HUTCHISON CHINA MEDITECH

ASCO Investor Update

June 1, 2020

Nasdaq/AIM: 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.

Agenda

1	Introduction	Christian Hogg Chief Executive Officer
2	Savolitinib: MET exon 14 skipping NSCLC	Weiguo Su Chief Scientific Officer
3	Savolitinib: Papillary Renal Cell Carcinoma	Weiguo Su Chief Scientific Officer
4	Surufatinib international data	Marek Kania Chief Medical Officer, Int'l
5	Conclusion and Q&A	Christian Hogg, All

Portfolio summary

Multiple waves of innovation - progressing rapidly

Dose Finding / Safety Run-In	Proof-of-Concept	Registration Intent	NDA Filed / Marketed
Fruquintinib + Tyvyt (PD-1) Solid Tumors [1]	**Savolitinib** MET Exon 14 Skipping NSCLC	**Savo + Tagrisso (SAVANNAH)** 2L/3L Tagrisso-Refractory MET+ NSCLC	**Elunate (Fruquintinib capsules)** ≥3L Colorectal Cancer
Fruquintinib + tislelizumab (PD-1) Solid Tumors [1]	**Savo / Savo + Imfinzi (CALYPSO)** x2: PRCC & ccRCC [2]	**Savolitinib (SAVOIR)** PRCC [1]	**Surufatinib (SANET-ep)** Non-Pancreatic NET (Under Review)
Surufatinib + Tuoyi (PD-1) Solid Tumors [1]	**Savolitinib (VIKTORY)** MET+ Gastric Cancer [2]	**Fruquintinib (FRESCO-2)** Colorectal Cancer [1]	**Savolitinib** MET Exon 14 Skipping NSCLC (Under Review)
Surufatinib + tislelizumab (PD-1) Solid Tumors [1]	**Savolitinib (CCTG I234B)** MET+ Prostate Cancer [2]	**Surufatinib** NET [1]	**SXBX** [3] **Pills** Coronary Artery Disease
HMPL-523 (Syk) Indolent NHL	**Savolitinib** MET+ Colorectal Cancer [2]	**Fruquintinib + Taxol (FRUTIGA)** 2L Gastric Cancer	**›10 other Rx / OTC drugs**
HMPL-689 (PI3Kδ) Indolent NHL	**Fruquintinib** Breast Cancer and Other Solid Tumors	**Surufatinib (SANET-p)** Pancreatic NET	
Fruquintinib + Tyvyt (PD-1) Solid Tumors	**Surufatinib** NET, Biliary Tract Cancer, Soft Tissue Sarcoma	**Surufatinib** 2L Biliary Tract Cancer	
Fruquintinib + geptanolimab (PD-1) Solid Tumors	**Surufatinib + Tuoyi (PD-1)** Solid Tumors (7 settings)		
Fruquintinib + tislelizumab (PD-1) Solid Tumors [1]	**HMPL-523** Indolent NHL (6 settings)		
Surufatinib + Tyvyt (PD-1) Solid Tumors [1]	**HMPL-523** Immune Thrombocytopenia Purpura		
Surufatinib + tislelizumab (PD-1) Solid Tumors [1]	**HMPL-689** Indolent NHL (8 settings)		
HMPL-453 (FGFR1/2/3) Solid Tumors	**HMPL-453** Mesothelioma		
HMPL-306 (IDH1/2) Myeloid Leukemia [1]			

Global Innovation

China Oncology

China Commercial

IN TRANSITION

[1] In planning; [2] Investigator initiated trials (IITs); [3] SXBX = She Xiang Bao Xin (cardiovascular); [4] Previously genolimzumab (GB226).

Savolitinib – selective MET inhibitor

FAST APPROVAL OF MONOTHERAPY

PAPILLARY RCC
~8% RCC. No biomarker therapies approved.

EXON14 MUTATION NSCLC
NDA under review. First in China.
Global in planning.

COMBINATION OPPORTUNITIES

PD-L1 COMBINATION
Preliminary signal with Imfinzi®.
Exploring further.

POST-EGFR TKI NSCLC
~30% Tagrisso®-resistant pts.
(Tag. 2019 $3.2bn, #1 globally).

