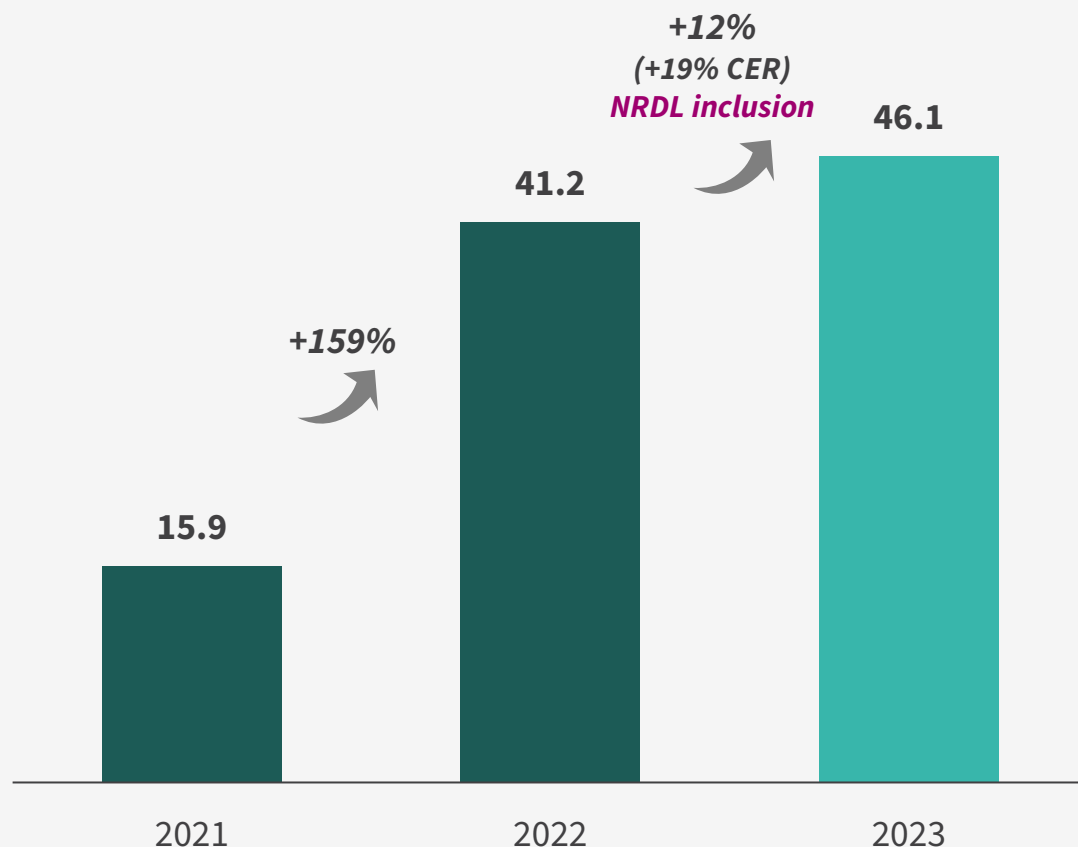
[2] IQVIA NET Tracking Study conducted April 2023.

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

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

- Strong 1L clinical results

## Publications

- ELCC <sup>[1]</sup> March 2024 (PFS 13.7mo; ORR 62.1%)
- WCLC <sup>[2]</sup> 2023

## Inclusion in key treatment guidelines

- NHC, CSCO, CACA, CMA, CTONG <sup>[3]</sup>
- 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®

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

[3] New treatment guidelines with National Health Commission (NHC), Chinese Society of Clinical Oncology (CSCO), Chinese Anti-Cancer Association (CACA), China Medical Association (CMA), Chinese Thoracic Oncology Group (CTONG).

# 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)	Status	Est. (s)NDA filing if positive
FRUQ**	<b>FRESCO-2</b>	3L+ colorectal cancer	Global	~690, treatment vs. BSC, OS	US FDA approved EU CHMP positive opinion; Japan NDA filed	FDA approved EU, JP pending
FRUQ^^	<b>FRUTIGA</b>	2L GC, combo with chemo	China	~700, combo vs. chemo, OS & PFS	sNDA in China accepted April 2023	Review ongoing
SOVLE	<b>ESLIM-01</b>	2L immune thrombocytopenia	China	~180, 2 arms (placebo), DRR	NDA in China accepted January 2024 priority review status	Review ongoing
SAVO*	<b>Confirmatory</b>	NSCLC, MET Exon 14 alteration	China	~160, 1 arm, ORR	sNDA in China accepted March 2024	Review ongoing
FRUQ^^	<b>FRUSICA-1</b>	2L EMC, combo with PD-1	China	~140, 1 arm, ORR	NDA in China accepted April 2024 China BTB, priority review status	Review ongoing
TAZ^	<b>Bridging</b>	3L follicular lymphoma	China	~40, 2 arms (EZH2+ or wt), ORR	LPI Sep'23	Mid 2024
SAVO*	<b>SAVANNAH</b>	2/3L TAGRISSO® refractory NSCLC, MET+	Global	New cohort for potential AA	LPI Feb '24	Late 2024
FRUQ^^	<b>FRUSICA-2</b>	2L RCC, combo with PD-1	China	~260, 2 arms, PFS	LPI Dec'23	2025
SURU	<b>SURTORI-01</b>	2L NEC, combo with PD-1	China	~190, combo vs. chemo, OS	Enrolling	2025
SAVO*	<b>SACHI</b>	2L EGFR TKI refractory NSCLC, MET+	China	~250, combo vs. chemo, PFS	Enrolling	2025
SAVO*	<b>GASTRIC</b>	3L GC, MET amplified	China	~60, 1 arm, ORR	Enrolling	Reg. cohort opened Mar 2023 2025
SOVLE	<b>ESLIM-02</b>	2L wAIHA	China	~110, 2 arms (placebo), Hb response	FPI Mar'24	2026
SAVO*	<b>SANOVO</b>	1L EGFRm+ NSCLC, MET+	China	~320, combo vs. Tagrisso, PFS	Enrolling	2026
SAVO*	<b>SAMETA</b>	MET driven PRCC, combo with PD-L1	Global	~200, 3 arms combo vs. monos, PFS	Enrolling	2026
SAVO*	<b>SAFFRON</b>	2/3L TAGRISSO® refractory NSCLC, MET+	Global	~320, combo vs. chemo, PFS	Enrolling	2026
HMPL-453	<b>IHCC, FGFR2</b>	IHCC, FGFR2 fusion	China	~90, 1 arm, ORR	Enrolling	Reg. cohort opened Mar 2023 2026



