



HUTCHISON CHINA MEDITECH

# JP Morgan 38<sup>th</sup> Annual Healthcare Conference

January 2020 | San Francisco, CA

AIM/Nasdaq: HCM



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*Use of Non-GAAP Financial Measures* - This presentation includes certain non-GAAP financial measures. Please see the appendix slides titled “Non-GAAP Financial Measures and Reconciliation” for further information relevant to the interpretation of these financial measures and reconciliations of these financial measures to the most comparable GAAP measures.

CHI-

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Company Overview

# Building a global science-focused biopharma company from an established base in China...



## Global Innovation

- 5 clinical drug candidates in US/EU development
- Building global clinical development footprint
- World-class ~500-person scientific team



## China Oncology

- Major market potential driven by regulatory reforms & high unmet medical need in oncology
- Elunate® (fruquintinib capsules) first ever home-grown cancer drug launched in China<sup>[1]</sup>
- 8 oncology assets in China development



## Existing China Business

- Cash generative China Commercial Platform
- Platform for future innovative drug launches

[1] China-discovered novel oncology drug to receive unconditional NDA approval in China.

# Proven innovation & commercial operations

Management Team		Industry / Chi-Med (years)	
	<b>Mr. CHRISTIAN HOGG, BSc, MBA</b> Chief Executive Officer	Procter & Gamble	30 / 19
	<b>Dr. WEIGUO SU, PhD</b> EVP, Chief Scientific Officer		29 / 14
	<b>Mr. JOHNNY CHENG, BEC, CA</b> Chief Financial Officer	  	30 / 11
	<b>Dr. ZHOU JUN JIE, MD, MBA</b> General Manager, SHPL		28 / 18
	<b>Dr. MAREK KANIA, MD, MBA</b> SVP, Chief Medical Officer, International		25 / 1
	<b>Dr. ZHENPING WU, PhD, MBA</b> SVP, Pharmaceutical Sciences	 	25 / 11
	<b>Mr. CHEN HONG, BSc, MBA</b> SVP, Chief Commercial Officer		21 / 9
	<b>Dr. MAY WANG, PhD</b> SVP, Bus. Dev. & Strategic Alliances		25 / 9
	<b>Mr. ANDREW SHIH, DiplIE, MBA</b> SVP, HR - Org./Leadership Dev.		23 / 1
	<b>Mr. MARK LEE, BEng, MBA</b> SVP, Corp. Finance & Development		20 / 10
	<b>Mr. ENRICO MAGNANELLI, BA, MBA</b> Head of International Operations		20 / 1

## Integrated Innovation Organization <sup>[1]</sup>



**~500**  
person scientific team  
in Shanghai, Suzhou  
& New Jersey

## Commercial Team & Joint Ventures <sup>[1]</sup>

Commercial Team (subsidiaries):	50/50 Joint Ventures:
<p>&gt;200 staff covering:</p> <ul style="list-style-type: none"> <li>Drug distribution &amp; marketing operations; &amp;</li> <li>New Oncology Business Dept.</li> </ul>	<p>&gt;2,400 Rx medical sales reps;</p> <p>~900 person OTC sales team; &amp;</p> <p>&gt;1,500 staff in two major factories</p>

[1] Headcount as of Oct 30, 2019; Chem. = Chemistry; DMPK = Drug, Metabolism, & Pharmacokinetics; Tox. = Drug Safety Evaluation; QA: Quality Assurance; Mfg. = Manufacturing; Reg. = Regulatory; BD = Business Development.

# Portfolio summary

## Multiple waves of innovation - progressing rapidly



Dose Finding / Safety Run-In	Proof-of-Concept	Registration Intent	Marketed
Fruquintinib + Tyvyt (PD-1) Solid Tumors <sup>[1]</sup>	Savolitinib MET Exon 14 deletion NSCLC →	Savo + Tagrisso (SAVANNAH) 2L/3L Tagrisso-refractory MET+ NSCLC	Elunate (Fruquintinib capsules) ≥3L Colorectal cancer
Surufatinib + Tuoyi (PD-1) Solid Tumors <sup>[1]</sup>	Savo / Savo + Imfinzi (CALYPSO) x2: PRCC & ccRCC →	Savolitinib MET Exon 14 deletion NSCLC →	SXBX <sup>[3]</sup> Pills Coronary artery disease
HMPL-523 (Syk) Indolent NHL <sup>[2]</sup>	Savolitinib (VIKTORY) MET+ Gastric cancer	Fruquintinib + Taxol (FRUTIGA) 2L Gastric cancer	>10 other Rx / OTC drugs
HMPL-689 (PI3Kδ) Indolent NHL	Savolitinib (CCGT 1234B) MET+ Prostate cancer	Surufatinib (SANET-p) Pancreatic NET	
Fruquintinib + Tyvyt (PD-1) Solid tumors <sup>[1]</sup>	Fruquintinib 3L/4L Colorectal cancer <sup>[1]</sup> →	Surufatinib (SANET-ep) Non-Pancreatic NET →	
Fruquintinib + genolimzumab (PD-1) Solid tumors	Surufatinib 2L NET →	Surufatinib 2L Biliary Tract cancer	
Surufatinib + Tuoyi (PD-1) →	Savolitinib + Iressa 2L 1 <sup>st</sup> Gen EGFR TKI ref. NSCLC →		
Surufatinib + Tyvyt (PD-1) Solid tumors	Fruquintinib + Iressa 1L EGFRm+ NSCLC		
HMPL-453 (FGFR1/2/3) →	HMPL-523 Indolent NHL →		
	HMPL-523 + azacitidine AML		
	HMPL-523 Immune thrombocytopenia purpura		
	HMPL-689 Indolent NHL →		
	Epitinib Glioblastoma		

-  Global Innovation
-  China Oncology
-  Existing China Business
-  IN TRANSITION

[1] In planning / imminent; [2] Proof-of-concept in Australia; [3] SXBX = She Xiang Bao Xin (cardiovascular); [4] Drugs licensed from third parties. Targets: Savolitinib = MET; Fruquintinib = VEGFR1/2/3; Surufatinib = VEGFR1/2/3 / FGFR1 / CSF-1R; HMPL-523 = Syk; HMPL-689 = PI3Kδ; Epitinib = EGFRm in the brain; Theliatinib = EGFR wild-type; HMPL-453 = FGFR1/2/3. Indications: NHL = Non-Hodgkin's Lymphoma; NET = Neuroendocrine tumors; RCC = Renal cell carcinoma; AML = Acute myeloid leukemia; ITP = Immune thrombocytopenia; NSCLC = Non-small cell lung cancer.

# Potential 2020 upcoming events



## Global Innovation

**Savo + Imfinzi®**  
Papillary RCC (CALYPSO)  
Ph. II Interim Data

**Savo**  
2L gastric (VIKTORY)  
Ph. II Data

**Savo + Tagrisso®**  
NSCLC (TATTON)  
Ph. Ib Data (AACR)

**HMPL-689 (PI3Kδ)**  
Indolent NHL  
Ph. I Start (US/EU)

**HMPL-523 (Syk)**  
Indolent NHL  
Ph. I Start (US/EU)

**Savo + Imfinzi®**  
Papillary RCC (CALYPSO)  
Ph. II Data Update

**Savo + Tagrisso®**  
NSCLC (SAVANNAH)  
Ph. II Interim\*

**Savo NSCLC + RCC + GC**  
Anticipate further  
Ph. II/III studies

**Fruq**  
3L/4L colorectal (US/EU)  
Ph. III Start\*\*

**Fruq / Suru + PD-1**  
Initiation of U.S  
development

**HMPL-523 (Syk)**  
Hem malignancies  
Ph. I Exp Start\*\*\*

**Savo**  
Papillary RCC (SAVOIR)  
Ph. III Early Data

**Suru**  
NET (US/EU)  
Ph. III Start\*\*

**HMPL-689 (PI3Kδ)**  
Hem malignancies  
Ph. I Exp Start\*\*\*



## China Oncology

**Savo**  
NSCLC Exon14del  
Ph. II Data (AACR)

**Savo**  
NSCLC Exon14del  
Reg. Study Enrolled

**Suru**  
P NET (SANET-p)  
Ph. III Interim

**Savo**  
NSCLC Exon14del  
NDA Submission\*\*

**Savo**  
NSCLC Exon14del  
Ph. II Data\*

**Suru**  
2L Biliary tract  
Ph. II/III Start

**Suru**  
Non-P NET (SANET-ep)  
Ph. III Data (ESMO)  
NDA Submission

**Fruq + Taxol®**  
2L gastric (FRUTIGA)  
2<sup>nd</sup> Ph. III Interim

**Savo + Iressa®**  
2L NSCLC  
Ph. III Start

**Suru**  
Ep NET (SANET-ep)  
Launch

**Fruq / Suru**  
PD-1 combos  
Phase I Start

**Fruq**  
3L NSCLC (FALUCA)  
Ph. III Data (WCLC)

**HMPL-523 (Syk)**  
Indolent NHL  
Reg. Study Start\*\*\*

**Suru**  
2L Biliary tract  
Ph. III Interim

**HMPL-689 (PI3Kδ)**  
Indolent NHL  
Reg. Study Start\*\*\*

**Fruq + Taxol®**  
2L gastric (FRUTIGA)  
1<sup>st</sup> Ph. III Interim

**Fruq NRDL**  
Reimbursement

**Fruq / Suru + PD-1**  
Initiation of China  
Ph. II development

**HMPL-306**  
IDH 1/2 inhibitor  
Ph. I Start

**Discovery Candidate**  
Ph. I Start

= Data milestone/readout.  
 = Development/commercial progress.

