# DELIVERING GROWTH THROUGH SCIENCE & VISION

**FY2022 RESULTS & BUSINESS UPDATE** 

February 28, 2023

Nasdaq/AIM:HCM | HKEX:13





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#### **HUTCHMED 2022**





# STRATEGIC FOCUS

- ✓ **Global vision unchanged** access to our medicines for patients worldwide
- ✓ Portfolio prioritization
- ✓ **Global partnering approach**Takeda licensing agreed



#### **LATE STAGE**

- ✓ Fruq FRESCO-2 global Ph III (CRC)
- ✓ Fruq FRUTIGA China Ph III (GC)
- ✓ Savo SAVANNAH data (2L NSCLC)

#### **2ND WAVE**

- ✓ Sovle ESLIM Ph III enrolled (ITP)
- ✓ Amdiz reg Ph II enrolled (FL)
- ✓ Taz bridging enrolled in 2023 (FL)





- ✓ Goal to become a profitable, sustainable business
- ✓ Oncology/Immunology rev.+37% (+41% CER) in line with guidance
- ✓ Combined in-market sales
   +70% for ELUNATE®,
   SULANDA® & ORPATHYS®

### Agenda

# HUTCHMED

1

### **Commercial delivery**

Novel oncology products continue to bring growth

2

### Financial review & outlook

*Underpinned by strong financial & strategic fundamentals* 

3

### **Strategic partnerships**

Optimizing ex-China development & commercialization

4

### Late-stage pipeline

15+ potential NDAs & sNDAs in the next 3 years

5

### **Our strategy**

Revenue growth & strategic actions on path to profitability





**Johnny Cheng** *Chief Financial Officer* 



**Karen Atkin**Chief Operating Officer



**Michael Shi** Chief Medical Officer & Head of R&D



Weiguo Su Chief Executive Officer & Chief Scientific Officer



















# **Commercial coverage**



China sales benefitting from robust & carefully planned commercial infrastructure

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

Dec 31, 2022 vs. Dec 31, 2021



# Commercial organization at optimal scale, with capacities to grow sales further

- 900+ oncology commercial team
- >33,000 oncology physicians covered (+14% vs. 2021)
- 500+ more hospitals covered versus 2021
- Many more and highly effective digital promotion events held to mitigate the COVID challenges, e.g.
  - ELUNATE®: 7,200 events (+50% vs 2021), with
     >215,000 HCP attendances in 2022 (+115% vs. 2021)
  - SULANDA®: 4,900 events (+53% vs 2021), with
     >120,000 HCP attendances in 2022 (+110% vs. 2021)









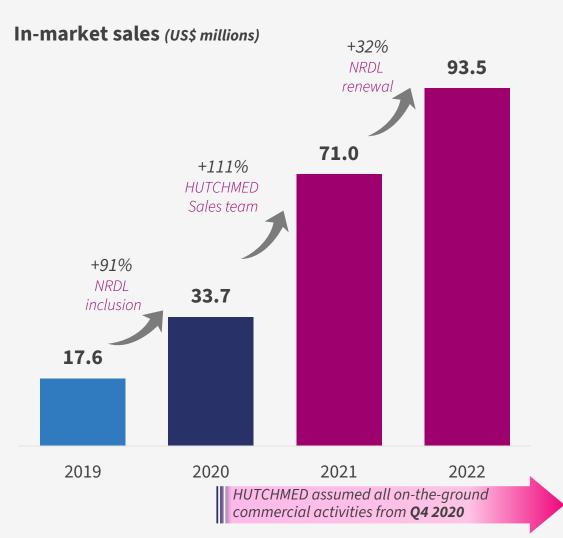




## **ELUNATE®** (fruquintinib) remains market leader in 3L CRC







#### **Continuing to increase new patients treated in 2022**

• **~32,000 est. new patients** treated, up ~45% versus 2021

#### **Strong competitive position**

- Inclusion in CSCO & CACA CRC Guidelines<sup>[1]</sup>
- Maintaining leadership in patient share in 3L CRC (IQVIA<sup>[2]</sup>) despite later launch

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



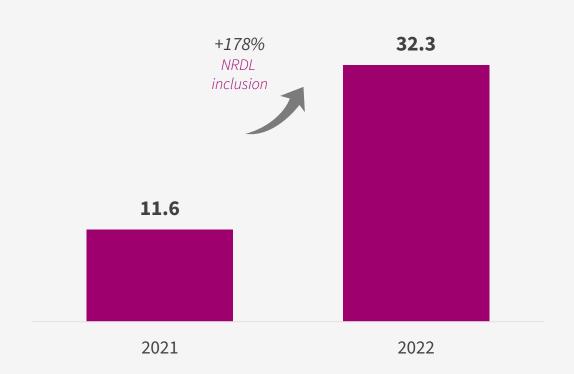
# **SULANDA®** (surufatinib) China momentum building





NRDL inclusion allowing wider patient access in 2022

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



#### **Impact of NRDL inclusion**

- Sales value increased 178% despite the 52% price reduction in NRDL negotiation
- **~17,000 est. new patients** treated, up ~250% vs 2021

#### 2022 focus on expanding access & awareness

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

Q3 2022	SANDOSTATIN®	SULANDA®	SUTENT®	AFINITOR®	Other
Rx share	42%	16%	14%	10%	18%



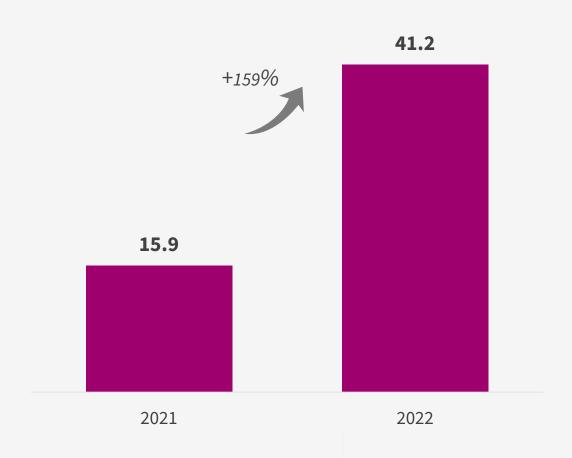
# **ORPATHYS®** (savolitinib) first-in-class MET inhibitor



#### The first and only selective MET TKI in China



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



- 2022 revenues driven by self-pay patients, and benefitted from a full year of availability (vs ~ 6 months in 2021)
- Brand share more than doubled since end of 2021
- NRDL inclusion from March 1, 2023
- Inclusion in 5 new treatment guidelines
  - NHC, CSCO, CACA, CMA, CTONG [1]

#### AZ a strong China commercial partner

- Top lung cancer franchise synergies
- MET diagnostic testing is now recommended as SOC for late-stage NSCLC





# **Continuing growth of Oncology revenues**

Oncology consolidated revenues guidance for 2023: **\$450-\$550 million** (including partial recognition of upfront payment from Takeda, subject to closing)