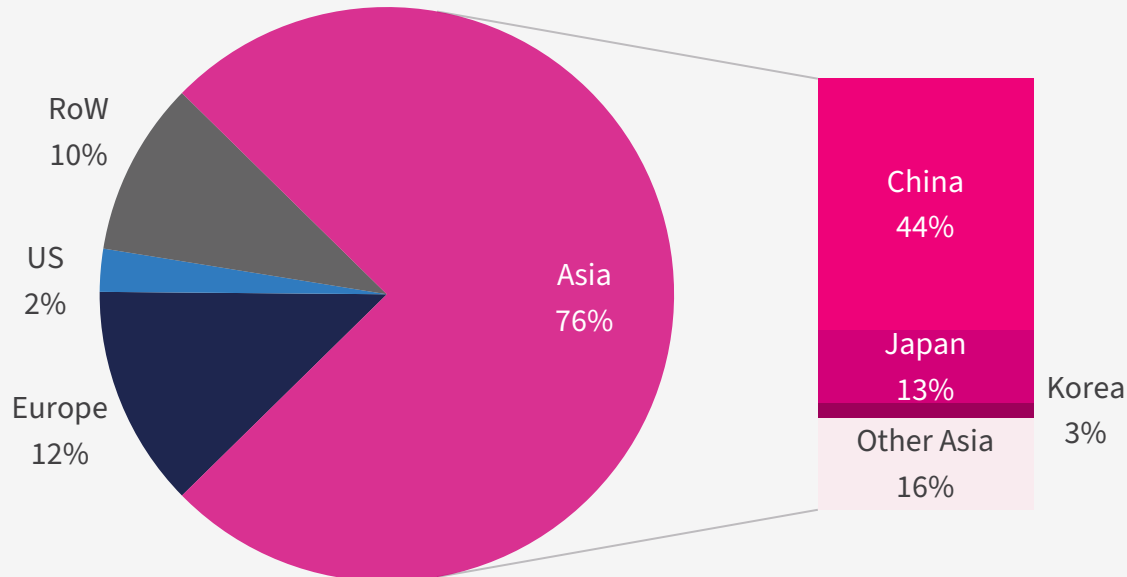
# Fruquintinib 2L gastric cancer: China sNDA accepted for review April 2023

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 Trial

**sNDA with NMPA accepted April 2023**

### Dual primary endpoints:

- ✓ Progression free survival: clinically and statistically significant 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**

### Eligible patients

- Gastroesophageal junction or gastric cancer
- Progressed after 1<sup>st</sup> line chemo w/ fluoropyrimidine & platinum

**Fruquintinib**  
+  
Paclitaxel  
N=350

**Placebo**  
+  
Paclitaxel  
N=350



# Fruquintinib 2L gastric cancer: phase III data highlights

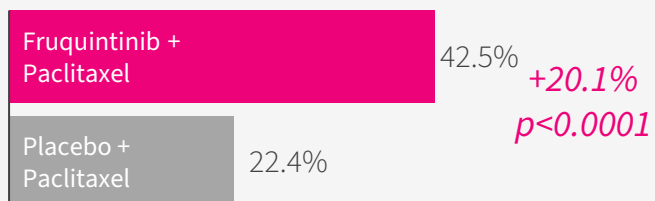
Promising 2L treatment option for patients with advanced G/GEJ adenocarcinoma



**FRUTIGA**<sup>[1]</sup>  
703pts  
100% Chinese

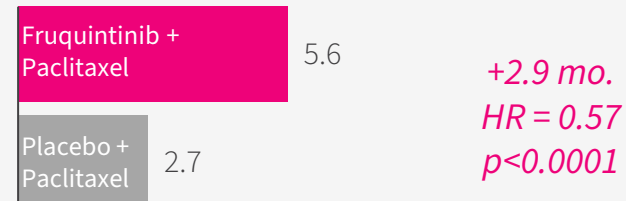
## Objective Response Rate

**Δ ORR**



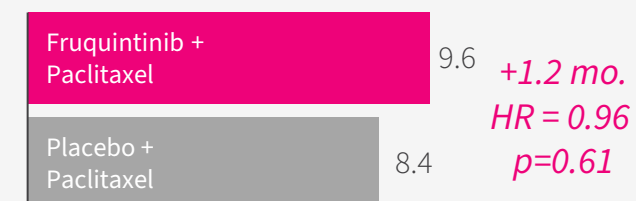
## Progression Free Survival

**Δ PFS**

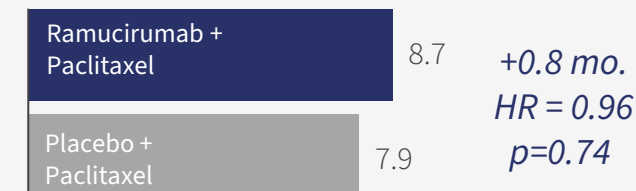
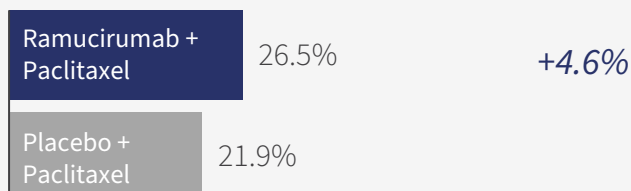


## Overall Survival

**Δ OS**



**RAINBOW-Asia**<sup>[2]</sup>  
440pts  
100% Asians  
87-92% Chinese



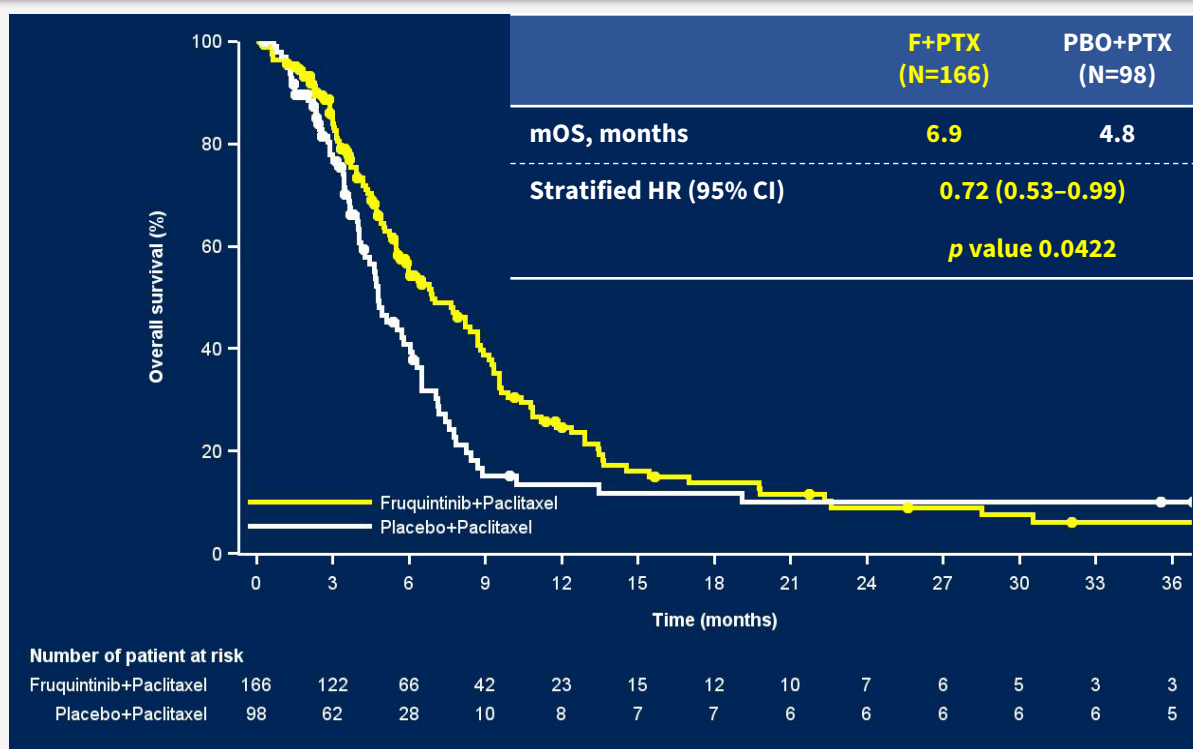
Note: Illustrative comparison only. No head-to-head studies have been conducted. Study parameters differ.