\* submission to scientific conference; \*\*subject to regulatory interaction; \*\*\* subject to supportive data; Targets: Savolitinib = MET; Fruquintinib = VEGFR1/2/3; Surufatinib = VEGFR1/2/3 / FGFR1 / CSF-1R; HMPL-523 = Syk; HMPL-689 = PI3Kδ; Indications: NHL = Non-Hodgkin's Lymphoma; NET = Neuroendocrine tumors; RCC = Renal cell carcinoma; NSCLC = Non-small cell lung cancer.

# Global clinical drug portfolio (1/2)

## Savolitinib (c-MET)

Potential First-in-class small molecule selective MET inhibitor

**Indications:** MET-driven NSCLC; RCC; Gastric; Prostate cancer

**Dosed to-date:** [2] ~1,000 patients

**Summary Data:** NSCLC - Tagrisso® EGFR TKI refractory combinations:  
 Post 1<sup>st</sup>-gen TKI (n=105): ORR 64-67%  
 Post 3<sup>rd</sup>-gen TKI (n=69): ORR 30%  
 PRCC (n=44): ORR 18%; mPFS 6.2mo.

**SAVANNAH global Ph.II/reg. underway**[3]  
 Tagrisso® + savo

## Fruquintinib (VEGFR1/2/3)

Potential Best-in-class small molecule selective VEGFR 1/2/3 inhibitor

**Indications:** Colorectal; NSCLC; Gastric cancer

**Dosed to-date:** ~1,650 patients in trials

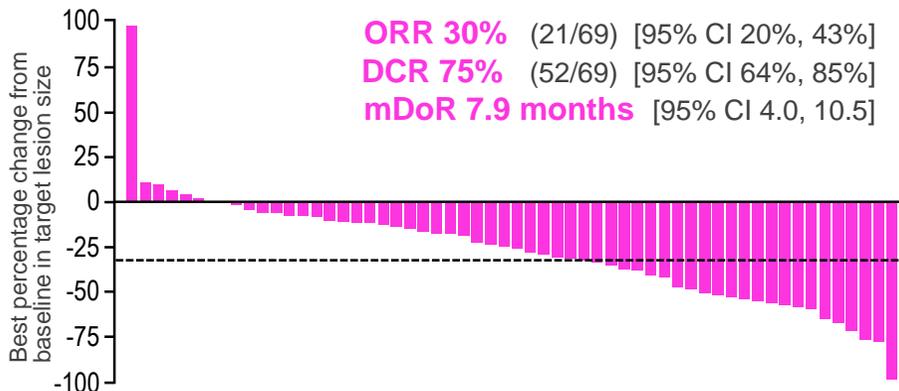
**Launched in CRC**  
 Nov 2018 in China

**Summary Data:** 3L CRC (n=416): mOS 9.3mo. vs. 6.6mo. (SoC)  
 3L NSCLC (n=91): ORR 13%; mPFS 3.8mo. vs 1.1 mo. (SoC)  
 1L NSCLC (Iressa® combo) (n=50): ORR 76% [1]  
 2L Gastric (Taxol® combo) (n=28): ORR 36%



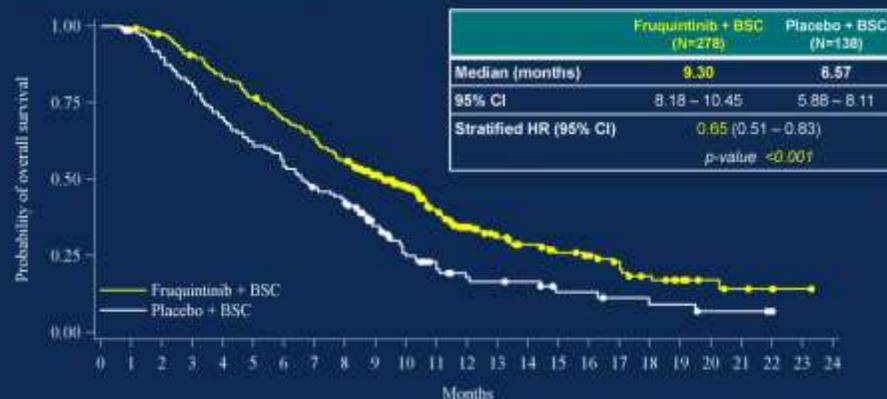
SINGAPORE  
 22-24 NOVEMBER 2019

**Osimertinib plus savolitinib for patients with disease progression on prior third-generation EGFR-TKI: Preliminary anti-tumor activity**



PRESENTED AT: ASCO ANNUAL MEETING '17

**Overall Survival (Primary Endpoint)**  
 FRESCO clearly succeeded in meeting the primary efficacy endpoint of OS



# Global clinical drug portfolio (2/2)

## Surufatinib (VEGFR, FGFR1, CSF-1R)

Unique small molecule VEGFR 1/2/3, FGFR1 & CSF-1R inhibitor

**Indications:** Neuroendocrine tumors (pNET/ep-NET); Thyroid; Biliary Tract

**Dosed to-date:**<sup>[1]</sup> ~800 patients

**Ep-NET China NDA Filing Accepted**

**Summary Data:** Ep-NET (n=198): ORR 10%; mPFS 9.2mo vs 3.8mo (Pbo)  
PhII interim pNET (n=41): ORR 17%; mPFS 19.4mo.

## HMPL-523 (Syk)

Potential First-in-class small molecule selective Syk inhibitor

**Indications:** Indolent non-Hodgkin's lymphoma; AML; Immunol.

**Dosed to-date:** >150 pts. & ~118 healthy vol.

**Summary Data:** FL (n=10): ORR 30%  
CLL/SLL (n=3): ORR 33%

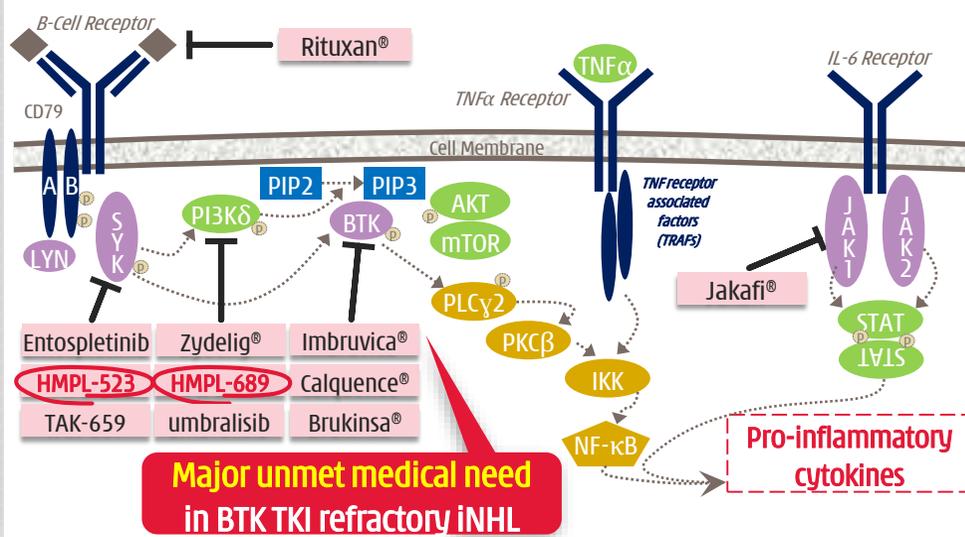
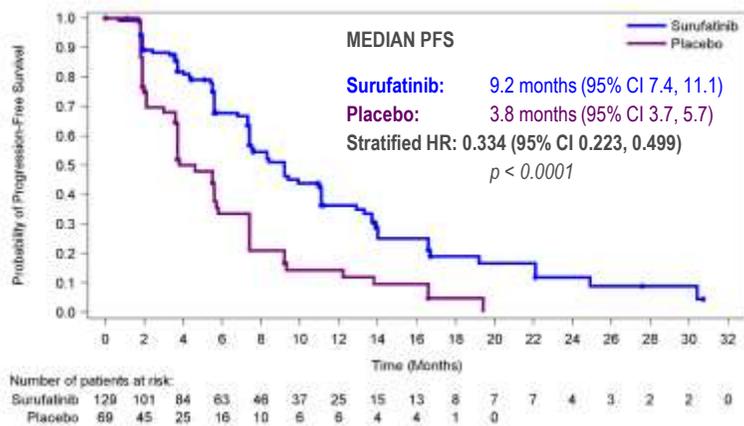
## HMPL-689 (PI3Kδ)

Potential Best-in-class small molecule selective PI3Kδ inhibitor

**Indications:** Indolent non-Hodgkin's lymphoma

**Dosed to-date:** ~40 pts. & ~48 healthy vols.

**Summary Data:** Phase I dose escalation data not yet published



[1] Dosed to-date = patients in all clinical trials (treatment & placebo); [2] American Society of Hematology. Blood, vol. 132 no. Suppl 1 5324 (Nov 2018); VEGFR = vascular endothelial growth factor receptor, FGFR1 = fibroblast growth factor receptor 1, CSF-1R = colony stimulating factor-1 receptor, Syk = spleen tyrosine kinase, PI3Kδ = Phosphatidylinositol-3-Kinase delta, pNET = pancreatic neuroendocrine tumors, ep-NET = non-pancreatic neuroendocrine tumors, AML = acute myeloid leukemia, FL = follicular lymphoma, CLL = chronic lymphocytic leukemia, SLL = small lymphocytic leukemia.