(US\$ in millions)	FY2022	FY2021	% Change	FY2022	FY2021	% Change
	In-ma	rket Sales	[1]	Consolida	ated Reve	nues
ELUNATE® (fruquintinib)	\$93.5	\$71.0	+32%	\$69.9	\$53.5	+31%
SULANDA® (surufatinib)	\$32.3	\$11.6	+178%	\$32.3	\$11.6	+178%
ORPATHYS® (savolitinib)	\$41.2	\$15.9	+159%	\$22.3	\$11.3	+97%
TAZVERIK® (tazemetostat)	\$0.1	-	-	\$0.1	-	-
<b>Product Sales</b> <sup>[2]</sup>	\$167.1	\$98.5	+70%	\$124.6	\$76.4	+63%
Other R&D Service income				\$24.2	\$18.2	+33%
Milestone payment				\$15.0	\$25.0	-40%
Total				\$163.8	\$119.6	+37%

<sup>[1]</sup> Total sales to third parties provided by Lilly (ELUNATE®), AstraZeneca (ORPATHYS®) and HUTCHMED (ELUNATE®, SULANDA® and TAZVERIK®);

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







<b>Condensed Consolidated Balance Sheets</b> (US\$ in millions)	Dec 31, 2022	Dec 31, 2021
Assets		
Cash, cash equivalents & short-term investments	631.0	1,011.7
Accounts receivable	98.0	83.6
Other current assets	110.9	116.8
Property, plant and equipment	75.9	41.3
Investments in equity investees	73.8	76.5
Other non-current assets	39.8	42.8
Total assets	1,029.4	1,372.7
Liabilities and shareholders' equity		
Accounts payable	71.1	41.2
Other payables, accruals and advance receipts	264.6	210.9
Bank borrowings [1]	18.1	26.9
Other liabilities	38.7	54.2
Total liabilities	392.5	333.2
Company's shareholders' equity	610.4	986.9
Non-controlling interests	26.5	52.6
Total liabilities and shareholders' equity	1,029.4	1,372.7

As of Dec 31, 2022

#### **Cash Resources:**

- **\$631m cash** / cash eq. / ST inv. <sup>[2]</sup>
  - Including short-term investment of \$318m
- \$140m unutilized banking facilities
  - \$90m unutilized fixed asset loan facility

#### **Others:**

\$34m additional cash at SHPL JV

#### Impact of Takeda transaction

• \$400m upfront payment on closing



# **Oncology sales growth & Other Ventures income**

#### Help offset R&D investment

Condensed Consolidated Statements of Operations	Year ende	d Dec 31,
(US\$ in millions, except share and per share data)	2022	2021
Revenues:	10.1.0	70.4
Oncology/Immunology – Marketed Products	124.6	76.4
Oncology/Immunology – R&D	39.2	43.2
Oncology/Immunology consolidated revenues	163.8	119.6
Other Ventures T. J.	262.6	236.5
Total revenues	426.4	356.1
Operating expenses:	(0.1.1.1)	(0 = 0 0)
Costs of revenues	(311.1)	(258.2)
R&D expenses	(386.9)	(299.1)
Selling & general admin. expenses	(136.1)	(127.1)
Total operating expenses	(834.1)	(684.4)
	(407.7)	(328.3)
Gain on divestment of an equity investee	_	121.3
Other expense, net	(2.7)	(8.7)
Loss before income taxes & equity in earnings of equity investees	(410.4)	(215.7)
Income tax benefit/(expense)	0.3	(11.9)
Equity in earnings of equity investees, net of tax	49.7	44.7
Equity in earnings of divested equity investee, net of tax	~	15.9
Net loss	(360.4)	(167.0)
Less: Net income attrib. to non-controlling interests	(0.4)	(27.6)
Net loss attributable to HUTCHMED	(360.8)	(194.6)
Losses/share attributable to HUTCHMED – basic & diluted (US\$ per share)	(0.43)	(0.25)
Losses/ADS attributable to HUTCHMED – basic & diluted (US\$ per ADS)	(2.13)	(1.23)

#### **Total Consolidated Revenues up 20% to \$426m**

- Oncology revenues up 37% to **~\$164m** (2021: ~\$120m)
- **\$15m** development milestone from AZ (for initiation of SAFFRON study)

# R&D spending supporting 15+ registration enabling programs

R&D expenses up 29% to ~\$387m

# Our share of SHPL JV's income partially offsets our R&D investment

• Net income attributable to HUTCHMED from equity investees up 11% to ~**\$50m** (2021: ~\$45m)

# Our partnership strategy is focused on 3 main activities





- ORPATHYS® worldwide AstraZeneca
- Launched in China
- 7 registration studies in NSCLC, PRCC & gastric cancer







- Surufatinib Japan and ex-China
- Sovleplenib ex-China
- HMPL-760 3G BTKi ex-China
- HMPL- 306 IDH1/2i ex-China



- ELUNATE® China Lilly
  - **FIPSEN**
- Tazemetostat
- NDA stage or approved products to leverage our strong HUTCHMED China Commercial team

# Two major global partnerships



Broadens development and potential commercialization while increasing bandwidth to advance pipeline



**Fruquintinib** 



**Savolitinib** 

# STAGE OF DEVELOPMENT at licensing

- Launched in China with leading market share
- U.S. FDA NDA rolling submission underway
- Europe & Japan filings
   being prepared
- INDs submitted
- First-in-human studies pending in Australia & China

#### **SCOPE**

Takeda responsible for

- All territories ex-China (U.S., Japan, Europe & ROW)
- All development, manufacturing, selling & marketing
- **HCM leads China** development
- AZ leads ex-China development
- AZ responsible for global commercial

# FURTHER DEVELOPMENT & LAUNCH

- Launch readiness
- Indications beyond mCRC being evaluated
- HUTCHMED ongoing programs in China may inform decisions

**FINANCIAL TERMS** 

- Upfront: \$400m\*
- Additional: \$730m
- Tiered royalties from 2024\* consistent with commercial-launch stage licensing transactions

- AZ launched in China
- NRDL listing March 2023
- 7 Registration studies ongoing in China / U.S. / ROW in several NSCLC subtypes, PRCC & gastric
- Could file NDA in 2024

- Upfront: \$20m
- Additionally paid to date: \$65m (\$120m potential)
- Expense reimbursement
- 9-18% tiered royalty ex-China
- 30% flat royalty in China