[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

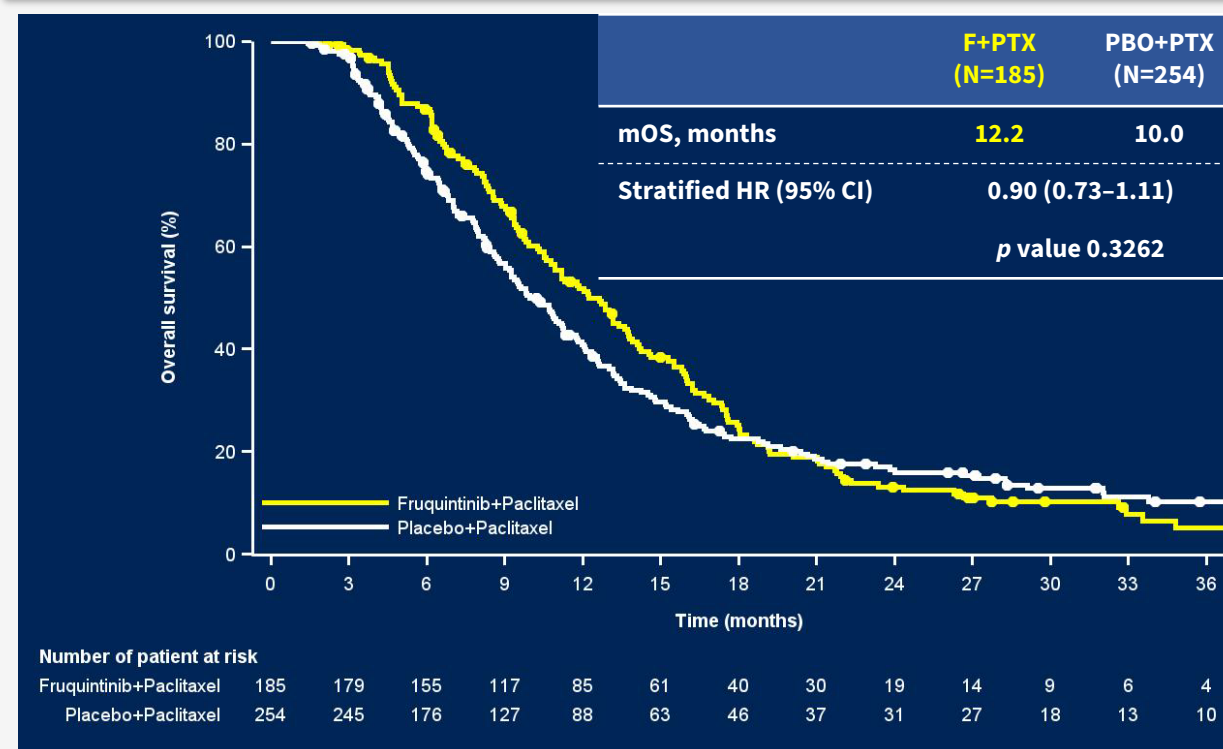
# FRUTIGA: OS with or without subsequent antitumor therapy

ASCO  
Plenary  
2024

## Patients **did not receive** subsequent antitumor therapy



## Patients **received** subsequent antitumor therapy

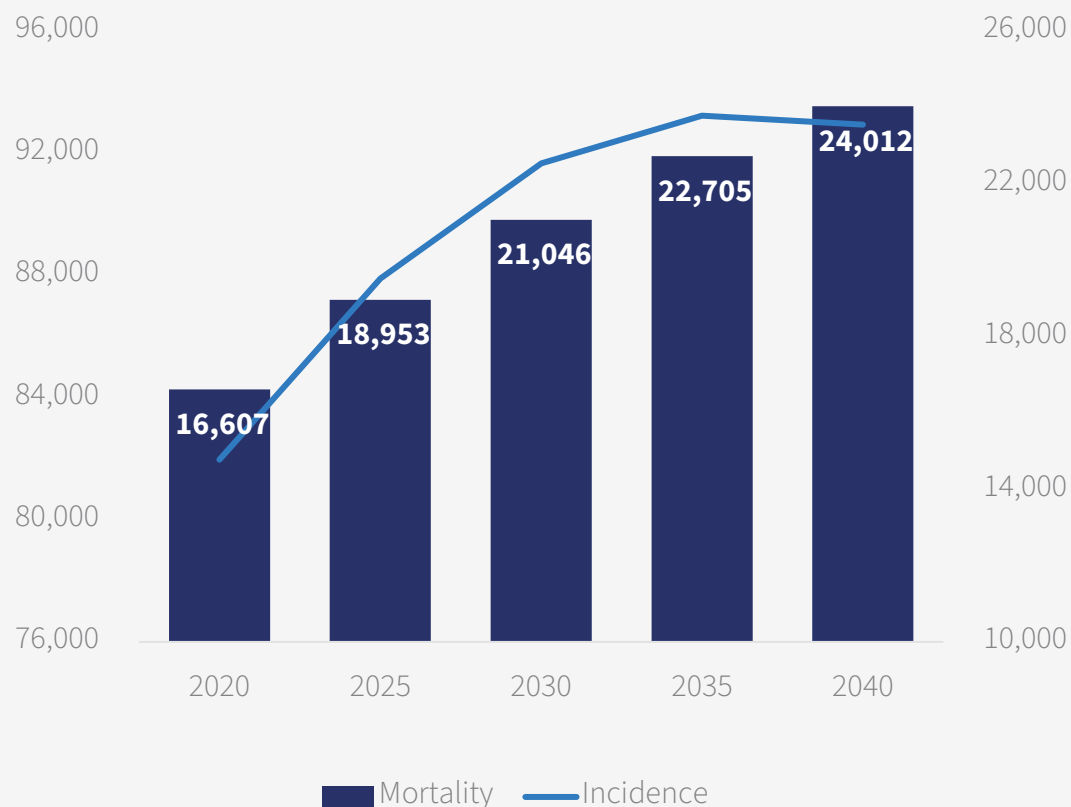


F+PTX demonstrated the trend for OS benefit **regardless of receiving subsequent antitumor therapy**