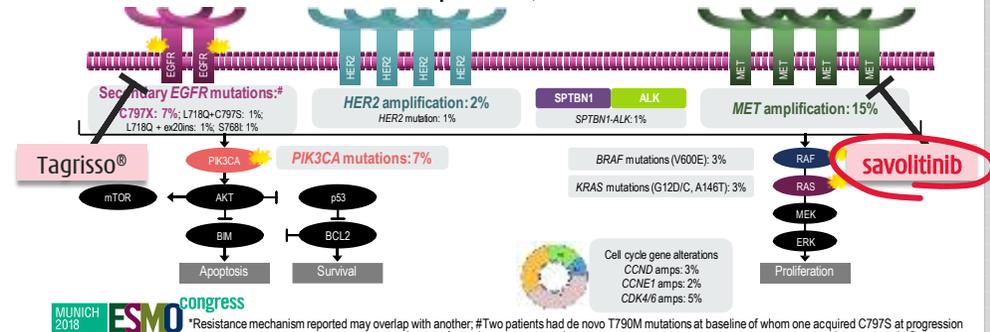
# Superior safety allows for combinations TKI + TKI combos to address acquired resistance



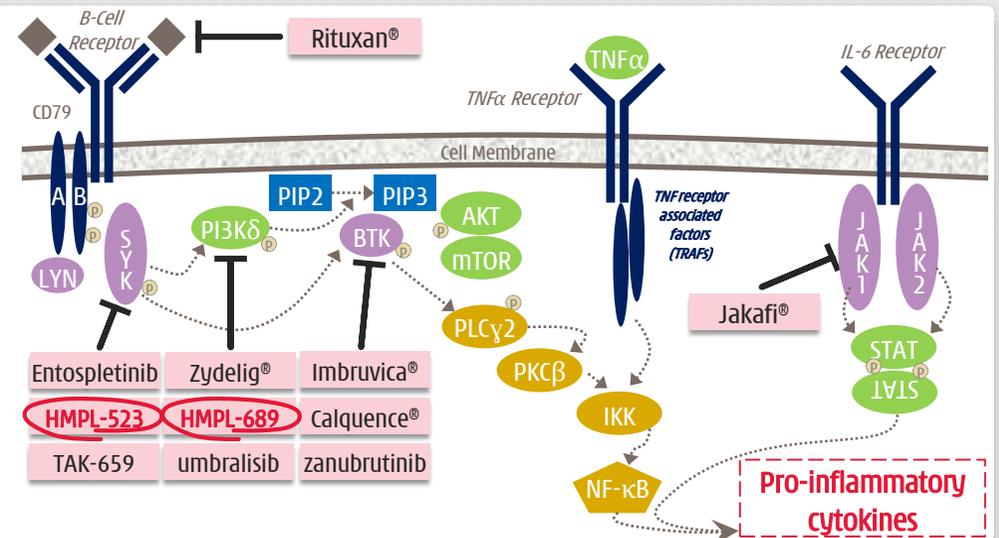
- **MET amplification** is the most common resistance mechanism for Tagrisso®.
- Requires addition of **MET inhibitor - savolitinib** - in combo with Tagrisso®.

## RESULTS: CANDIDATE ACQUIRED RESISTANCE MECHANISMS WITH OSIMERTINIB (n=91)\*

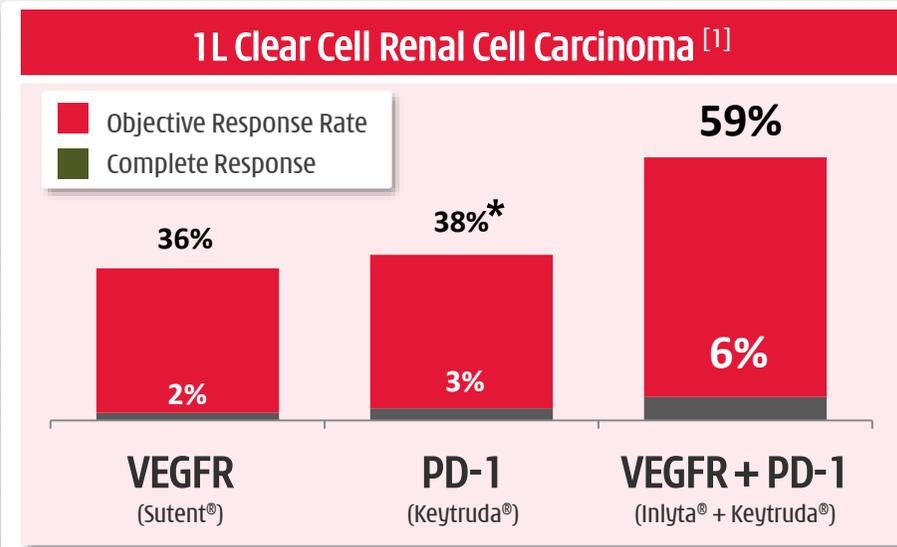
- No evidence of acquired EGFR T790M
- The most common resistance mechanisms were **MET amplification** and **EGFR C797S mutation**
- Other mechanisms included **HER2 amplification**, **PIK3CA** and **RAS** mutations



- **C481S or PLCγ** are the most common resistance mechanisms for Imbruvica®.
- Invalidating BTK inhibitor requires a **possible Syk, PI3Kδ &/or BTK TKIs**.



# Immunotherapy combinations... assets potentially ideal TKI combo partners for immunotherapy



**Potent two-prong attack - BTD [2]:**  
Anti-angiogenesis + activated T-cell response

	Inlyta®	Fruquintinib	Surufatinib
<b>Selectivity</b>	Relatively selective	Highly selective	Selective angio-immuno kinase inhibitor
<b>Status</b>	Launched	Launched	Ph. IIIs ongoing
<b>VEGFR1 (nM)</b>	3	33	2
<b>VEGFR2 (nM)</b>	7	25	24
<b>VEGFR3 (nM)</b>	1	0.5	1
<b>Phos-KDR (nM)</b>	0.2	0.6	2
<b>Other kinases (IC<sub>50</sub> &lt; 100nM)</b>	PDGFR $\alpha$ PDGFR $\beta$ c-Kit	none	CSF-1R FGFR1 FLT3 TrkB
<b>Patent Expiration</b>	2025/04/29 (US6534524B1)	2029 (without extension)	2030 (without extension)

**Fruq. uniquely selective** - unlike other TKIs with off-target toxicity  
**Suru. inhibits TAM production** - amplifying PD-1 induced immune response

Multiple global immunotherapy combo deals...

Managed by AstraZeneca	Jointly managed by Chi-Med & partners	Jointly managed by Chi-Med & partners
<p><b>savolitinib + Imfinzi® (PD-L1)</b></p> <p>ccRCC/PRCC</p>	<p><b>fruquintinib + Tyvyt® (PD-1)</b> <b>surufatinib + Tyvyt® (PD-1)</b></p> <p>Solid tumors</p>	<p><b>surufatinib + Tuoyi® (PD-1)</b></p> <p>Solid tumors</p>
<p><b>3 Global PD-1 / PD-L1 combos</b> - Development now underway / in planning on savo, fruq &amp; suru</p>		

[1] Sources: (i) B. Rini et al, for the KEYNOTE-426 Investigators, NEJM 2019 Feb 16. doi: 10.1056/NEJMoa1816714, Pembrolizumab plus Axitinib versus Sunitinib for Advanced Renal-Cell Carcinoma; (ii). D.F. McDermott et al, ASCO 2018 #4500, Pembrolizumab monotherapy as first-line therapy in advanced clear cell renal cell carcinoma (accRCC): Results from cohort A of KEYNOTE-427; \* ORR =38.2% for all PD-L1 expression combined positive scores (CPS) - ORR=50.0% for CPS≥1 pts, ORR=26.4% for CPS<1 pts.; [2] BTD = Breakthrough Therapy Designation.