# HUTCHMED's deep & broad portfolio

#### 12 molecules in development

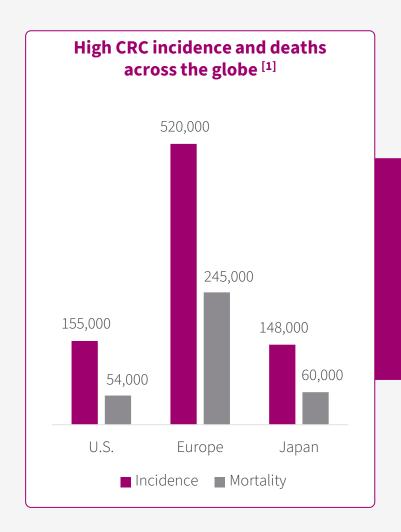
PRODUCT	MOA	INDICATIONS	PARTNER	CHINA <sup>[1]</sup>	GLOBAL <sup>[1]</sup>
Fruquintinib	VEGFR 1/2/3	Colorectal, gastric, EMC, RCC (multiple I/O & TKI combos)	Lilly Takeda (China) <sup>[3]</sup> (Ex-China) <sup>[4]</sup>	Marketed (Colorectal); Preparing filing (Gastric) Ph.III ongoing (RCC) Ph.II reg-intent ongoing (EMC)	<b>Preparing filings</b> in U.S., E.U., Japan based on positive MRCT (Colorectal)
Savolitinib	MET	NSCLC, kidney, gastric, colorectal <sup>[2]</sup> (multiple I/O & TKI combos)	AstraZeneca (Worldwide)[5]	Marketed (NSCLC mono) Ph.III (NSCLC combo) Ph.II reg-intent (Gastric)	Ph.II/III global (multiple NSCLC) Ph.III global (PRCC)
Surufatinib	VEGFR 1/2/3, FGFR1 & CSF-1R	NET, NEC (multiple I/O combos)	None <sup>[6]</sup>	Marketed (NET, pNET) Ph.III (NEC)	<b>Ph. III ready</b> US, EU <b>PMDA consultation</b> for JNDA filing
Amdizalisib	РІЗКδ	B-cell malignancies – indolent NHL	None <sup>[6]</sup>	Ph.II reg-intent (FL & MZL) Ph.II combo with tazemetostat	Ph. II; de-prioritized
Sovleplenib	Syk	ITP, B-cell malignancies	None <sup>[6]</sup>	Ph. III (ITP) TBD (NHL)	Ph. II
Tazemetostat	EZH2	Solid tumors, hematological malignancies	FIPSEN (ex-China) <sup>[7]</sup>	Marketed (ES & FL, Hainan) Bridging (3L FL) Global Ph. Ib	Marketed by Ipsen <sup>[8]</sup>
HMPL-453	FGFR 1/2/3	Cholangiocarcinoma	None	Ph.II reg-intent study in preparation	-
HMPL-306	IDH 1/2	Hematological malignancies, solid tumors	None <sup>[6]</sup>	Ph. I	Ph. I; de-prioritized
HMPL-295	ERK (MAPK pathway)	Solid tumors	None	Ph. I	-
HMPL-760	3G BTK	Hematological malignancies	None <sup>[6]</sup>	Ph. I	Ph. I; de-prioritized
HMPL-653	CSF-1R	Solid tumors	None	Ph. I	-
HMPL-A83	CD47	mAb – solid tumors, hematological malignancies	None	Ph. I	-

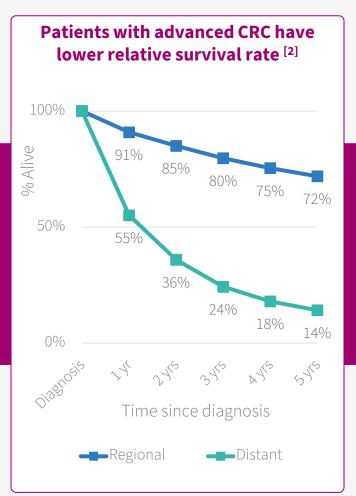
[1] Represents the most advanced clinical trial stage and indication; [2] Investigator initiated trials (IITs); [3] HCM has WW rights ex-China; Subject to meeting pre-agreed sales targets, Lilly will pay HUTCHMED an estimated total of 70%-80% of ELUNATE® sales in the form of royalties, manufacturing costs and service payments; [4] subject to customary closing conditions, including completion of antitrust reviews; [5] AZ has WW rights: China (30% royalty), ex-China (9-18% tiered royalty); [6] Open to partnering outside of Greater China; [7] HCM has commercial & development rights in Greater China; [8] Tazemetostat was developed by and is marketed in the U.S. by Epizyme, Inc., which was acquired by Ipsen SA in August 2022.

# Colorectal cancer a significant burden...



...but there are still limited treatment options for most patients





#### **Unmet medical need**

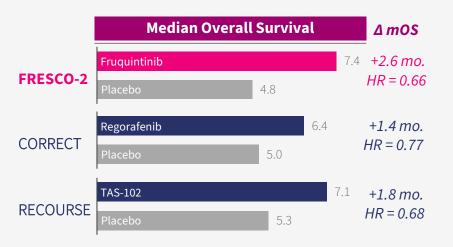
- Limited use of approved 3L treatments
  - Regorafenib (approved Q3 2012)
  - TAS-102 (approved Q3 2015)
- Chemotherapy, anti-VEGF & anti-EGFR agents used across all lines
- Newer treatment options focus on discrete actionable mutations
  - ~10% BRAF mutation [3]
  - ~15% MSI-H or dMMR [4]
  - 3-5% HER2 alterations [5]

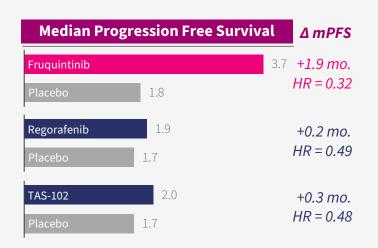
# Fruquintinib's FRESCO-2 showed a highly competitive profile

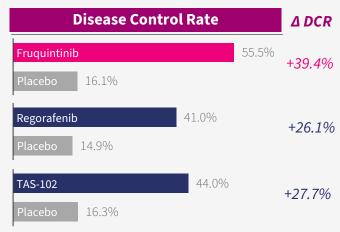


FRESCO-2 results have potential to change clinical practice worldwide









Fruquintinib is well tolerated with a safety profile consistent with the previously established monotherapy profile

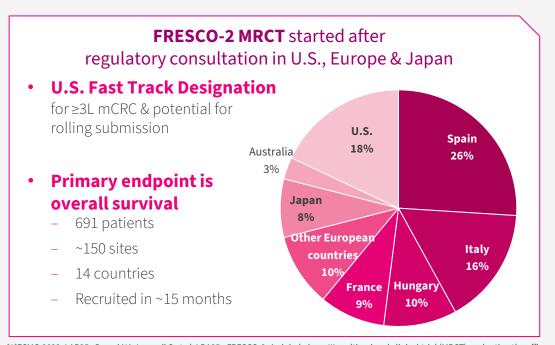
	FRESC	0-2 [1]	CORR	ECT [2]	RECOU	IRSE [3]
Tolerability	Fruquintinib	Placebo	Regorafenib	Placebo	TAS-102	Placebo
Discontinuation due to AE	20%	21%	17%	12%	4%	2%
<b>TEAE Grade ≥ 3</b>	63%	50%	54%	14%	69%	52%
Major TEAE Grade ≥ 3						
Hypertension	14%	1%	7%	1%	n/a	n/a
Hand-foot syndrome	6%	0%	17%	<1%	n/a	n/a
Asthenia / fatigue	8%	4%	15%	9%	7%	9%
Other AEs of note	n/a		<ul><li>Blackbox warning</li><li>Monitor liver func during treatment</li></ul>	tion prior to and	<ul> <li>Severe myelosupp</li> <li>Obtain complete band on day 15 of e</li> </ul>	olood counts prior to