› Global collaboration with AstraZeneca

Global Innovation

China Oncology

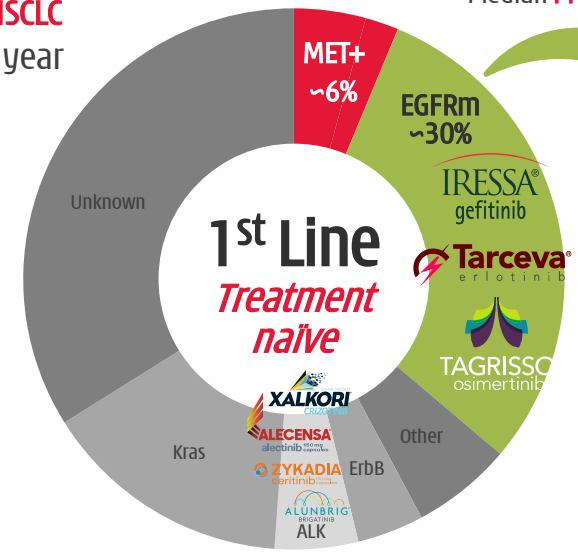
Note: Market size and patient population estimates are from Frost & Sullivan.

Savolitinib

Biggest opportunity is MET+ NSCLC

Primary NSCLC

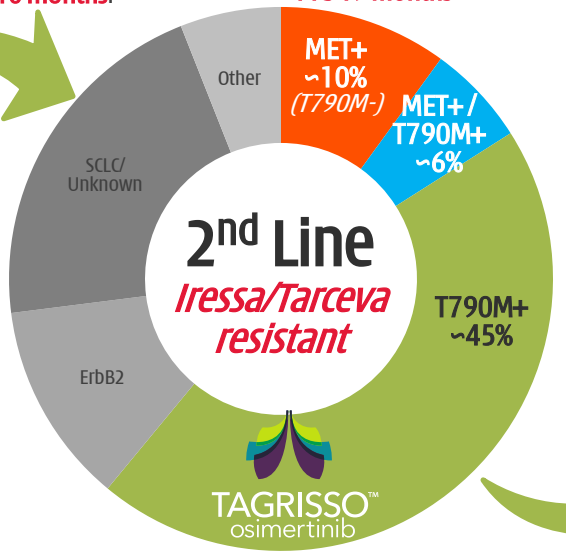
1.8 million NSCLC patients per year



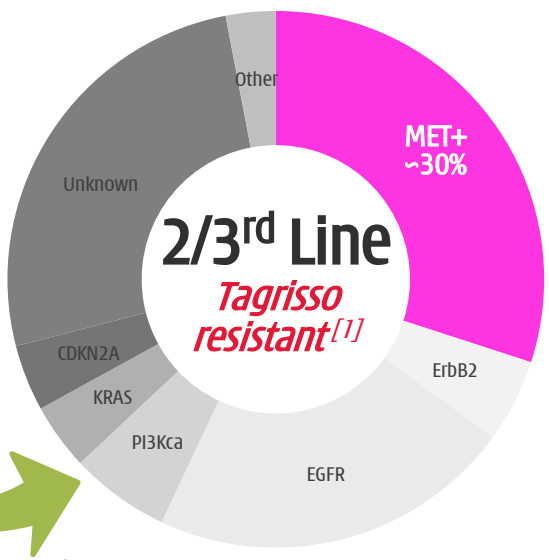
All **Iressa/Tarceva** patients relapse
Median **PFS 9-10 months**.

Resistance-driven EGFRm+ NSCLC

Tagrisso
1L Median **PFS 19 months**.



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



	Target	Launch	2019 ($m)[3]
Iressa	EGFRm	2003	423
Tarceva	EGFRm	2004	300
Tagrisso	EGFRm / T790M	2015	3,189
Xalkori	ALK / ROS1 / MET	2011	530
Alecensa	ALK	2015	881
Alunbrig	ALK	2017	60
Total Sales			5,383

Launch	2016	2017	2018	2019
Dec-15	423	955	1,860	3,189 (+74%)

TAGRISSO™ osimertinib

Est. global sales of ~$6-8 bn by 2023[2].