# What is next from discovery?

## Differentiated assets against multiple targets

### Priming & activations

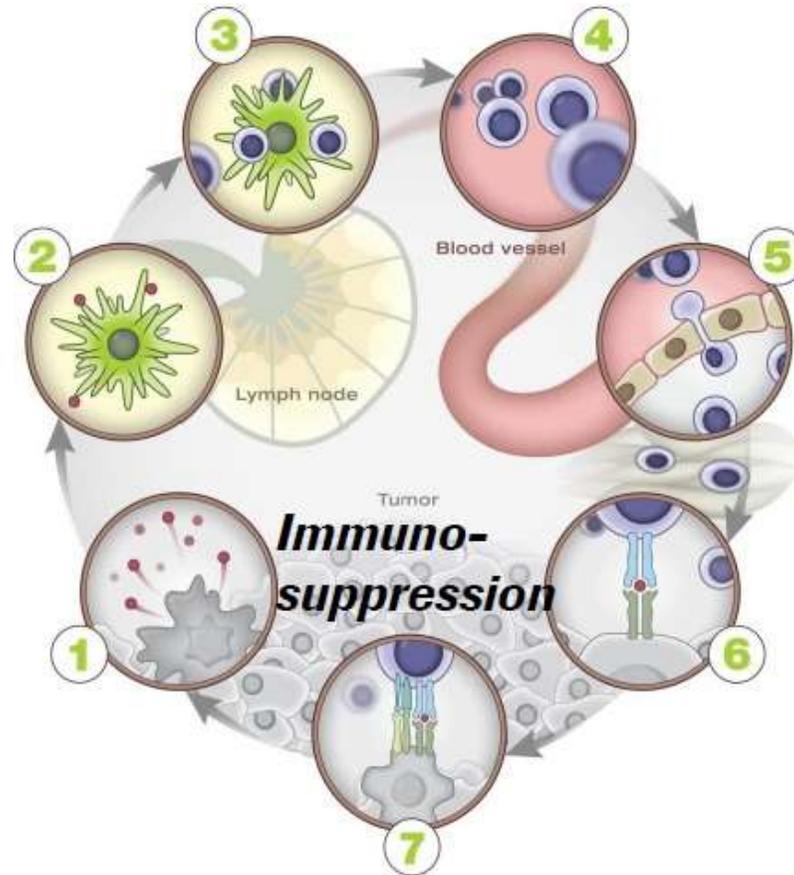
- aOX40
- 4-1BB

### Antigen release

- MET (savolitinib)
- EGFR (epitinib/theliatinib)
- Syk (HMPL-523)
- PI3K $\delta$  (HMPL-689)
- FGFR (HMPL-453)
- IDH 1/2 (HMPL-306)

● ERK

● RIP1K



### Anti-angiogenesis

- VEGFR (fruquintinib)
- VEGFR/FGFR (surufatinib)
- FGFR (HMPL-453)

### Negative regulators

- Treg (HMPL-689)
- CSF-1R (surufatinib)

● IDO1

● AhR1

● TIM3

● TCBS

- Pre-clinical - small molecule
- Pre-clinical - antibody

Creating highest-quality range of assets against novel targets for use in combos



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*AstraZeneca and Chi-Med*  
Harnessing the power of Chinese Innovation

2a

Savolitinib

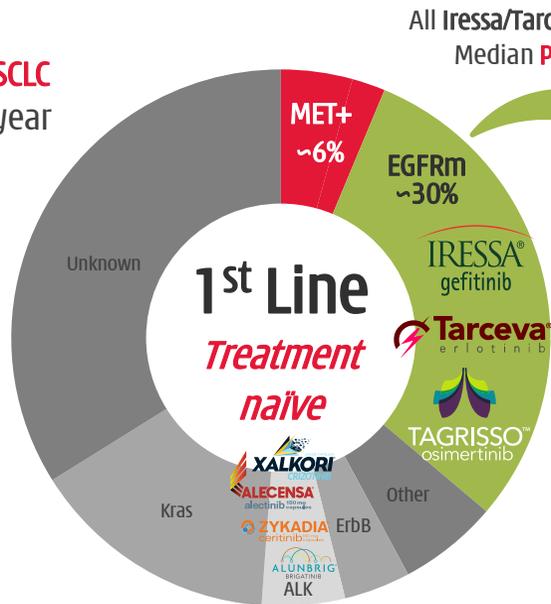
# Savolitinib

Biggest opportunity is MET+ NSCLC



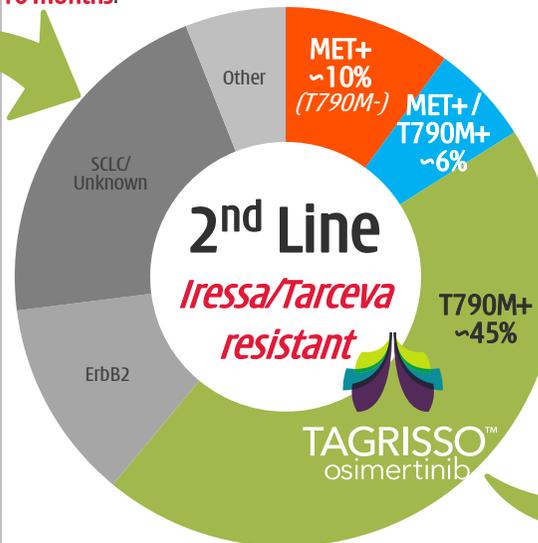
## Primary NSCLC

1.8 million NSCLC patients per year



All Iressa/Tarceva patients relapse  
Median PFS 9-10 months.

## Resistance-driven EGFRm+ NSCLC



All Tagrisso patients relapse  
2L Median PFS 9-10 months.



	Target	Launch	2018 (\$m) <sup>[3]</sup>
Iressa	EGFRm	2003	\$518m
Tarceva	EGFRm	2004	550
Tagrisso	EGFRm / T790M	2015	1,860
Xalkori	ALK / ROS1 / MET	2011	524
Zykadia	ALK	2015	Not disc.
Alecensa	ALK	2015	650
<b>Total Sales</b>			<b>&gt; 4.1b</b>

Launch	2016	2017	2018	9M 2019
Dec-15	423	955	1,860	2,305 (+82%)

Est. global sales of ~\$4-5 bn by 2022<sup>[2]</sup>.

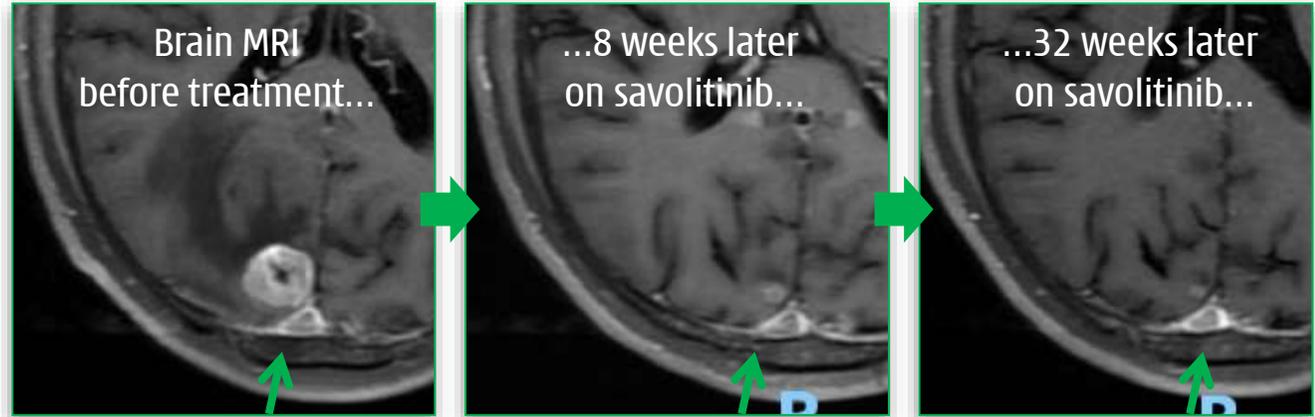
[1] Primary drivers, based on aggregate rocletinib/Tagrisso data published at 2016/2017 ASCO; [2] Research estimates; [3] company annual reports and Frost & Sullivan.

# Savolitinib - MET Exon 14 deletion NSCLC [1]

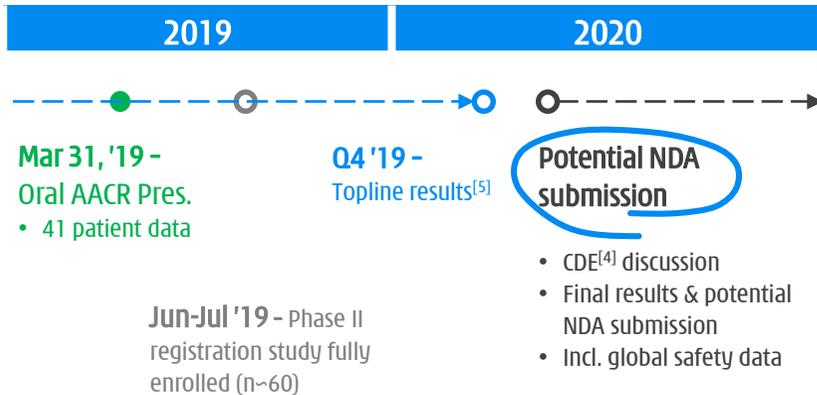
## Potential China NDA submission in 2020 [2]

### 4. Encouraging MET Exon14d NSCLC study China data at AACR 2019 [3]

- 41 pts; 31 pts efficacy evaluable.
- Promising antitumor activity.
- Rapid, durable tumor response observed.**
- Anti-tumor activity observed in brain mets.
- Savolitinib generally well tolerated; most related 1 TEAEs were grade 1 or 2.