# FRESCO-2 MRCT, consistent with FRESCO, basis for filings

Initiated US rolling NDA submission; plan to complete filings in the U.S., Europe and Japan in 2023





Consistency of effect across late-stage settings enriches the continuum of care				
	FRES	CO-2 [1]	FRESCO [2]	
	<b>Fruq</b> (n=461)	<b>Placebo</b> (n=230)	<b>Fruq</b> (n=278)	<b>Placebo</b> (n=138)
Prior Tx				
VEGFi	97%	96%	30%	30%
EGFRi as % of RASwt	>100%	>100%	~25%	~25%
TAS-102	52%	53%	0%	0%
Regorafenib	9%	8%	0%	0%
Both TAS-102 & rego	39%	40%	0%	0%
mOS, mo.	7.4	4.8	9.3 +2	6.6
[95% CI]	[6.7-8.2]	[4.0-5.8]	[8.2-10.5]	[5.9-8.1]
HR	0.	66	0.	.65
(95% CI, p-value)	(0.55-0.8)	0, p<0.001)	(0.51-0.83	3, p<0.001)
m.DEC	2.7	1.0	2.7	1.0
mPFS, mo.	3.7	1.9	3.7	1.8
[95% CI]	[3.5-3.8]	[1.8-1.9]	[3.7-4.6]	[1.8-1.8]
HR	0.	32	0.	.26
(95% CI, p-value)	(0.27-0.3	9, p<0.001)	(0.21-0.3	4, p<0.001)
DCR	55.5%	16.1%	62.2%	12.3%
	DCO: Jui	ne 24, 2022	DCO: Janu	uary 17, 2017

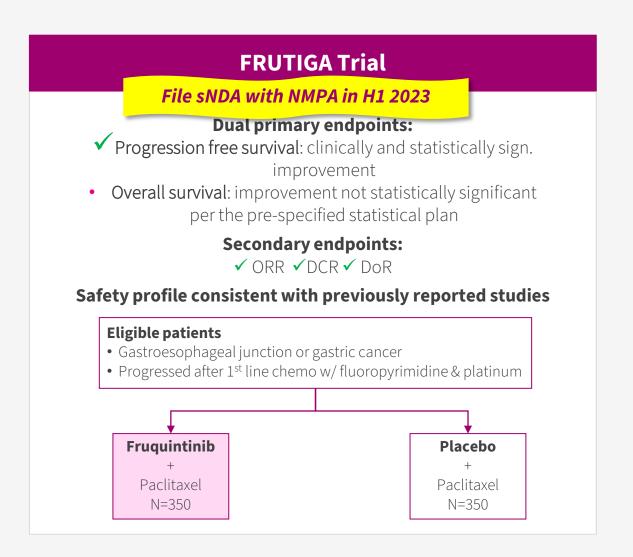
[1]ESMO 2022, LAB25. Dasari NA, Lonardi S et al. LBA25 - FRESCO-2: A global phase III multiregional clinical trial (MRCT) evaluating the efficacy and safety of fruquintinib in patients with refractory metastatic colorectal cancer. 12 Sep 2022, Proffered Paper session 2: GI, lower digestive Session. Annals of Oncology (2022) 33 (suppl\_7): S808-S869. 10.1016/annonc/annonc1089; [2] Li J, et al. Effect of Fruquintinib vs Placebo on Overall Survival in Patients With Previously Treated Metastatic Colorectal Cancer: The FRESCO Randomized Clinical Trial. JAMA. 2018;319(24):2486-2496. doi:10.1001/jama.2018.7855.

### FRUTIGA: combo with paclitaxel in 2L gastric cancer



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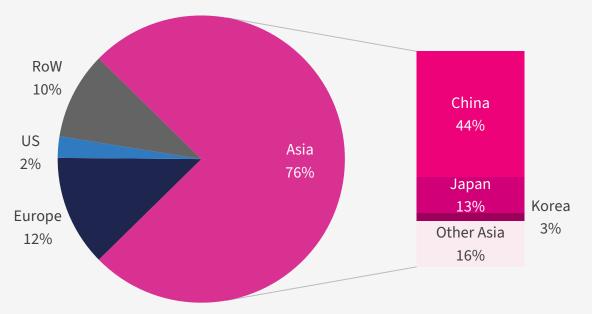
sNDA filing in H1 2023; data will be submitted for presentation at an upcoming scientific conference



# 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



International Agency for Research on Cancer



# 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 – continue evaluation for potential accelerated approval; first data presentation at WCLC

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

• Savolitinib + TAGRISSO® Phase III registration study –\$15 million milestone from AstraZeneca – **SAFFRON Study** initiated in 2022

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

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

#### **CHINA** – led by HUTCHMED

#### **MET Exon14 skipping NSCLC**

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

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

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

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

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

#### **Gastric cancer w/ MET amplification**

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



# HUTCHMED

## Sovleplenib progressing towards NDA in 2023 in ITP

Highly differentiated oral syk inhibitor with breakthrough therapy designation in China

#### **Treatment landscape for chronic ITP**

#### SYK a validated target – targets B cells & macrophages

- Fostamatinib approved in the U.S.; international consensus report considers evidence for fostamatinib use to be robust [1]
- ASH guideline considers evidence for fostamatinib use in 2L patients insufficient [2]

Agent	Response (1x PLT ≥50×10 <sup>9</sup> /L)	Durable response	Response after discontinuation
TPO-RA treatmen	t increases platelet p	roduction	
NPLATE® (romiplostim) [2]	79-88% (24 wks)	38-61% (6/8 visits, wks 16-24)	14% sustained response ≥ 6 mths after discont.
PROMACTA® (eltrombopag)	59-70% (6 wks) <sup>[3]</sup>	60% (6/8 visits, wks 18-26)	~50% maintained response
Treatments to de	crease platelet destr	uction	
RITUXAN® (rituximab)	67% (4 wks)	Median response duration 27-36 months	
<b>TAVALISSE®</b> (fostamatinib) <sup>[5]</sup>	<b>44%</b> (12 wks)	<b>24-26%</b> (4/6 visits in wks 14-24)	n/a

#### Sovleplenib

#### 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

ASH	Sovleplenib – 300 mg, once daily			
2021	<b>Double-blinded Pts</b> 8 + 16 wks	Cross-over Pts 16 wks	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)	

ESLIM-01 pivotal Phase III study recruitment completed Dec 2022

As of June 15, 2021. ASH 2021 #16. Yang H, Zhou Y, Hu JY, et al. Safety, Pharmacokinetics and Preliminary Efficacy of HMPL-523 in Adult Patients with Primary Immune Thrombocytopenia: A Randomized, Double-Blind and Placebo-Controlled Phase 1b Study. *Blood* 2021; 138 (Supplement 1): 16. doi: https://doi.org/10.1182/blood-2021-149895