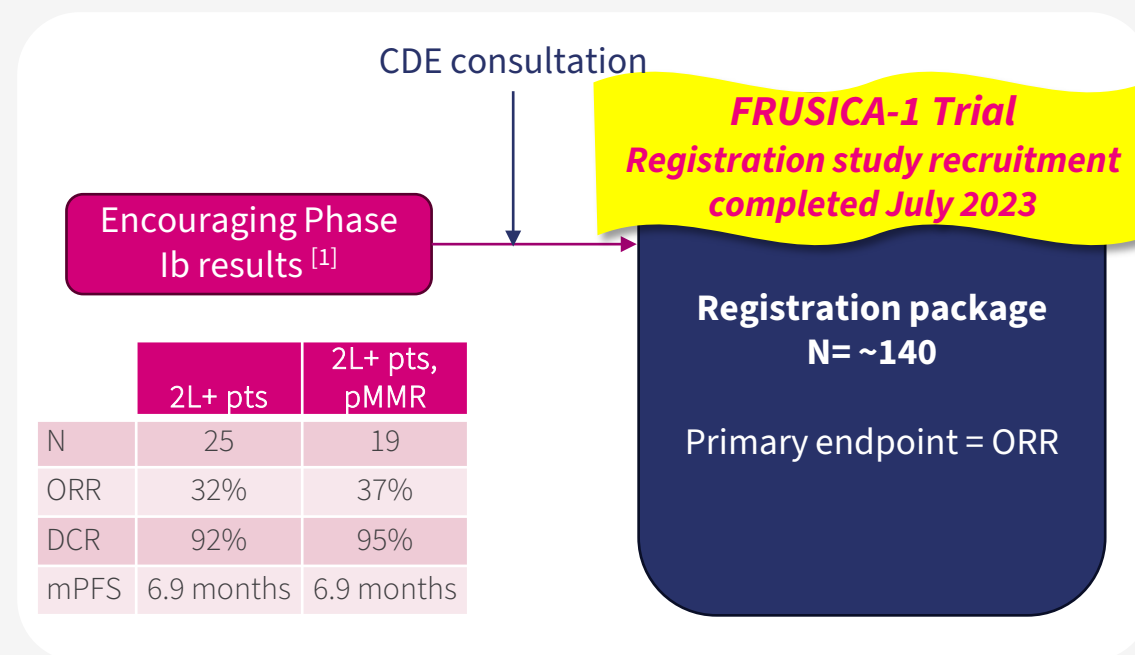
# Fruquintinib endometrial cancer: Lead ICI combo in China