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

PRCC – unmet medical need

Lower response rates to treatments

1. Limited treatment options for non-ccRCC

Several approved therapies in ccRCC [3]

Immunotherapy setting new treatment paradigm

FIRST LINE – clear-cell RCC [4]	ORR	mPFS	mOS
Placebo (avg. multiple studies)	~2%	~3.5	~15.0
Torisel® (mTOR)	8.6%	5.5	10.9
VEGFR, multi-kinase small molecule (multiple compounds)	12-31%	6-11	21-28
Opdivo® + Yervoy® (PD-1/CTLA-4 immunotherapy) [5]	42%	~11.6	NR
Keytruda® + Inlyta® (PD-1/VEGFR combo)	59.3%	15.1	NR
Bavencio® + Inlyta® (PD-L1/VEGFR combo)	51.4%	13.8	NR
SECOND LINE – clear-cell RCC			
Placebo (avg. multiple studies)	~0%	~2.0	~14.0
Cabometyx® (VEGFR/MET, multi-kinase SM) *(METEOR)*	17%	7.4	21.4
Inlyta® (VEGFR, multi-kinase SM)	23%	8.3	20.1
Lenvima® + Afinitor® (VEGFR, multi-kinase SM + mTOR)	35%	14.6	25.5
Opdivo® (PD-1 mAb) *(CheckMate025)*	25%	4.6	25.0

non-ccRCC: *NCCN preferred strategy: clinical trials*

No category 1 recommendation

FIRST LINE – non clear-cell RCC [4]	ORR	mPFS	mOS
Sutent® (VEGFR, multi-kinase SM) [4]	9%	6.1	16.2
Afinitor® (mTOR) [4]	3%	4.1	14.9
SECOND LINE – non-clear-cell RCC [4]			
Sutent® (VEGFR, multi-kinase SM) [4]	10%	1.8	na
Afinitor® (mTOR) [4]	9%	2.8	na

2. RCC est. ~$13.0 bn. market by 2030 [1]

Clear-cell RCC (~$10.4b)

~80% of RCC

~ 290k new patients/yr. [2]

Non-Clear-cell RCC (~$2.6b)

~20% of RCC

~ 73k new patients/yr.[2]

3. Unmet medical need:

MET+ Papillary RCC (~$1.0b)

~8% of RCC

~ 28k new patients/yr.[2]

MET- Papillary RCC (~$1.0b)

~8% of RCC

~ 28k new patients/yr.[2]

Other non-ccRCC (~$0.6b)

~5% of RCC

~ 16k new patients/yr.[2]

[1] Frost & Sullivan; [2] Frost & Sullivan, based on US incidence mix and global incidence rate in 2018; [3] NCCN Guideline for kidney cancer (Version 1.2020, June 7, 2019) preferred or category 1 options, RCC = renal cell carcinoma;
[4] ORR = Objective Response Rate, mPFS = median Progression-Free Survival, mOS = median Overall Survival, NR = not reached; For approved subgroup of patients; [5] only approved for patients with intermediate or poor risk RCC.

Surufatinib – VEGFR, CSF-1R & FGFR1 inhibitor

FAST APPROVAL OF MONOTHERAPY

BILIARY TRACT CANCER
Poor prognosis patients.

NET REGISTRATION (GLOBAL)
Fast Track Designation in U.S.
Dialogue in EU & Japan.

NET LAUNCH (CHINA)
NDA under review; target launch Q4-20; Commercial team in place.

COMBINATION OPPORTUNITIES

PD-1 COMBINATIONS
Multiple PD-1s approach;
MOA synergy CSF-1R & PD-1.

PD-1 COMBINATIONS
Multiple PD-1s approach;
MOA synergy CSF-1R & PD-1.

Global Innovation

China Oncology

High-level NET landscape

Long-term disease - rapid deterioration in later stages [1][2][3]

Grade 1 (G1) NET
Localized / Regional

~8-35% NET patients - Functional NET - *Hormone related symptoms:*

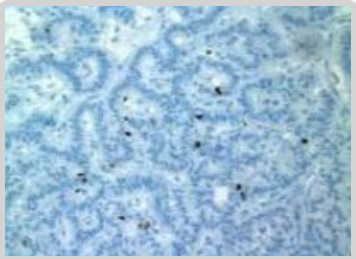
- *94% flushing*
- *78% diarrhea*
- *53% heart plaque*
- *51% cramping*

Symptoms allow early diagnosis

Somatostatin Analogue Treatment - *modulate/ control symptoms related to hormone overproduction & tumor growth:*

- *Octreotide: $1.6b revenue (2019)*
- *Lanreotide: $1.2b revenue (2019)*

mOS: 16.2 yrs.