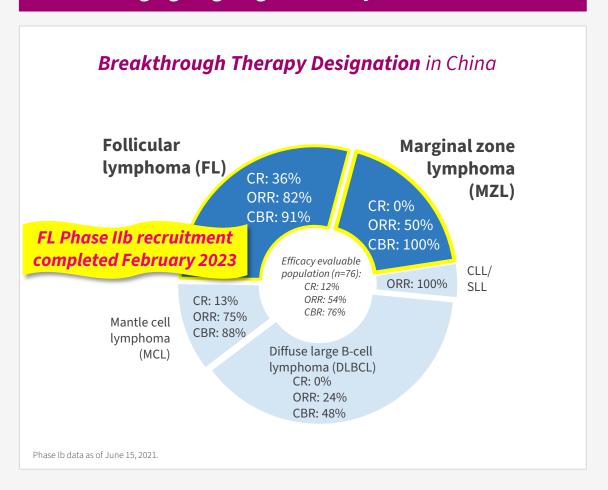
[1] Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. Blood Adv. 2019;3(22):3780-3817. doi:10.1182/bloodadvances.2019000812; [2] Study 1 & 2 from USPI; [3] Study 773A and B from US PI; [4] RAISE study from US PI; [5] US PI; [6] Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia [published correction appears in Blood Adv. 2020 Jan 28;4(2):252]. Blood Adv. 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966 .

# HUTCHMED

# 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

	Amdizalisib (4)	<b>Zydelig</b> " (idelalisib) <sup>[2]</sup>	Aliqopa® (copanlisib) <sup>[2]</sup>	Copiktra® (duvelisib) <sup>[2]</sup>
n	90	146	168	442
Neutropenia*	29% / 11%	53% / <b>28%</b>	32% / <b>29%</b>	63% / <b>43%</b>
Leukopenia	21% / 4%	na	36% / 27%	29% / 8%*
Anemia	12% / 4%	28% / 2%*	na	20% / 11%
Thrombocytopenia	<10% / 2%	26% / 6%*	22% / 8%	17% / 10%
Diarrhea	11% / 2%	47% / 14%	36% / 5%	50% / 23%
Rash	16% / 6%	21% / 4%	15% / 2%	31% / 9%
ALT increased	27% / 0%	50% / <b>19%</b>	na / 2%	40% / <mark>8%</mark>
AST increased	19% / 0%	41% / <b>12%</b>	na / 2%	37% / <b>6%</b>
Pyrexia	<10% / 1%	28% / 2%	Na	26% / 2%
Pneumonia	18% / 13%	25% / 16%	21% / 14%**	21%/15%
Hypertension	<10% / 0%	na	35% / 29%	na
Hyperglycemia	<10% / 0%	na	54% / 34%	na
AES leading to:				
Discontinuation	5.6%	23%	24%	35%
Dose reduction	na	41%	24%	23%
Dose interruption	na	4170	64%	64%
Current status	In late-stage development for iNHL	Approved 2L+CLL; Withdrawn SLL, FL	Approved 2L+ FL	Approved 2L+ CLL/SLL; Withdrawn 2L+ FL



# **Tazemetostat: China development strategy**

Bridging study for rapid registration and indication expansion through combinations

#### **Encouraging combo activity with R<sup>2</sup>**

#### **Preliminary efficacy**

Median follow-up was 11.2 months 41/44 were efficacy evaluable\*



Best Overall Response <sup>a</sup> (%)	TAZ + R <sup>2</sup> (n=41) <sup>b</sup>
Objective response rate	98%
Complete response <sup>c</sup>	51%
Partial response	46%
Stable disease	2%
Progressive disease	0

<sup>&</sup>lt;sup>a</sup> Overall, there were 31 PET-CT-based responses and 10 CT-based responses. For complete response, 19 were PET-CT-based responses and 2 was a CT-based response.

DCO: June 14, 2022

No new safety signals identified in Phase 1b data of this study

#### **Current status**

# Monotherapy bridging study in 3L+ R/R follicular lymphoma

FPI in July 2022 – LPI H2 2023, file 2024

# **SYMPHONY-1 study** – combo w/ R<sup>2</sup> global Phase III in 2L follicular lymphoma

FPI September 2022 in China

#### **Hainan Health Tourism Policy**

• U.S. FDA approved oncology drugs channel in Hainan Province

#### **Combo study with amdizalisib** (PI3Kδi)

FPI February 2023

to target relapsed/refractory lymphomas

CT, computed tomography; KM, Kaplan-Meier; mDOR, median duration of response; mPFS, median progression-free survival; NE, not evaluable; ORR, objective response rate; PET, positron emission tomography; R², lenalidomide plus rituximab; TAZ, tazemetostat.



# **HUTCHMED** registration/potential registration studies



23

### 15+ programs for six 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, EU, JP filings to complete in 2023	Started Dec '22
FRUQ	FRUTIGA	2L GC, combo with chemo	China	~700, combo vs. chemo, OS & PFS	To file sNDA in China	H1 2023
SOVLE	ESLIM-01	2L immune thrombocytopenia	China	~180, 2 arms (placebo), DRR	LPI Dec'22	H2 2023
AMDIZ	3L FL	3L follicular lymphoma	China	~100, 1 arm, ORR	LPI Feb '23	H2 2023
SURU	Bridging	Neuroendocrine tumors	Japan	~34, 1 arm, ORR	FPI Sept '21	H2 2023
SAVO*	Confirmatory	NSCLC, MET Exon 14 alteration	China	~160, 1 arm, ORR	FPI Aug '21	2024
FRUQ	2L EMC	2L EMC, combo with PD-1	China	~130, 1 arm, ORR	FPI Oct '21	2024
AMDIZ	2L MZL	2L marginal zone lymphoma	China	~80, 1 arm, ORR	FPI Apr'21	2024
TAZ^	Bridging	3L follicular lymphoma	China	~40, 2 arms (EZH2+ or wt), ORR	FPI Jul '22	2024
SAVO*	GASTRIC	2L GC, MET amplified	China	~75, 1 arm, ORR	FPI Jul '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'19 Re-opened in Sept 2022	2024
SURU	SURTORI-01	2L NEC, combo with PD-1	China	~190, combo vs. chemo, OS	FPI Sep '21	2024
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+	Global	~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® refractory NSCLC, MET+	Global	~320, combo vs. chemo, PFS	FPI Nov '22	2026

# Clinical deliverables in 2023



### To make significant progress with multiple late-stage programs

Regulatory activities			
<b>Fruquintinib</b> mono US, EU, Japan for 3L+ CRC	$\rightarrow$	Complete regulatory filings H1 2023 for US, EU & JP to follow	
<b>Fruquintinib</b> + chemo China for 2L GC	$\rightarrow$	Initiate sNDA filing H1 2023	
<b>Surufatinib</b> mono Japan for refractory NET*	$\rightarrow$	Initiate consultation Mid-2023	