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

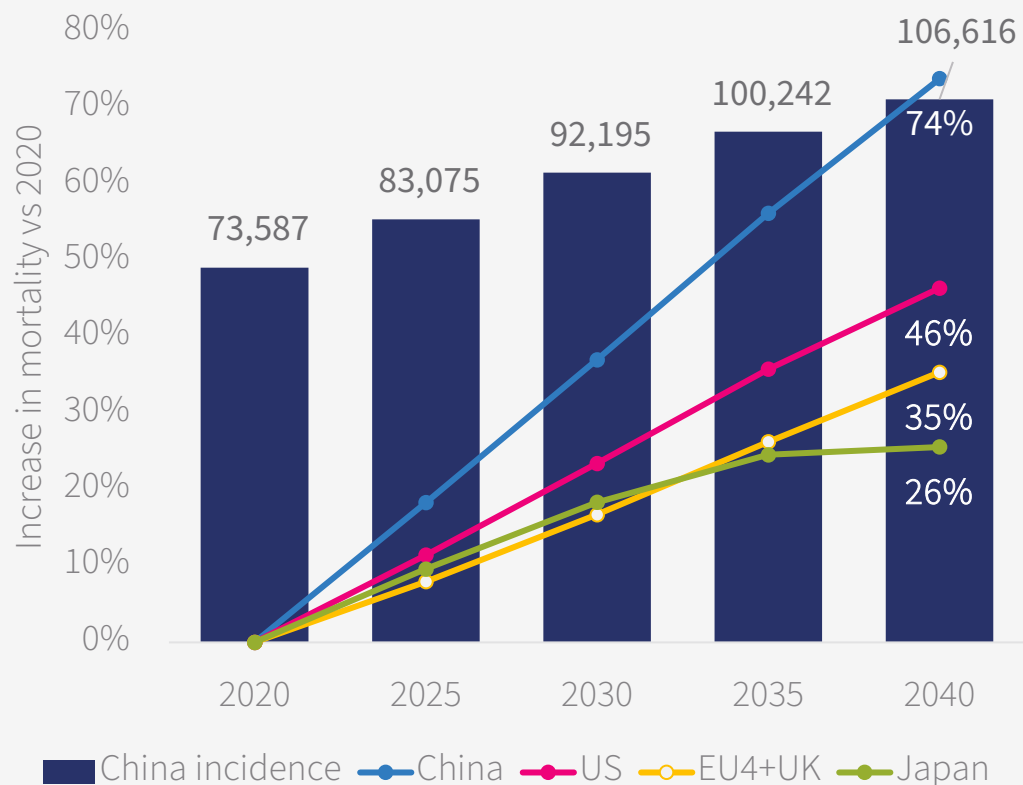


[1] CSCO 2021

[2] International Agency for Research on Cancer

# 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

**enrollment completed Dec 2023**

**Fruquintinib  
+  
Sintilimab  
N ≈120**


**Axitinib  
or  
everolimus  
N ≈120**

Contribution of  
component  
Fruquintinib mono  
N ≈15-20

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

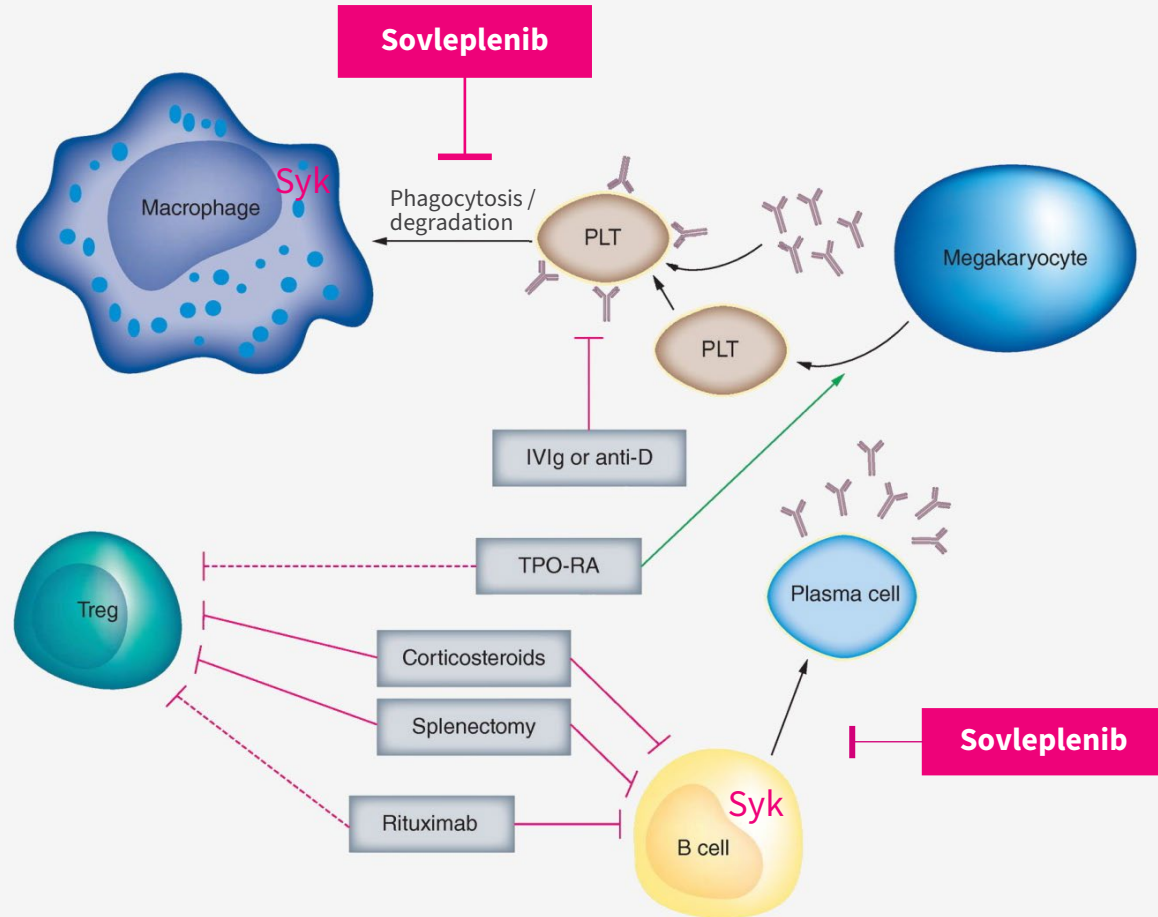
No PD-1/VEGFi combo approved in 1L or 2L RCC in China

Robust and durable responses seen in previously treated advanced RCC

	 <b>Fruquintinib + Sintilimab P2 POC Study</b> <sup>[1]</sup>	<b>CONTACT-03</b> <sup>[2]</sup> <b>Cabozantinib +/- atezolizumab</b>		<b>KEYMAKER-U03</b> <sup>[3]</sup> <b>Belzutifan + lenvatinib</b>	<b>Lenvatinib + pembrolizumab (KEYNOTE-146)</b> <sup>[4]</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 mg 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	
N	20	259	263	24	17	104
ORR [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% CI]	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]
<b>mPFS, months</b> [95% CI]	<b>15.9</b>	<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]

# 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)

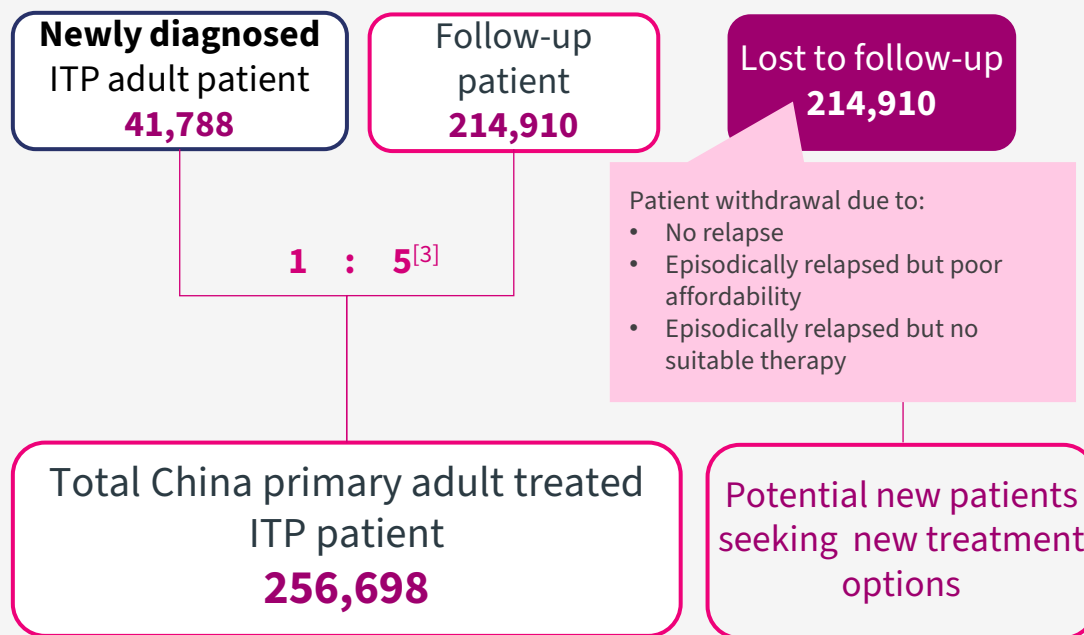
- ✓ China Phase III completed – met all primary and secondary endpoints, NDA accepted by China NMPA in Jan 2024 with priority review status
- ✓ BTD granted by China NMPA in Jan 2022 for ITP
- ✓ US IND cleared, Phase Ib/II for ITP patients in start-up