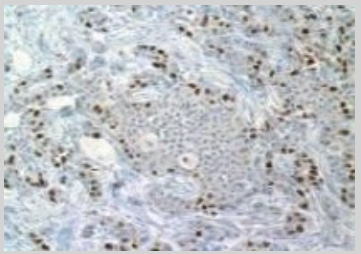


Well Differentiated
Ki-67 Index ≤2; Mitotic Count <2

G1/2 - Advanced NET
Regional / Distant

~60% NET patients - *first diagnosis at advanced disease stage* - **Mostly non-Functional NET** - *TKIs [4]; chemo/ radiotherapy*

mOS: 8.3 yrs.

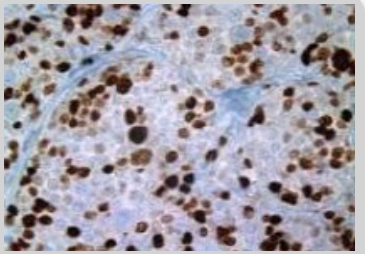


Moderately Differentiated
Ki-67 Index 3-20 ; Mitotic Count 2-20

G3 - NET/NEC
Distant

No approved treatments
- exploring *I/O [5]* *+ TKI combos*

mOS: 10 mos.



Poorly Differentiated
Ki-67 Index >20; Mitotic Count >20

[1] Arvind Desari et. al. Trends in the Incidence, Prevalence, and Survival Outcomes in Patients With Neuroendocrine Tumors in the US, JAMA Oncol. *2017;3(10):1335-1342;* [2] Van Cutsem et al. ESMO - Neuroendocrine Tumors Diagnostic & Therapeutic Challenges; [3] mOS = median overall survival; [4] TKIs = Tyrosine Kinase Inhibitors; [5] I/O = Immuno oncology/immunotherapy

G1/2 Advanced NET [1] *(Ki-67 Index 0-20)*

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

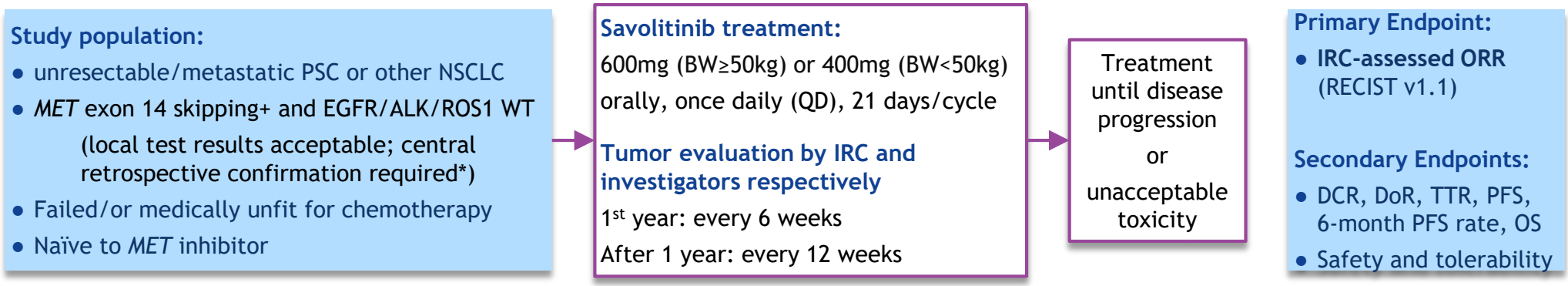
Site		est. %	Octreotide	Lanreotide	^{177}Lu-Dotatate	Streptozocin	Sunitinib	Everolimus	Surufatinib *(not approved)*
Disease status			Treatment naïve	Stable disease	Progressed in past 3 yrs.	Historical	Progressed in past 12 mo.	Progressed in past 6 mo.	Progressed in past 12 mo.
GI Tract	Stomach	7%		CLARINET [2]	Historical Ph. II *SSR over expression*			RADIANT-4 [3]	SANET-ep
	Small bowel / appendix	9%	PROMID	CLARINET [2]	NETTER-1			RADIANT-4 [3]	SANET-ep
	Colon & Rectum	31%		CLARINET [2]	Historical Ph. II *SSR over expression*			RADIANT-4 [3]	SANET-ep
Pancreas		6%		CLARINET [2]	Historical Ph. II *SSR over expression*	Historical	PHASE III	RADIANT-3 [3]	SANET-p
Lung		20%						RADIANT-4 [3]	SANET-ep
Other	Other	~17%							SANET-ep
	Unknown Primary	~10%						RADIANT-4 [3]	SANET-ep

Global (ex-China) China

[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.