### 5. MET Exon14d NSCLC potential NDA filing 2020 [2]



### 6. Savolitinib monotherapy China market opportunity

		Annual Incidence	Estimated mPFS	Pricing Reference
<b>Non-small Cell Lung Cancer</b> [4]	100%	737,400		
<b>MET Exon 14d NSCLC</b>	2%	14,700	TBD	Tagrisso® -- China NRDL
<b>MET gene ampl. NSCLC</b>	2-4%	14,700 - 29,000		
<b>Gastric Cancer</b>	100%	442,300		
<b>MET gene ampl. Gastric Cancer</b>	4-10%	18,000 - 44,000		

Potential first savo monotherapy indication MET Exon 14d NSCLC

Two further MET-driven patient populations - savo monotherapy

[1] The trial is focused on patients with MET Exon 14 mutation who have failed prior systemic therapy, or are unable to receive chemotherapy, however the target patient population is intended to be all MET Exon 14 mutation patients; [2] We expect that the Phase II study of savolitinib in MET Exon 14d NSCLC would, if successful, be sufficient to support NDA submission; [3] Data cut-off Feb. 26, 2019. Lu S et al, CT031 - Preliminary efficacy and safety results of savolitinib treating patients with pulmonary sarcomatoid carcinoma (PSC) and other types of non-small cell lung cancer (NSCLC) harboring MET Exon 14 skipping mutations. Presented at American Association of Cancer Research Annual Meeting 2019, Atlanta, GA, Mar. 31, 2019; [4] Center for Drug Evaluation of the National Medicinal Products Administration of China; [5] submission in planning.

# Tagrisso<sup>®</sup> + savo in EGFR TKI refractory NSCLC

## TATTON B & D data - efficacy



	TATTON Part B osimertinib 80 mg + savolitinib 600 mg <sup>[1]</sup>			TATTON Part D osimertinib 80 mg + savolitinib 300 mg
	Part B1 (n=69) Prior third-generation EGFR-TKI	Part B2 (n=51) No prior third-generation EGFR-TKI (T790M negative)	Part B3 (n=18) No prior third-generation EGFR-TKI (T790M positive)	Part D (n=36) No prior third-generation EGFR-TKI (T790M negative)
<b>Objective response rate,* % [95% CI]</b>	30% [20, 43]	<b>65% [50, 78]</b>	67% [41, 87]	<b>64% [46, 79]</b>
Complete response, %	0	0	0	0
Partial response, %	30%	65%	67%	64%
<b>Non-response, %</b>				
Stable disease (≥ 6 weeks)	45%	24%	33%	28%
Progressive disease	10%	6%	0	3%
Not evaluable	14%	6%	0	6%
<b>Disease control rate,# % [95% CI]</b>	75% [64, 85]	88% [76, 96]	100% [81, 100]	92% [78, 98]
<b>Median DoR, months [95% CI]</b>	7.9 [4.0, 10.5]	9.0 [6.1, 22.7]	12.4 [2.8, NR]	8.0 [4.5, NR]
<b>Median PFS, months [95% CI]</b>	5.4 [4.1, 8.0]	<b>9.0 [5.5, 11.9]</b>	11.0 [4.0, NR]	<b>9.1 [5.4, 12.9]</b>

**No reduction in efficacy with 300mg savo – SAVANNAH converted to 300mg dose**

[1] Most patients were enrolled to Part B1, B2, B3 on 600 mg savolitinib, prior to weight-based dosing implementation, but following a protocol amendment in response to a safety signal of hypersensitivity, the final 21 patients enrolled in Part B were dosed with savolitinib by body weight as follows: patients who weighed ≤55 kg (n=8) received 300 mg daily and those weighing >55 kg (n=13) received 600 mg daily; Best response data are for patients who had an opportunity to have two follow-up scans; \*Complete or partial response confirmed at ≥4 weeks. #Disease control rate = confirmed complete response + confirmed partial response + stable disease at ≥5 weeks.; CI, confidence interval; NR, not reached.

# Tagrisso<sup>®</sup> + savo in EGFR TKI refractory NSCLC

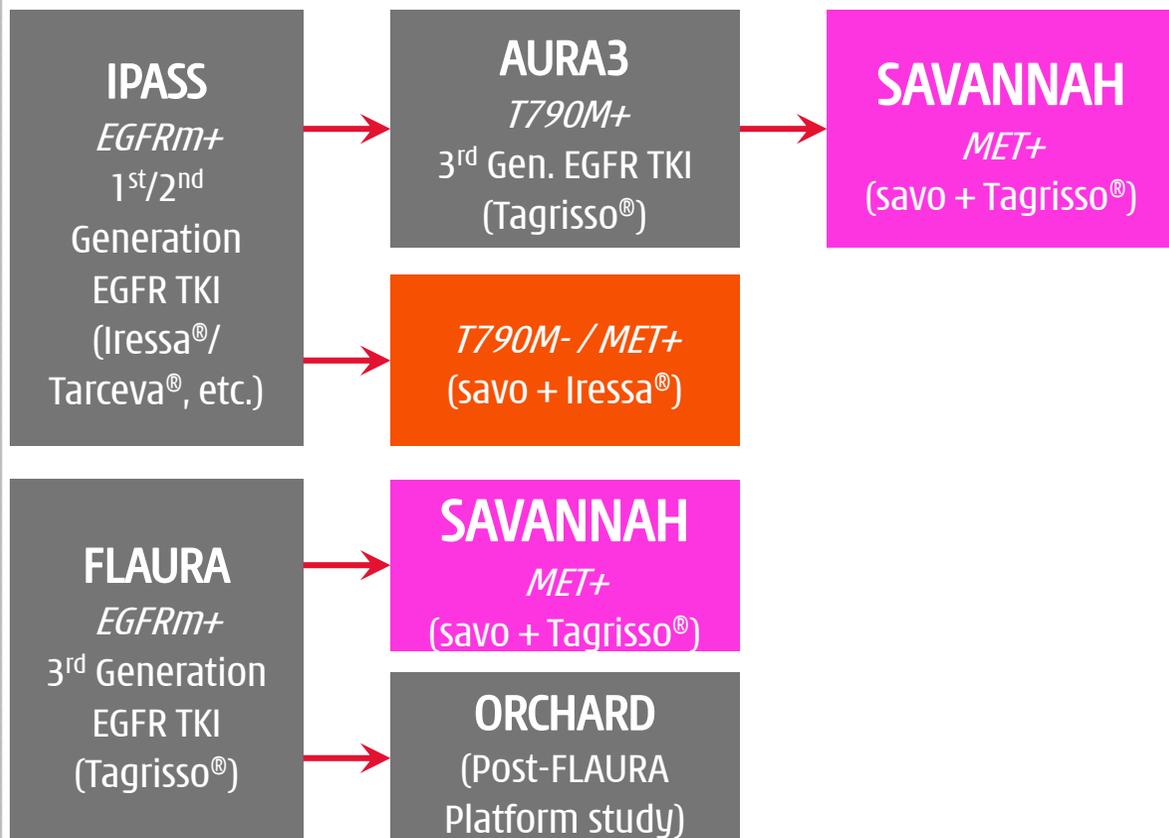
## SAVANNAH - global registration intent study



Addressing resistance with combinations

1<sup>st</sup> Line Metastatic

2<sup>nd</sup> Line+ Metastatic



### SAVANNAH (NCT03778229)

#### Phase II single-arm study:

- Global - N. & S. America, Eur., & Asia.
- Primary endpoint ORR.
- Secondary endpoints: PFS, OS, DoR & percent change in tumor size.
- Interim Analysis, potentially BTD enabling, mid 2020.
- Primary data completion est. 2021.

#### ■ ORCHARD study:

- Post FLAURA Platform study offering targeted treatments for all patients - expect high enrollment.
- MET+ patients prioritize to SAVANNAH.