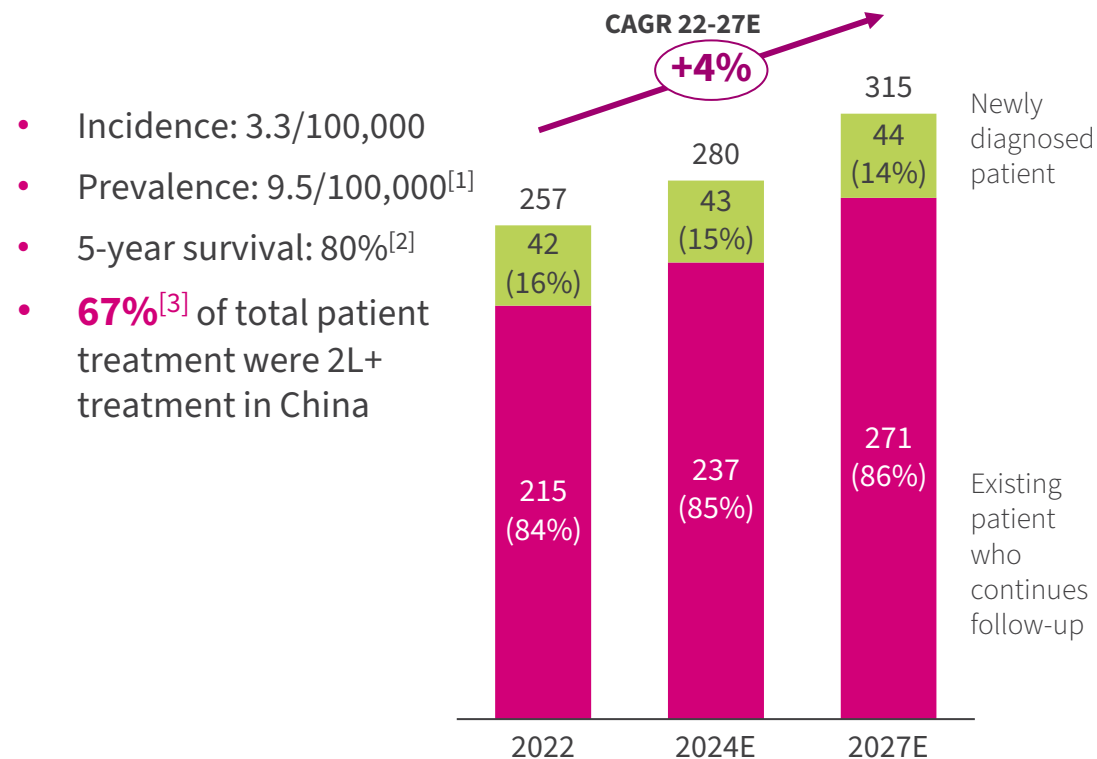
# China adult ITP patients

Significant burden of disease remains

## China primary adult ITP patient size (2022, ppl)



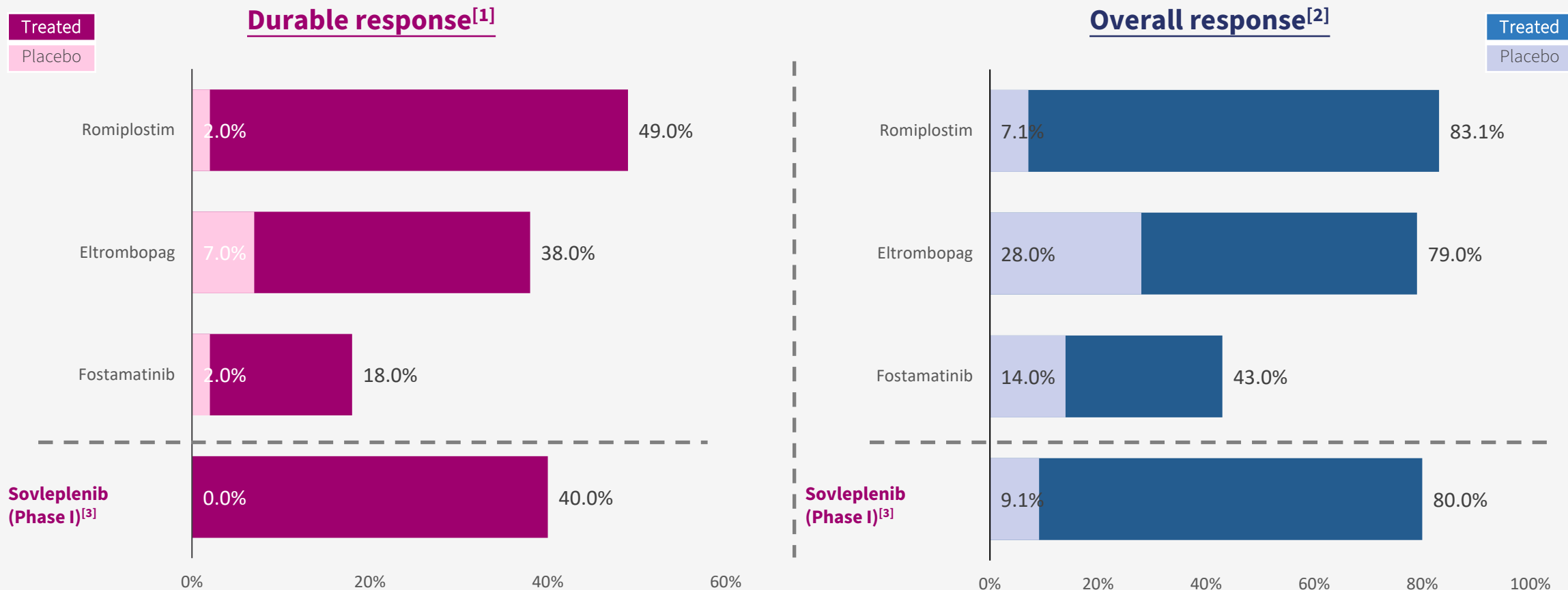
## China primary adult ITP patients (2022-2027E, K ppl)



# 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

## Efficacy comparison of Sovleplenib vs launched products



[1] Definition of durable response:

Fostamatinib: same with HMPL-523

Eltrombopag/Hetrombopag: platelets  $\geq 50 \times 10^9/L$  at  $\geq 75\%$  of their platelet count assessments

Romiplostim/Avatrombopag: platelets  $\geq 50 \times 10^9/L$  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

# 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		
	Double-blinded Pts 0-24 weeks	Cross-over Pts 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, double-blind, 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  $\geq 50 \times 10^9 /L$  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 300mg QD  
N ≈ 126