Readout & potential NDA filing				
<b>Sovleplenib</b> mono <i>China for 2L ITP</i>	$\rightarrow$	H2 2023		
<b>Amdizalisib</b> mono China for 3L FL*	$\rightarrow$	H2 2023		

Continued progress on a	dditi	onal registration studies
<b>Savolitinib</b> mono China confirm. for NSCLC, MET ex14	$\rightarrow$	Complete recruitment Mid 2023
<b>Fruquintinib</b> + sintilimab  China for 2L EMC*	$\rightarrow$	Complete recruitment Mid 2023
<b>Amdizalisib</b> mono China for 2L MZL*	$\rightarrow$	Complete recruitment Mid 2023
<b>Tazemetostat</b> mono <i>China for 3L FL*</i>	$\rightarrow$	Complete recruitment H2 2023
<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 H2 2023
<b>Savolitinib</b> mono China for 2L GC, MET+*	$\rightarrow$	Readout from Phase II part H1 2023
<b>Sovleplenib</b> mono China for 2L wAIHA*	$\rightarrow$	Fully enroll Phase II part H1 2023

# The path to a sustainable business...

**HUTCHMED** medium-term & long-term strategy

#### **AMBITION**

to mature into a profitable biopharma from an emerging growth co

#### **VISION UNCHANGED:**

discovering, developing & bringing new innovative medicines to patients worldwide

#### 2022

2<sup>nd</sup> sNDA-enabling Phase III



Peak year for cash burn

# Target 2025 to be self-sustaining

6-7 products potentially launched in China



# **Growth & operating leverage**

HUTCHME

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



2023 - 2024

**Reduction in R&D** costs

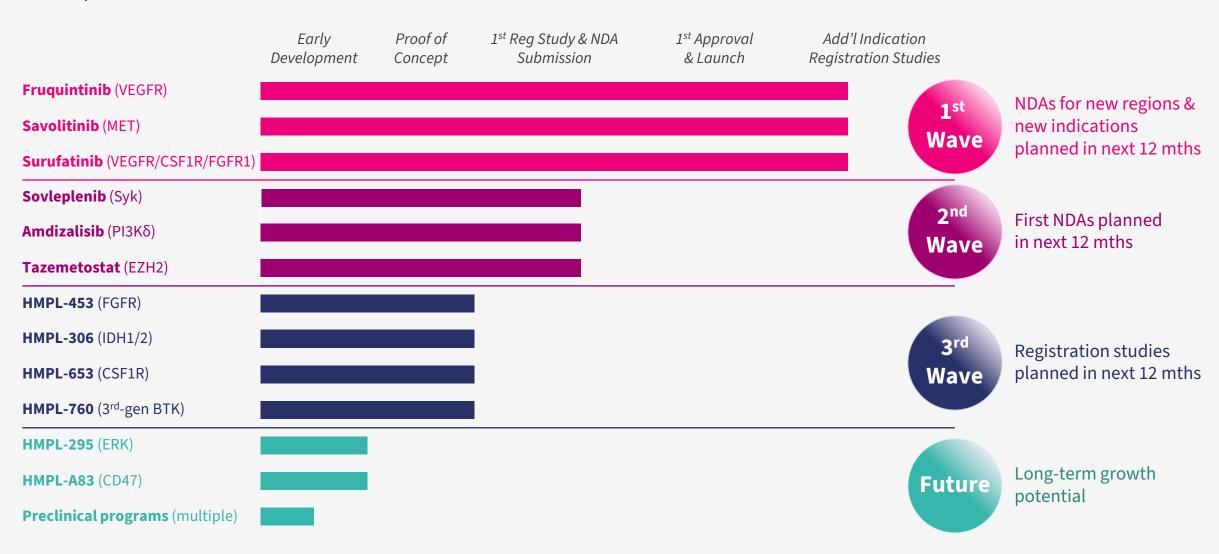
**Continued revenue growth** from new indications / regions

**Global commercialization** through partnerships

# HUTCHMED

## ...underpinned by several near-term pipeline waves

Next potential new indications & medicines



Q&A



**Weiguo Su**Chief Executive
Officer &
Chief Scientific
Officer



Johnny Cheng Chief Financial Officer



Karen Atkin Chief Operating Officer



Hong Chen Chief Commercial Officer



Michael Shi Chief Medical Officer & Head of R&D



Zhenping Wu EVP, Pharmaceutical Science & Manufacturing



Mark Lee Corporate Finance & Development



**Charles Nixon** *General Counsel* 

HUTCHMED

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**APPENDIX** 

### **HUTCHMED's deep leadership team**



World-class team with track record of success in HUTCHMED & multinational pharma

#### **Executive Management Committee**



Dr. Weiguo Su Chief Executive Officer & Chief Scientific Officer





Mr. Johnny Cheng Chief Financial Officer Bristol Myers Squibb **Nestle** 





Dr. Michael Shi Head of R&D and Chief Medical Officer /// TRANSCENTA U NOVARTIS Pfizer • MERCK



Dr. Karen Atkin **Chief Operating Officer** AstraZeneca 🕏



Dr. Zhenping Wu Pharmaceutical Sciences



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Dr. Junjie Zhou General Manager, SHPL





**KPMG** 

Mr. Hong Chen Chief Commercial Officer, China Bristol Myers Squibb **b** NOVARTIS



Dr. May Wang Business Dev. & Strategic Alliances





Mr. Mark Lee Corporate Finance & Development





Ms. Yiling Cui **Government Affairs** 



Bristol Myers Squibb



**Mr. Charles Nixon** General Counsel





Ms. Selina Zhang **Human Resources b** NOVARTIS



Dr. Thomas Fu Quality **Pfizer** 



Company logos denote prior experience.

### 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



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

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



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

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

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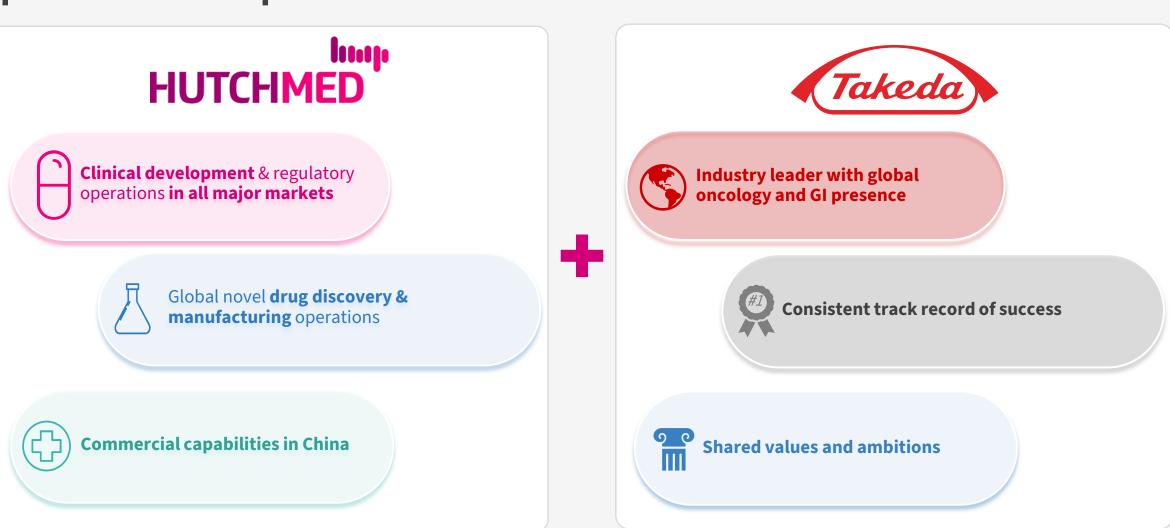
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# Takeda is the right partner for HUTCHMED to maximize the potential of fruquintinib