2 Savolitinib: Exon 14 Skipping NSCLC

Abstract 9519: Phase II study of savolitinib in patients (pts) with pulmonary sarcomatoid carcinoma (PSC) and other types of non-small cell lung cancer (NSCLC) harboring MET exon 14 skipping mutations (METex14+)



The study was designed to reject the null hypothesis that the ORR does not exceed 30%, with at least 90% power. Assuming the ORR was at least 55%, the minimum required sample size were 50 efficacy evaluable patients.

- A total of 593 patients were prescreened/screened, 87 patients were identified METex14+, 70 patients were treated.
- As of March 31, 2020, 50 patients discontinued treatment, 20 patients were still on treatment, follow-up was ongoing.

*Gene status verified by Sanger or NGS (Geneseeq Tetradecan Panel) in central lab.
Abbreviations: BW: Body weight; ORR: Objective response rate; DCR: disease control rate; DoR: duration of response; TTR: time to response; PFS: progression free survival; OS: overall survival; PSC: pulmonary sarcomatoid carcinoma; NSCLC: non-small cell lung cancer; RECIST: Response Evaluation Criteria In Solid Tumors.

Demographics & Baseline Characteristics

- Most of the patients were of senior age, with stage IV disease and previously treated with systemic antitumor treatment.
- The proportion of pts with PSC was 35.7% (25/70); half of pts with PSC were prior treatment naïve.
- Pts with brain metastasis was 24.3% (17/70).

Demographics		PSC N=25	Other NSCLC N=45	Total N=70
Age, years median (range)		69.3 (54.1-84.8)	68.1 (51.7-85.0)	68.7 (51.7-85.0)
Height, cm median (range)		161.0 (145.0, 182.0)	164.0 (144.0, 183.0)	163.5 (144.0, 183.0)
Weight, kg median (range)		61.0 (44.0, 89.5)	60.0 (41.5, 84.0)	60.0 (41.5, 89.5)
Smoking history, n (%)	Former/ current smoker	12 (48.0)	16 (35.6)	28 (40.0)
	Non-smoker	13 (52.0)	29 (64.4)	42 (60.0)
Gender, n (%)	Male	17 (68.0)	24 (53.3)	41 (58.6)
	Female	8 (32.0)	21 (46.7)	29 (41.4)

Disease characteristics		PSC N=25	Other NSCLC N=45	Total N=70
ECOG performance status, n (%)	0	3 (12.0)	9 (20.0)	12 (17.1)
	1	22 (88.0)	35 (77.8)	57 (81.4)
	3	0	1 (2.2)	1 (1.4)
TNM stage, n (%)	III	1 (4.0)	4 (8.9)	5 (7.1)
	IV	24 (96.0)	41 (91.1)	65 (92.9)
Tumor histology, n (%)	Adenocarcinoma	NA	40 (88.9)	40 (57.1)
	Others	NA	5 (11.1)	5 (7.1)
Presence of brain metastases, n (%)		3 (12)	14 (31.1)	17 (24.3)
Prior systemic treatment	Naïve	13 (52.0)	15 (33.3)	28 (40)
	Treated	12 (48.0)	30 (66.7)	42 (60)