Placebo QD  
N ≈ 62

# 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

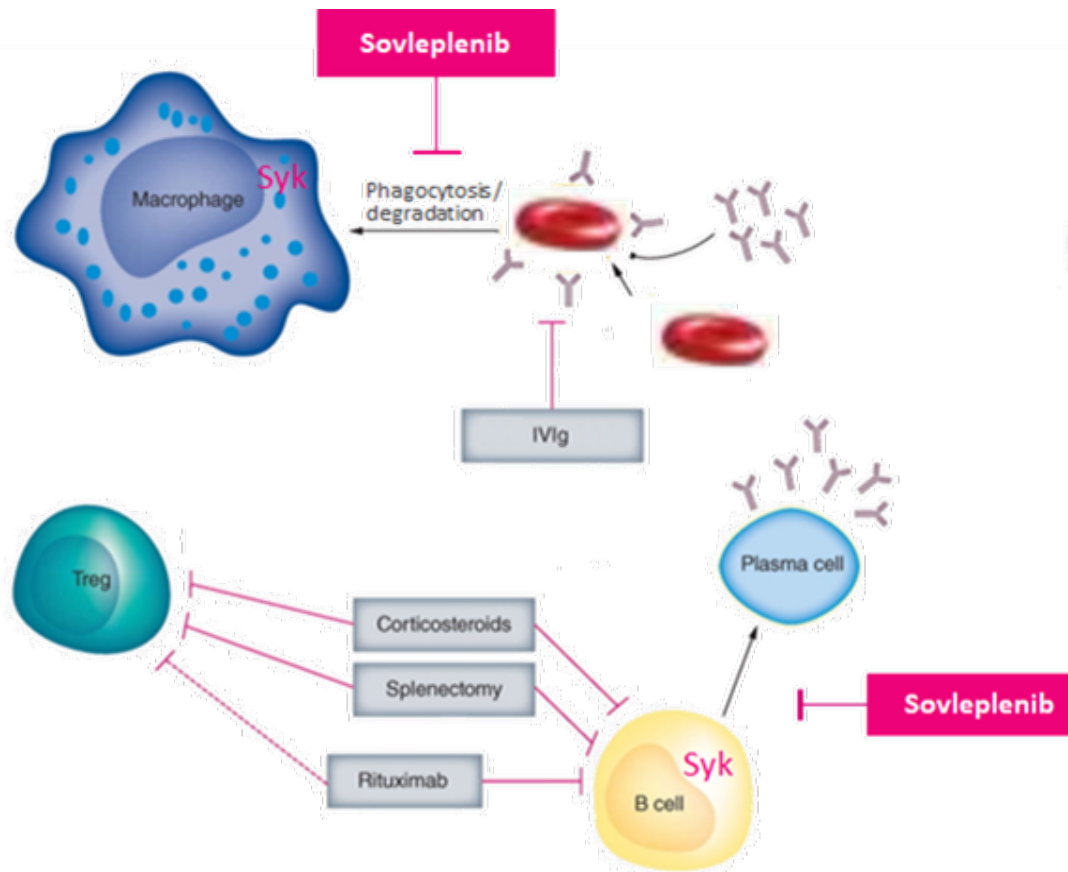
No FDA approved therapy yet, high unmet medical needs exist

- 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/m<sup>2</sup> 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

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

WCLC 2022

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

- 2** • Savolitinib + TAGRISSO® Phase III registration study – **SAFFRON Study** ongoing enrollment

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

- 3** • Savolitinib + IMFINZI® vs. SUTENT® monotherapy vs. IMFINZI® monotherapy Phase III registration study – **SAMETA Study** ongoing enrollment

## CHINA – led by HUTCHMED

### MET Exon14 skipping NSCLC

- 4** • NDA conditional approval in June 2021  
• **Confirmatory Phase IIIb study** – final data at ELCC 2024

WCLC 2023

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

- 5** • Savolitinib + TAGRISSO® Phase III registration study  
• **SACHI Study** to complete enrollment in late 2024

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

- 6** • Savolitinib + TAGRISSO® Phase III registration study  
• **SANOVO Study** to complete enrollment in late 2024

### Gastric cancer w/ MET amplification

- 7** • **Single arm study with potential for registration**  
• Registration cohort FPI March 2023