# Savolitinib in papillary RCC

## Important data planned at ASCO

### 1. Could MET + PD-L1 inhibition be synergistic?

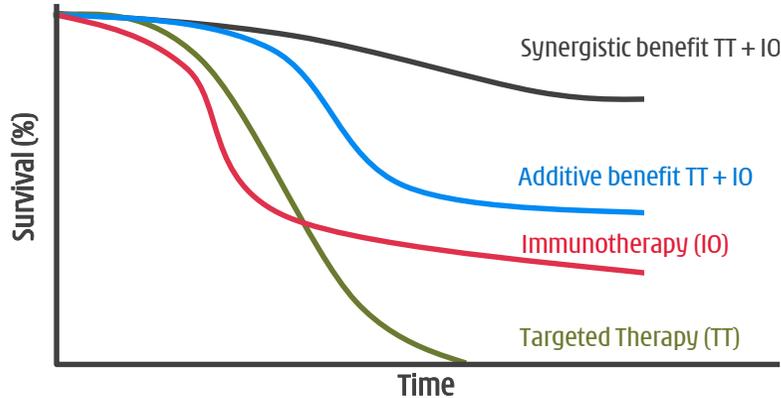
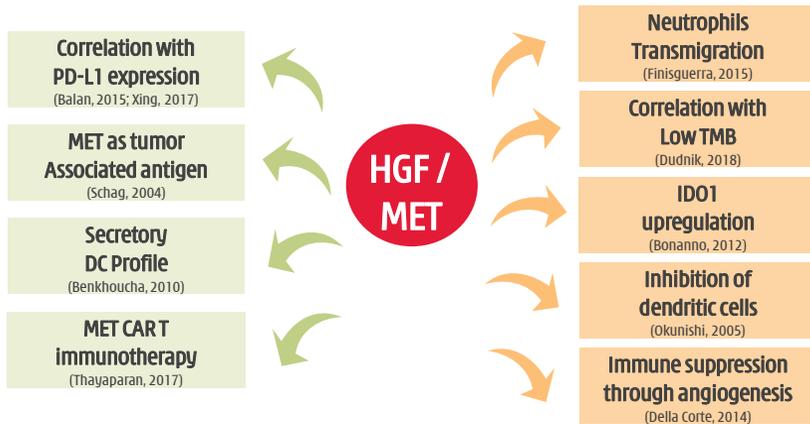


Illustration by Tracy L Rose MD MPH at ASCO GU 2019 presentation, showing what synergistic vs additive benefit could hypothetically look like; not based on clinical data.

### 2. MET/HGF complex interplay with immune system.



Papaccio et al Int J Molec Sciences, 2018; 19(3595)

### 3. PD-1/PD-L1s important in non-ccRCC but need to see mature mPFS/mOS & further biomarker analysis [1]

<p><b>MET+ Papillary RCC</b>                  (~\$1.0b)                  ~8% of RCC                  ~ 28k new patients/yr.</p>	<p><b>Savo mono.</b>                  All lines: (n=44)                  ORR 18.2%                  DCR 73.2%                  mPFS 6.2 mo.</p>
<p><b>MET- Papillary RCC</b>                  (~\$1.0b)                  ~8% of RCC                  ~ 28k new patients/yr.</p>	<p><b>Keytruda® mono.</b>                  First line: (n=118)                  ORR 25.4%                  DCR 43.2%                  mPFS na</p> <p><b>Savo + Imfinzi®</b>                  All lines: (n=41)                  ORR 26.8%                  DCR na                  mPFS 5.3 mo.</p> <p>First line: (n=28)                  ORR 32.1%                  DCR na                  mPFS na  <i>Interim Data</i></p>
<p><b>Other non-ccRCC</b>                  (~\$0.6b)                  ~5% of RCC                  ~ 16k new patients/yr.</p>	<p><b>Tecentriq® + Avastin®</b>                  All lines: (n=39)                  ORR 25.6%                  DCR na                  mPFS na</p> <p><b>Keytruda® mono. (all nRCC)</b>                  First line: (n=165)                  ORR 24.8%                  DCR 40.6%                  mPFS 4.1 mo.</p> <p><i>Not confirmed ORR</i></p>

[1] KEYNOTE 427 (Cohort B) ASCO GU 2019 D. McDermott; CALYPSO (PRCC cohort) ASCO GU 2019 C. Suarez; Abstract 548 (244057) ASCO GU 2019 R.McKay; ORR = Objective Response Rate; DCR Disease Control Rate; mPFS = median Progression-Free Survival.

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*Mechanism of Action*

*Anti-angiogenesis: cut off  
blood flow to tumor  
(VEGFR/FGFR).*

*Immunotherapy: inhibit  
expression of tumor-  
associated macrophages  
which cloak cancer cells from  
T-cell attack (CSF-1R).*

Tumor-associated  
macrophages

T-cells

Angiogenesis

2b Surufatinib: angio-immuno kinase inhibitor

# Surufatinib

Potentially our first un-partnered oncology drug launch



## Two Phase III neuroendocrine tumor ("NET") registration studies...

- 25 China sites.
- 1° endpoint: median PFS.
- 2° endpoints: ORR, DCR, DoR, TTR, OS.

### SANET-ep

Non-pancreatic NET  
(Actual N=198)

R  
2:1



- Met all efficacy endpoints
- Well tolerated

### SANET-p

Pancreatic NET  
(Planned N=195)

R  
2:1



- SANET-p Interim Analysis in **H1 2020.**

## ...preparing for our first China launch...

2019

2020

Jun 14, '19 - SANET-ep Interim Analysis

- Study stopped early, a year ahead of schedule.
- Pre-NDA meeting with CDE.

Sep 29, '19 - SANET-ep Presentation at ESMO

- mPFS primary endpoint
- Tumor control secondary endpoints
- Placebo control

Q4 '19 - ✓  
NDA Accepted

Current  
~120 ppl.

Building out Oncology  
Sales, Mkt., & Med. Aff. Org.

Est. Late 2020  
China launch

Full China  
coverage

# Surufatinib - China NET



Non-Pancreatic NET estimated to represent ~80% of China NET

## Epidemiology - China NET & BTC patient populations

Potential First surufatinib monotherapy indication Non-pancreatic NET

Two further surufatinib registration-intent studies underway

		Annual Incidence	Estimated Prevalence	mPFS	NRDL Pricing References
China NET	100%	67,600	~300,000 (Est. China ratio <sup>[1]</sup> )		<b>Sutent®</b> (~US\$ 2,007/mo. <sup>[2]</sup> ) <b>Afinitor®</b> (~US\$ 1,320/mo. <sup>[2]</sup> )
Non-Pancreatic NET	~80%	~54,100	~240,000 (Est. China ratio <sup>[1]</sup> )	9.2 mo. (SANET-ep Ph.III)	
Pancreatic NET	~20%	~13,600	~30,000 (Est. China ratio <sup>[1]</sup> )	19.4 mo. (Ph.II) (SANET-p Ph.III -- TBD)	
Biliary Tract Cancer	100%	64,000		TBD	

NET is major unmet medical need in China - with long treatment duration

[1] Current estimated Prevalence to Incidence ratio in China at 4.4, lower than U.S. 7.4 ratio due to lower access to treatment options.

[2] NRDL pricing references calculations assume exchange rate of RMB6.74 per US\$1.

# G1/2 Advanced NET <sup>[1]</sup> (Ki-67 Index 0-20)

## Global opportunity in lung/other NETs & China wide-open



Site		est. %	Octreotide	Lanreotide	<sup>177</sup> Lu-Dotatate	Streptozocin	Sunitinib	Everolimus	Surufatinib
Disease status			Treatment naive	Stable disease	Progressed in past 3 yrs.	Historical	Progressed in past 12 mo.	Progressed in past 6 mo.	Progressed in past 12 mo.
GI Tract	Stomach	7%		CLARINET <sup>[2]</sup>	Historical Ph.II <i>SSR over expression</i>			RADIANT-4 <sup>[3]</sup>	SANET-ep
	Small bowel/ Appendix	9%	PROMID	CLARINET <sup>[2]</sup>	NETTER-1			RADIANT-4 <sup>[3]</sup>	SANET-ep
	Colon & Rectum	31%		CLARINET <sup>[2]</sup>	Historical Ph.II <i>SSR over expression</i>			RADIANT-4 <sup>[3]</sup>	SANET-ep
	Pancreas	6%		CLARINET <sup>[2]</sup>	Historical Ph.II <i>SSR over expression</i>	Historical	PHASE III	RADIANT-3 <sup>[4]</sup>	SANET-p <i>H1 2020 interim</i>
	Lung	20%						RADIANT-4 <sup>[3]</sup>	SANET-ep
Other	Other	~17%							SANET-ep
	Unknown 1°	~10%						RADIANT-4 <sup>[3]</sup>	SANET-ep

[1] Yao ESMO 2019; [2] CLARINET approved only for Ki-67 Index <10 (i.e. est. ~50% of G1/G2); [3] Everolimus approved in non-Functional NET (~60% pNET; 90% Lung NET; majority mid-gut/small bowel NET); [4] RADIANT-3 - Progressed in past 12 months.