### **Takeda: A Global Biopharmaceutical Company**

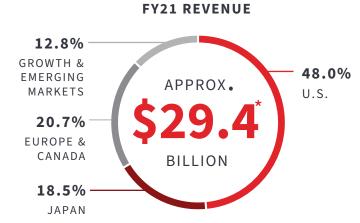


**TOKYO, JAPAN** 

NEW MOLECULAR ENTITY CLINICAL STAGE ASSETS CAMBRIDGE, MA, USA

PRESENCE: APPROX. IN

COUNTRIES
& REGIONS



Convenience translation of reported JPY figures into USD using rate of 121.44 JPY/USD, the Noon Buying Rate certified by the Federal Reserve Bank of New York on March 31, 2022.

FOUNDED IN

1781

OSAKA, JAPAN

30 + MANUFACTURING SITES

3 RESEARCH SITES

200+

PARTNERSHIPS TO HELP
US BRING INNOVATION
TO PATIENTS

TOP EMPLOYER® IN

39

**COUNTRIES & 4 REGIONS** 



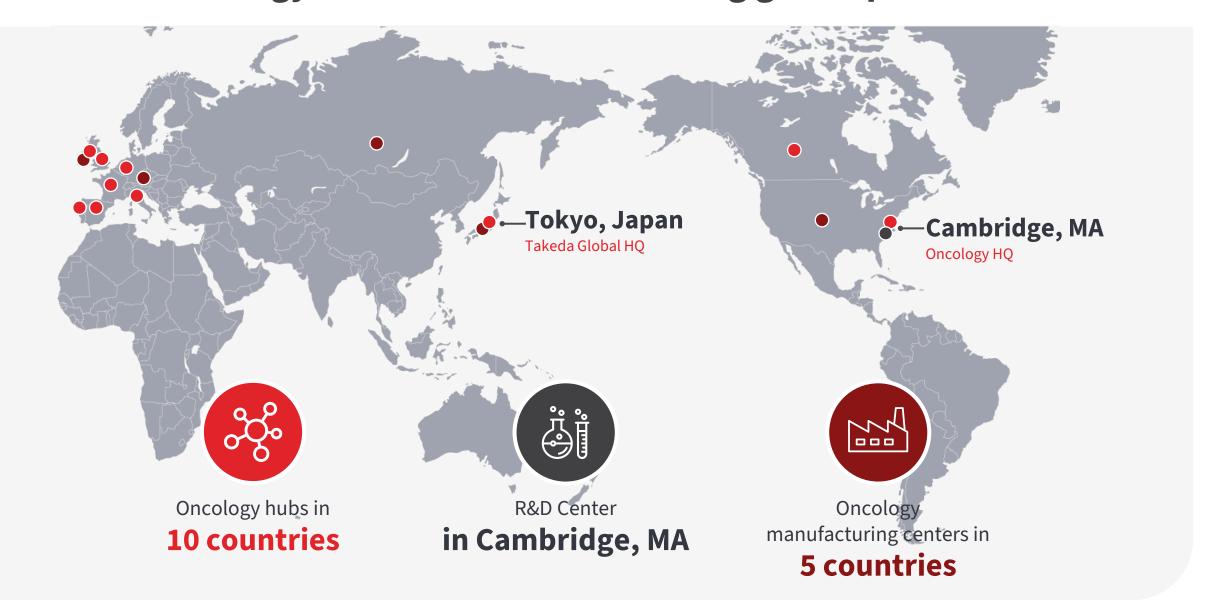
**PEOPLE** 

Source: Takeda, January 2023.



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# Takeda's Oncology Business Unit has a strong global presence



Source: Takeda, January 2023.

# Deep legacy in hematologic cancers; growing portfolio in solid tumors



### Best-in-class development and commercialization capabilities in oncology















### Europe





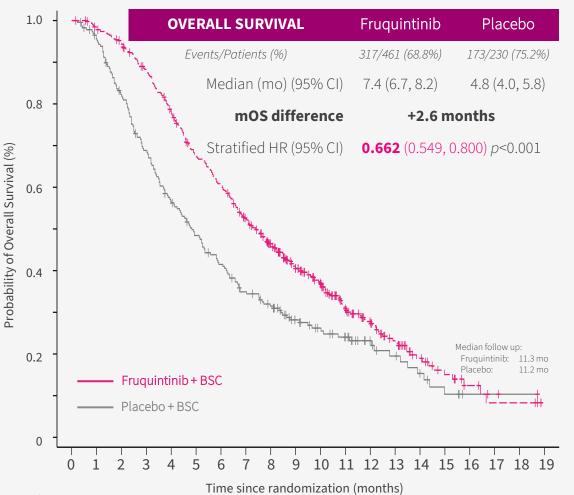
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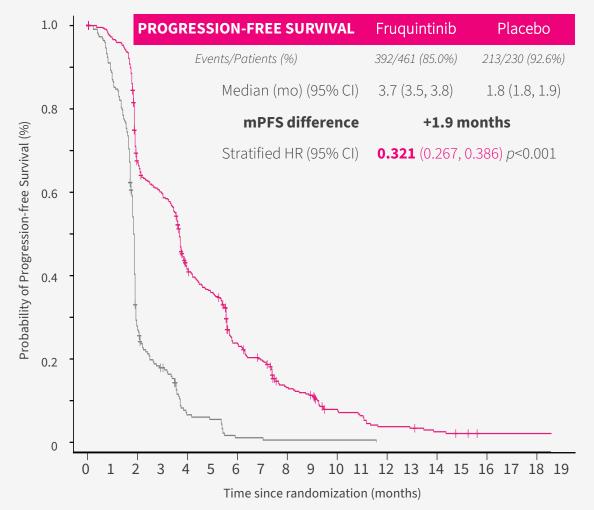
Source: Takeda, January 2023.



### FRESCO-2 met OS 1° Endpoint & PFS 2° Endpoint

"FRESCO-2 results are consistent with those of FRESCO and support a new global oral treatment option for patients with refractory mCRC, which enriches the continuum of care for these patients." – ESMO 2022 [1]





TT Population.