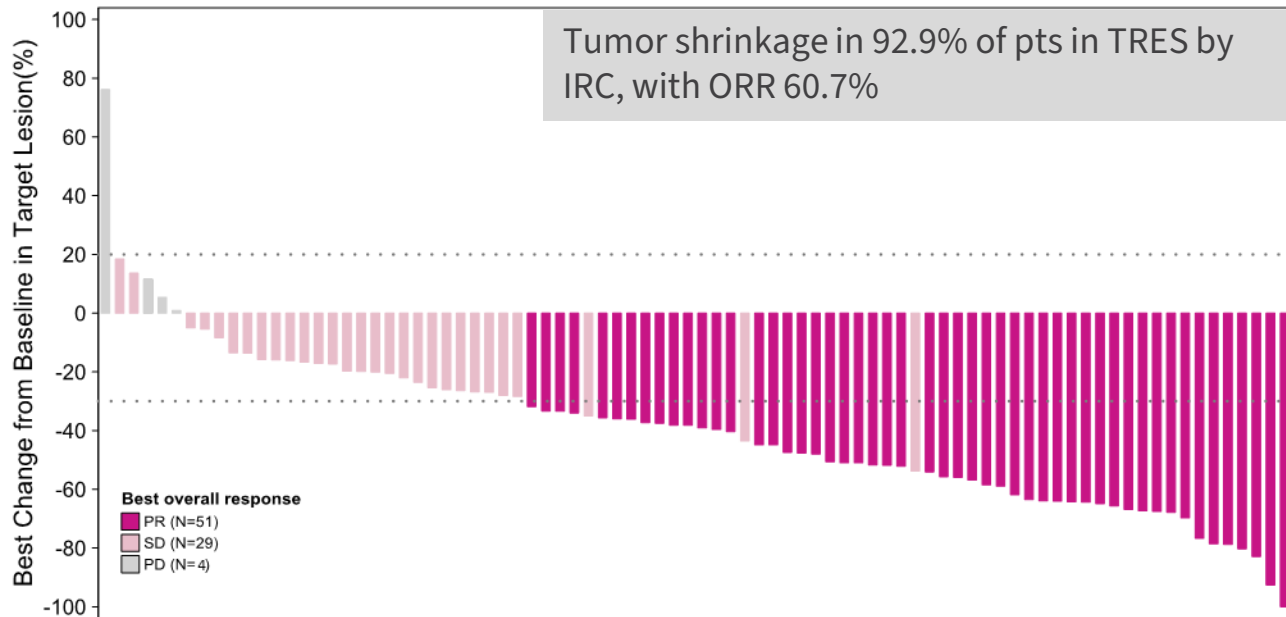
AACR 2023

**China Breakthrough designation for 3L+ Aug 2023**

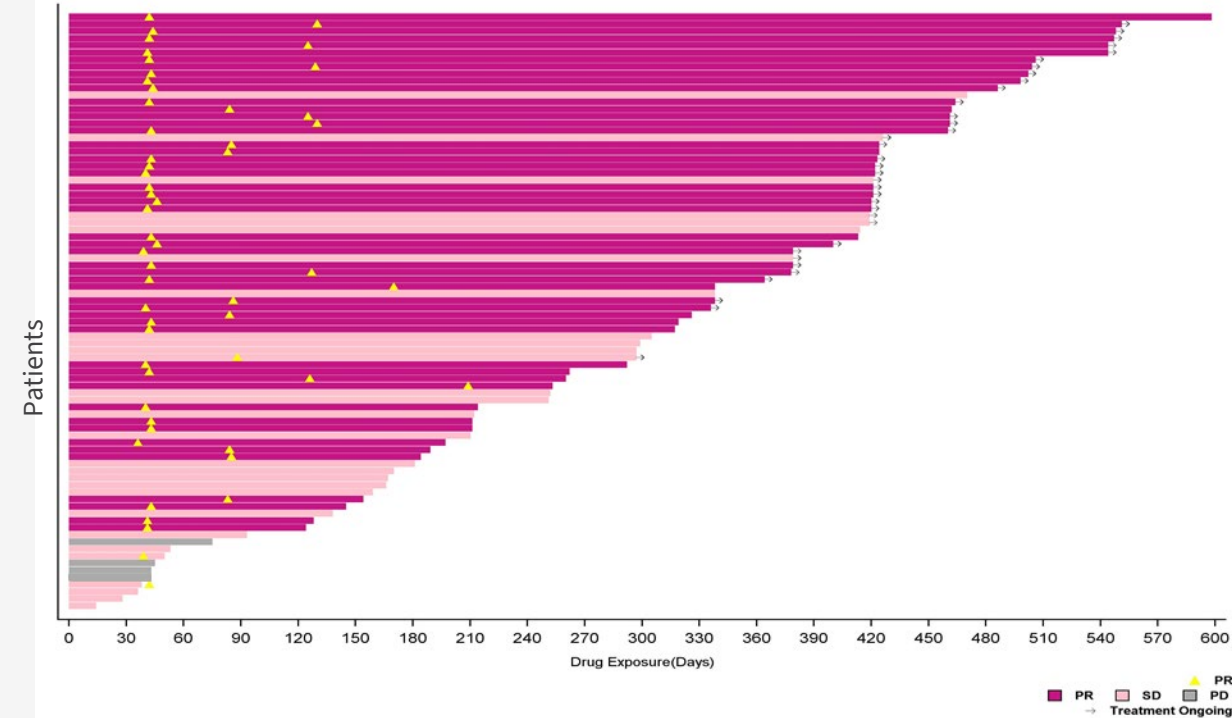
# Savolitinib: 1L MetEx14+ NSCLC Patients, WCLC 2023

Deep and Durable Response (IRC assessment)

**Waterfall Plot - Tumor Shrinkage of Target Lesion(IRC Assessment) - Tumor Response Evaluable Set**



**Swimmer Plot - (IRC Assessment) - Tumor Response Evaluable Set**



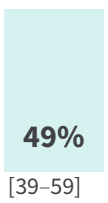
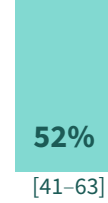
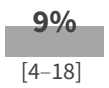
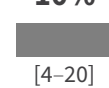


# Savolitinib: 2L EGFRm+ NSCLC w/ MET aberration

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

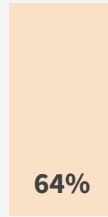
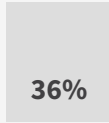
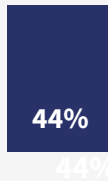
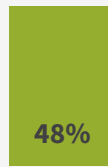
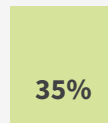
## MET specific

### Novel biomarker and patient enrichment strategy driven by SAVANNAH [1]

N=185* 300mg QD	<b>MET-high</b> IHC90+ and/or FISH10+		<b>MET-low</b> IHC50-90 and/or FISH 5-10	
<b>Prevalence among patients screened</b>	<b>34%</b>		<b>28%</b>	
Prior Chemo	20%	No prior chemo subset	18%	No prior chemo subset
Number of patients	n=108	n=87	n=77	n=63
				
<b>mDoR, [95% CI]</b>	<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, [95% CI]</b>	<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 ≥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

	<b>MARIPOSA-2</b> <sup>[2]</sup>		<b>TL05</b> <sup>[3]</sup>	<b>ORIENT-31</b> <sup>[4] [5]</sup>	
<b>Patient Screening</b>	EGFR-mutant advanced NSCLC after disease progression on osimertinib		Previously treated NSCLC with AGAs	EGFR-mutated non-squamous NSCLC after progression on EGFR-TKI Therapy	
	<b>Amivantamab + chemo</b>	<b>chemo</b>	<b>Dato-DXd</b>	<b>Sintilimab+ bevacizumab+ chemo</b>	<b>Sintilimab+ chemo</b>
Number of Patients	n=131	n=263	n=78 (EGFRm)	n=158	n=158
<b>ORR</b>					
<b>mDoR</b>	<b>6.9 mo.</b>	<b>5.6 mo.</b>	<b>7.0 mo.</b>	<b>8.5 mo.</b>	<b>7.4 mo.</b>
<b>mPFS</b>	<b>6.3 mo.</b>	<b>4.2 mo.</b>	<b>5.8 mo.</b>	<b>7.2 mo.</b>	<b>5.5 mo.</b>

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

## 3 medicines commercialized

## 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

## Growing US sales, indication expansion in China



- EU and JP approval for CRC
- China 3 indications (GC, EMC, RCC) filed or to be filed
- Ex-China: combination strategy



- U.S. filing for 2L NSCLC
- Expanding to 1L NSCLC, 3L GC and 2L PRCC

### Sovleplenib

- China ITP approval
- International dose-finding study to commence



- China 2L NEC Phase III ongoing
- Potential for new LCM indications



- China 3L+ follicular lymphoma filing mid 2024
- Global 2L follicular lymphoma Phase III ongoing

### HMPL-453 (FGFR1/2/3)

- 2L FGFR2 fusion IHCC
- China Phase II (registration phase) FPI Mar 2023

### HMPL-306 (IDH1/2)

- IDH1 or 2+ relapsed/refractory myeloid leukemia
- China Phase III planned for 2024

5

## Path to a sustainable business...

HUTCHMED medium-term & long-term strategy

HUTCHMED

### AMBITION

to mature into a  
sustainable biopharma  
from an emerging growth co

### 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

2023

Fruq FDA approved  
Reduction in R&D costs  
Global commercialization through  
partnerships

Target self-sustaining

2025

Accelerated growth

2024

More overseas product sales  
contribution

First immunology medicine  
approved in China

**Thank you**



[www.hutch-med.com](http://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  $\geq 5$

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 = 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®), 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  $\geq 50\%$  tumor cells.  
 IHC90+ = MET overexpression as detected by IHC with 3+ in  $\geq 90\%$  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.