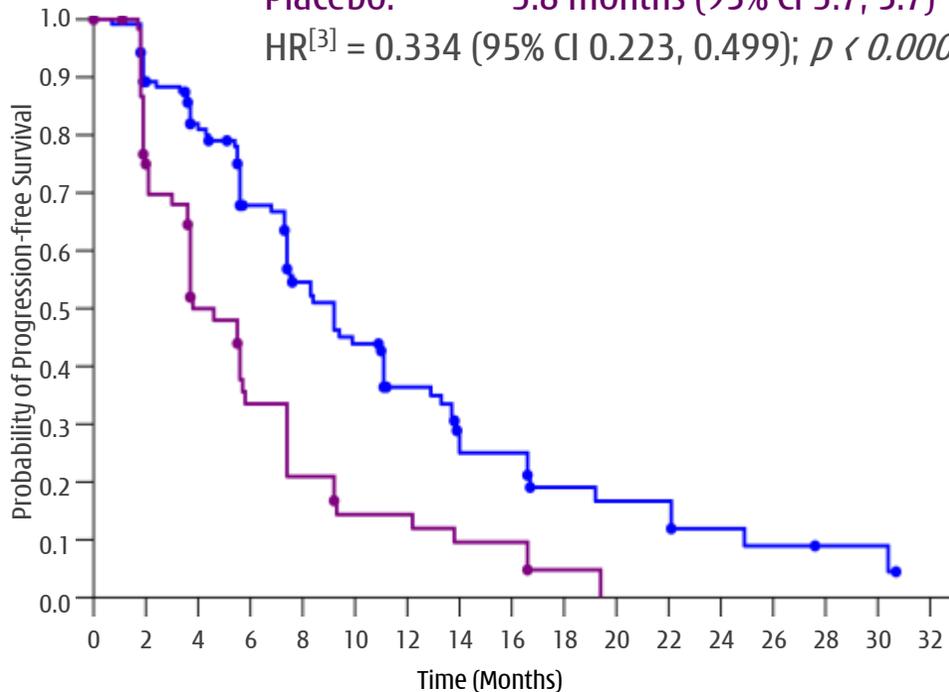
# G1/2 Advanced extra-pancreatic NET

Investigator assessed median PFS



## SANET-ep<sup>[1]</sup> (n=198)

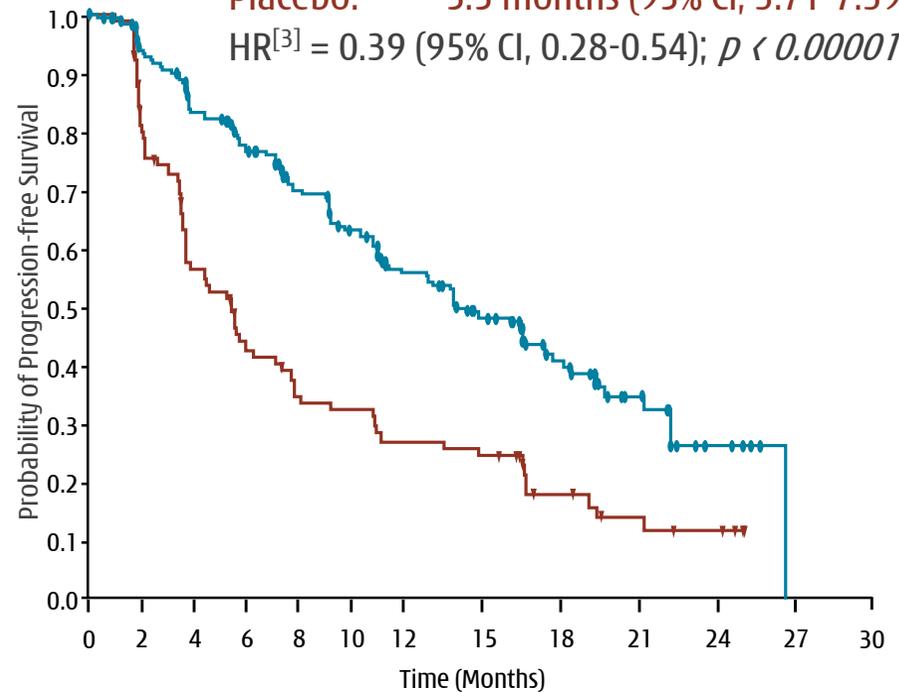
Surufatinib: 9.2 months (95% CI 7.4, 11.1)  
Placebo: 3.8 months (95% CI 3.7, 5.7)  
HR<sup>[3]</sup> = 0.334 (95% CI 0.223, 0.499);  $p < 0.0001$



SANET-ep Primary (1°) endpoint was Investigator mPFS  
BIIRC<sup>[4]</sup> mPFS for supportive analysis not 1° or 2° endpoint

## RADIANT-4<sup>[2]</sup> (n=302)

Everolimus: 14.0 months (95% CI, 11.24-17.71)  
Placebo: 5.5 months (95% CI, 3.71-7.39)  
HR<sup>[3]</sup> = 0.39 (95% CI, 0.28-0.54);  $p < 0.00001$



RADIANT-4 Primary (1°) endpoint was BIIRC<sup>[4]</sup> mPFS  
Investigator mPFS not 1° or 2° endpoint

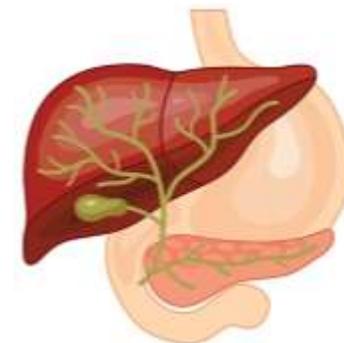
# Surufatinib

## Life cycle indications & other ongoing trials



### Phase IIb/III study in 2L BTC

- First patient dosed in March 2019;
- Nearly all planned sites now activated;
- Interim analysis mid-2020, based on first 80 patients;
- Total enrollment ~300 patients.



### PD-1 collaborations

- With Junshi (Tuoyi®): Dose expansion in multiple tumor types began YE2019;
- With Innovent (Tyvyt®): Global studies in planning.



### Ex-China development

- U.S. Phase Ib/II in P-NET & BTC initiated July 2018 - NET enrollment complete;
- FDA End of Phase II meeting targeted for H1 2020;
- U.S. & Europe Phase III registration study expected to initiate in mid-2020.



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Fruquintinib Capsules

ELUNATE®

5mg



Hutchison MediPharma

Lilly

2c

Elunate® (fruquintinib capsules)

# NRDL - highly competitive price

## Epidemiology

China Annual Incidence  
380,000 patients [1]

Surgery

1<sup>st</sup>-line treated ~15%

2<sup>nd</sup>-line treated

3<sup>rd</sup>-line treated

>55,000 patients [2]

## Launch pricing [3]

Launch pricing (OOP [4])

~US\$ 3,260 per cycle  
(RMB 21,966 per cycle)  
(one cycle 4 weeks)

Patient Access Program

Cycle 1: ~US\$ 3,260

Cycle 2: ~US\$ 3,260

Cycle 3: Free (PAP<sup>[5]</sup>)

Cycle 4: Free (PAP<sup>[5]</sup>)

Cycle 5: ~US\$ 3,260

Cycle 6 onwards: Free (PAP<sup>[5]</sup>)

Total OOP cost to patients

~US\$ 9,800 (RMB 65,880)

Average Usage

~Avg 5 mths / 5.5 cycles  
(to progression; 3.7 mo. mPFS<sup>[6]</sup>)

## National Reimbursed Drug List (NRDL)

2019 NRDL released by China's National Healthcare Security Administration ("NHSA")

- Announced Nov. 28, 2019; effective Jan. 1, 2020
- 8 newly listed oncology drugs, including Elunate®
- Reimburse 50-70% of patient costs under urban scheme

OOP costs for 3L CRC Patients per cycle		Urban Med. Insur. Scheme (UMI)	Non-UMI
Population		317m	1,053m
% China		23%	77%
Elunate® (fruquintinib)	Pre-NRDL	RMB21,966	RMB21,966
	Post-NRDL	7,938	7,938
3L CRC Pts OOP		2,381~3,969	7,938
Stivarga® (regorafenib)	Pre-NRDL	RMB30,240	RMB30,240
	Post-NRDL	16,464	16,464
3L CRC Pts OOP		4,939~8,232	16,464

[1] W. Chen, R. Zheng et al, CA Cancer J Clin. 2016 Mar-Apr;66(2):115-32. Cancer Statistics in China, 2015. doi:10.3322/caac.21338. Epub 2016 Jan 25; [2] Frost & Sullivan; [3] Pricing figures represent retail prices paid per patient to Lilly; [4] OOP = out of pocket; [5] PAP = Patient Access Program, subject to qualification criteria; [6] mPFS = median Progression-Free Survival; [7] PRDL = Provincial Reimbursement Drug List; [8] End-2017, 14,968k people covered by Shanghai PRDL including 10,054k employees and 4,914k retirees; Total SH population 24,183k incl. 14,456k local residents & 9,727k external population; [9] pay for 3 cycles x RMB2,860/box x 3 weeks/box = RMB 25,740 (RMB:US\$ exchange rate of 6.74:1).