[1] ESMO 2022, LBA25. Dasari NA, et al. LBA25 - FRESCO-2: A global phase III multiregional clinical trial (MRCT) evaluating the efficacy and safety of fruquintinib in patients with refractory metastatic colorectal cancer. 12 Sep 2022, Proffered Paper session 2: GI, lower digestive Session. Annals of Oncology (2022) 33 (suppl\_7): S808-S869. 10.1016/annonc/annonc1089.

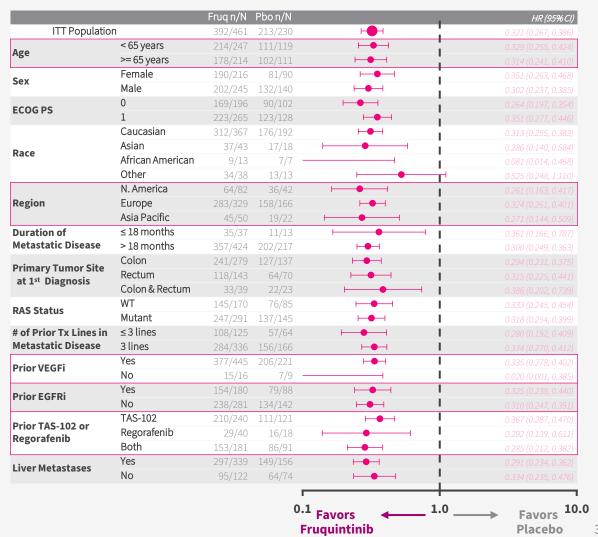
### Positive FRESCO-2 OS & PFS consistent across all subgroups



#### **Overall Survival by subgroups**

ITT Dawnlastan		Fruq n/N	Pbo n/N		HR (95% CI,
ITT Population		317/461	173/230	⊢ <b>⊕</b> ⊢	0.662 (0.549, 0.800)
Age	< 65 years	171/247	89/119	⊢•	0.694 (0.534, 0.903)
nge	>= 65 years	146/214	84/111	<b>⊢</b>	0.648 (0.494, 0.851
Sex	Female	149/216	61/90	<b>├</b>	0.828 (0.609, 1.125
sex	Male	168/245	112/140	<b>⊢</b>	0.584 (0.456, 0.749
ECOG PS	0	121/196	67/102	<b>⊢</b>	0.775 (0.573, 1.050
ECOG P3	1	196/265	106/128	<b>⊢●</b> ─	0.571 (0.449, 0.728
	Caucasian	260/367	145/192	<b>⊢●</b> ⊢	0.696 (0.567, 0.854
Race	Asian	24/43	14/18	<b>⊢</b>	0.377 (0.171, 0.833
Race	African American	7/13	5/7	•	H 0.550 (0.135, 2.231
	Other	26/38	9/13	<u> </u>	1.199 (0.478, 3.008
	N. America	50/82	29/42	<b>—</b>	0.620 (0.387, 0.995
Region	Europe	237/329	130/166	<b>⊢</b> • i	0.688 (0.554, 0.855
	Asia Pacific	30/50	14/22	<b>⊢</b>	0.631 (0.321, 1.241
Duration of	≤ 18 months	30/37	8/13	<b>├</b>	0.605 (0.260, 1.406
Metastatic Disease	> 18 months	287/424	165/217	<b>⊢</b>	0.642 0.529, 0.779
	Colon	195/279	109/137	<b>⊢●</b>	
Primary Tumor Site at 1st Diagnosis	Rectum	99/143	49/70	<b>⊢</b> • i	
at 13. Diagnosis	Colon & Rectum	23/39	15/23	H	0.686 (0.339, 1.388
RAS Status	WT	119/170	62/85	<b>⊢</b> •	0.667 (0.489, 0.909
KAS Status	Mutant	198/291	111/145	<b>⊢●</b> → <b> </b>	0.683 (0.539, 0.865
# of Prior Tx Lines in	≤3 lines	80/125	45/64	<b>⊢</b>	0.714 (0.488, 1.043
Metastatic Disease	3 lines	237/336	128/166	<b>⊢●</b> → <b>I</b>	
Prior VEGFi	Yes	306/445	167/221	<b>⊢●</b> ⊣ <b>I</b>	0.683 (0.565, 0.827
Prior VEGFI	No	11/16	6/9	<del></del>	0.193 (0.024, 1.557
D	Yes	127/180	64/88	⊢•⊣I	0.689 (0.507, 0.936
Prior EGFRi	No	190/281	109/142	⊢ <b>●</b> ⊣ I	0.666 (0.524, 0.846
Duian TAC 102 an	TAS-102	165/240	88/121	<b>⊢</b> •⊣I	0.723 (0.557, 0.938
Prior TAS-102 or Regorafenib	Regorafenib	25/40	12/18	<b>⊢</b>	0.772 (0.379, 1.573
regulatettib	Both	127/181	73/91	<b>⊢</b> • I	0.600 (0.447, 0.805
	Yes	255/339	132/156	⊢•⊣	0.576 (0.465, 0.713
Liver Metastases	No	62/122	41/74		0.771 (0.513, 1.158

#### **Progression Free Survival by subgroups**



### Savolitinib - EGFRm+ NSCLC w/ MET aberration



TAGRISSO® combo rationale now even stronger in SAFFRON Phase III NSCLC population

#### Novel biomarker and patient enrichment strategy driven by **SAFFRON MRCT enrolling** (NCT05261399) **SAVANNAH** 2022 **MET-high MET-low** N=185\* 300mg QD IHC90+ and/or FISH10+ IHC50-90 and/or FISH 5-10 Locally advanced or metastatic NSCLC **Prevalence** Progression on 1L/2L TAGRISSO® among patients 28% screened (osimertinib) therapy, no prior chemo No prior No prior EGFRm and MET-high Prior Chemo 20% chemo 18% chemo subset subset Number of patients n=108 n=87 n=77 n=63 49% ORR, [41-63] [39-59] N=324 [95% CI] 1:1 10% 9% [4-20] [4-18] 9.6 mo. 6.9 mo. 7.3 mo. 9.3 mo. **mDoR**, [95% CI] [7.6-10.6][7.6-14.9][4.1-16.9][4.1-NC] 2.8 mo. 7.1 mo. 7.2 mo. 2.8 mo. **mPFS**, [95% CI] Savolitinib 300 mg BID Platinum-based [4.7-9.2][5.3-8.0][2.6-4.3][1.8-4.2]doublet chemotherapy \*Evaluable for efficacy defined as dosed patients with measurable disease at baseline who had ≥2 on-Osimertinib 80 mg QD 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.

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### **Abbreviations**

# HUTCHMED

ADS = American depositary share.

AIHA = autoimmune hemolytic anemia.

ALK = anaplastic lymphoma kinase.

ALL = acute Lymphoblastic Leukemia

AML = acute myeloid leukemia.

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.

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  $\ge 2$ .

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.

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.

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 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 = microsatellite stable.

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.

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.