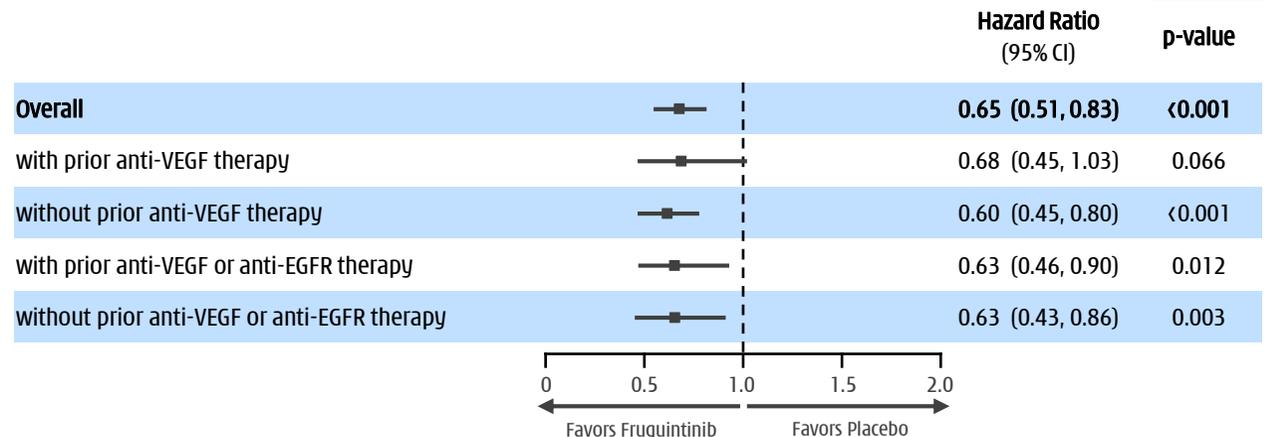
Third-Line Metastatic Colorectal cancer	FRESCO <sup>[1]</sup>		CONCUR		CONCUR		CORRECT	
	Mainland China		Chinese Patients (Mainland China, Hong Kong, Taiwan) <sup>[2]</sup>		Mainland China, Hong Kong, Taiwan, Vietnam, South Korea		Global	
Treatment arms	Elunate <sup>®</sup>	Placebo	Stivarga <sup>®</sup>	Placebo	Stivarga <sup>®</sup>	Placebo	Stivarga <sup>®</sup>	Placebo
Patients (n)	278	138	112	60	136	68	505	255
Objective Response Rate, n (%)	4.7%	0.0%	3.6%	0.0%	4.4%	0.0%	1.0%	0.4%
Disease Control Rate, n (%)	62.2% <b>+49.9</b>	12.3%	45.5% <b>+38.8</b>	6.7%	51.5% <b>+44.1</b>	7.4%	41.0% <b>+26.1</b>	14.9%
Median Progression-Free Survival (mPFS) (mo.)	3.7 <b>+1.9</b>	1.8	2.0 <b>+0.3</b>	1.7	3.2 <b>+1.5</b>	1.7	1.9 <b>+0.2</b>	1.7
Median Overall Survival (mOS) (mo.)	9.3 <b>+2.7</b>	6.6	8.4 <b>+2.2</b>	6.2	8.8 <b>+2.5</b>	6.3	6.4 <b>+1.4</b>	5.0

**Advantage for Elunate<sup>®</sup> efficacy vs. Stivarga<sup>®</sup> in Chinese metastatic CRC patients;**

**Advantage for Elunate<sup>®</sup> post VEGF/EGFR targeted therapy**

- mOS: 7.69 mo. vs. 5.98 mo. placebo (HR 0.63 & p-value 0.012)
- mPFS: 3.65 mo. vs. 1.84 mo. placebo (HR 0.24 & p-value <0.001)

## Overall Survival subgroup analysis by Prior Treatment <sup>[1]</sup>



[1] Effect of Fruquintinib vs Placebo on Overall Survival in Patients With Previously Treated Metastatic Colorectal Cancer: The FRESCO Randomized Clinical Trial; [2] Efficacy & safety of regorafenib monotherapy in Chinese patients with previously treated metastatic colorectal cancer: subgroup analysis of the CONCUR trial; R Xu.

BIOCHEMICAL ACTIVITY	IC <sub>50</sub> (nmol/L)	IC <sub>50</sub> (nmol/L)
<b>On-Target Kinases:</b>		
VEGFR1	33	13
VEGFR2	35	4.2
VEGFR3	0.5	46
<b>Off-Target Kinases:</b>		
Ret	128	1.5
FGFR1	181	202
c-kit	458	7
PDGFRβ	>10,000	22
RAF-1	>10,000	2.5
B-RAF	>10,000	28
B-RAF <sup>V600E</sup>	>10,000	19

**Stivarga® liver toxicity black-box warning:**

➔ Increased liver function test monitoring (weekly if elevated) & remedial dose interruption.

**STIVARGA (regorafenib) tablets, oral**  
Initial U.S. Approval: 2012

**WARNING: HEPATOTOXICITY**  
See full prescribing information for complete boxed warning.

- Severe and sometimes fatal hepatotoxicity has been observed in clinical trials. (5.1)
- Monitor hepatic function prior to and during treatment. (5.1)
- Interrupt and then reduce or discontinue Stivarga** for hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis, depending upon severity and persistence. (2.2)

3 <sup>rd</sup> -Line Metastatic Colorectal cancer	FRESCO Study Mainland China [1]		CONCUR Study (Mainland China, HK, Taiwan) [2]	
	Elunate®	Placebo	Stivarga®	Placebo
<b>Treatment arms</b>				
Patients (n)	278	138	112	60
≥G3 AE (Safety population)	61.1%	19.7%	69.6%	46.7%
SAE (Safety population)	15.5%	5.8%	31.3%	26.7%
<b>VEGFR on-target related AEs:</b>				
Hypertension ≥G3	21.2%	2.2%	12.5%	8.3%
Hand-Foot Syndrome (Palmar-plantar), ≥G3	10.8%	0.0%	17.0%	0.0%
<b>Off-target (i.e. non-VEGFR) related AEs:</b>				
Hypophosphatemia, ≥G3	0.0%	0.0%	8.0%	0.0%
Hypokalemia, ≥G3	0.7%	0.7%	6.3%	0.0%
Rash/desquamation, ≥G3	0.0%	0.0%	4.4%	0.0%
Lipase increase, ≥G3	0.0%	0.0%	6.3%	1.7%
<b>Hepatic function (Liver function) AEs:</b>				
ALT increased, ≥G3	0.7%	1.5%	7.1%	3.3%
AST increased, ≥G3	0.4%	0.7%	8.9%	0.0%
Blood bilirubin increased, ≥G3	1.4%	1.5%	8.9%	8.3%
<b>Tolerability:</b>				
AE Leading to dose interruption	35.3%	10.2%	68.8%	25.0%
AE Leading to dose reduction	24.1%	4.4%	23.2%	0.0%
AE Leading to treatment discontinuation	15.1%	5.8%	14.3%	6.7%

**Elunate® superior safety - advantage especially for liver mets patients**

## Phase III in 2L gastric cancer (FRUTIGA)

- Second interim analysis by IDMC expected mid 2020;
- On track to complete enrollment H2 2020.



## PD-1 collaborations

- With Innovent (Tyvyt<sup>®</sup>): dose/regimen finding ongoing;
- With Genor (genolimzumab): dose escalation ongoing;



## Phase II in 1L NSCLC (in combination with Iressa<sup>®</sup>)

- Study completed, keynote presentation of data at ESMO Asia in Nov 2019.



## Ex-China development

- U.S. Phase Ib/II in CRC initiated in 2019 - enrollment complete;
- FDA End of Phase II meeting targeted for H1 2020;
- U.S. & Europe Phase III registration study expected to initiate in mid-2020.



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Cash & Guidance

# Cash position & 2019 Guidance

**\$384 million** in available cash resources <sup>[1]</sup>

## Cash Position

(at end June 2019)

- **\$237 million cash** / cash equiv. / Short term inv. <sup>[2]</sup>
  - **\$147 million** additional unutilized banking facilities <sup>[3]</sup>
  - **\$64 million** additional cash in JVs
- 
- **\$0 million** in bank borrowings



Global  
Innovation



China  
Oncology

(US\$ millions)

2019 Guidance

Research & Development Expenses	(130) - (170)
Adj. (non-GAAP) Group Net Cash Flows <sup>[4]</sup>	<b>(90) - (120)</b>

- **Flexibility on future financing activity:**
  - Sufficient capability to advance pipeline through multiple major value inflection points;
  - Non-dilutive finance from non-core CP divest. <sup>[5]</sup>

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Summary

# 2020 Summary

Potential for break-out year



## Suru Launch

-  **Chi-Med's first** unpartnered oncology drug launch
-  Oncology commercial team **~300-350 reps by mid-2020**

## Savo Breakout

-  **Submit 1<sup>st</sup> NDA** (Exon14 NSCLC)
-  SAVANNAH (w/Tagrisso<sup>®</sup>) **interim**
-  SAVOIR **PRCC data & strategy**

## ELUNATE<sup>®</sup> NRDL

-  NRDL Jan 2020 - **broad China access**
-  Establish Elunate<sup>®</sup> as **best-in-class VEGFR TKI**

## US & EU C&R Team

-  **Fruq & Suru global Phase IIIs starting**
-  HMPL-523 (Syk) & HMPL-689 (PI3K $\delta$ ) global development

## M&A

-  **Add large molecule development** capability/assets
-  **Valuable non-core** commercial assets



HUTCHISON CHINA MEDITECH

Thank you