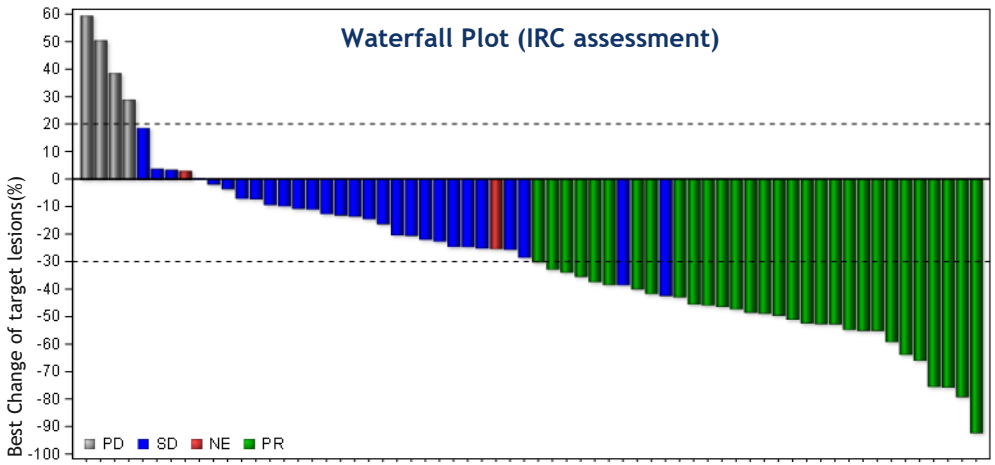
PSC: pulmonary sarcomatoid carcinoma; NSCLC: non-small cell lung cancer.

Savolitinib demonstrated promising anti-tumor activity in METex14+ NSCLC

Efficacy evaluable set included pts who had measurable lesions at baseline, received at least one dose of study drug, and had at least one adequate scheduled (≥ 6wks) post-baseline tumor assessment or radiological disease progression at anytime based on RECIST 1.1.

Pts excluded from efficacy evaluable set as below:

- 5 pts without post-baseline tumor assessment;
- 3 pts with 1 unscheduled tumor assessment of PR or SD within 6 wks; and
- 1 pt without target lesion as assessed by IRC.



Efficacy evaluable set	IRC (N=61)	Investigator (N=62)
Confirmed PR	30 (49.2)	32 (51.6)
SD	27 (44.3)	25 (40.3)
PD	4 (6.6)	5 (8.1)
Interim ORR, % (95% CI)	49.2 (36.1, 62.3)	51.6 (38.6, 64.5)
Interim DCR, % (95% CI)	93.4 (84.1, 98.2)	91.9 (82.2, 97.3)
Interim DoR, months, (95% CI)	9.6 (5.5, NR)	6.9 (5.0, NR)

Full analysis set	IRC (N=70)	Investigator (N=70)
Confirmed PR	30 (42.9)	32 (45.7)
SD	27 (38.6)	25 (35.7)
Non-CR/non-PD*	1 (1.4)	0
PD#	7 (10.0)	8 (11.4)
NE**	5 (7.1)	5 (7.1)
Interim ORR, % (95% CI)	42.9 (31.1, 55.3)	45.7 (33.7, 58.1)
Interim DCR, % (95% CI)	82.9 (71.2, 90.8)	81.4 (70.3, 89.7)
Interim DoR, months, (95% CI)	9.6 (5.5, NR)	6.9 (5.0, NR)

PR: partial response; SD: stable disease; PD: progressive disease, NE: non-evaluable; non-CR/non-PD: non-complete response/non-progressive disease; ORR: objective response rate; DCR: disease control rate; DoR: duration of response; IRC: independent review committee; NR: Not reached.

*1 pt without target lesion according to IRC assessment.
**NE: 2 pts without post-baseline tumor evaluation; 3 pts with 1 unscheduled tumor assessment within 6 weeks.
PD: besides pts with assessment of PD, 3 pts died early without post-baseline tumor evaluation were included.

Potent anti-tumor activity & durable response in subgroups

Subgroup: pathological subtypes

Efficacy evaluable set By IRC assessment	PSC (n=20)	Other NSCLC (n=41)
Interim ORR, n (%) [95% CI]	10 (50.0) [27.2, 72.8]	20 (48.8) [32.9, 64.9]
Interim DCR, n (%) [95% CI]	18 (90.0) [68.3, 98.8]	39 (95.1) [83.5, 99.4]
Interim DoR, months (95% CI)	NR (4.1, NR)	9.6 (4.2, NR)

Full analysis set By IRC assessment	PSC (n=25)	Other NSCLC (n=45)
Interim ORR, n (%) [95% CI]	10 (40.0) [21.1, 61.3]	20 (44.4) [29.6, 60.0]
Interim DCR, n (%) [95% CI]	18 (72.0) [50.6, 87.9]	40 (88.9) [76.0, 96.3]
Interim DoR, months (95% CI)	NR (4.1, NR)	9.6 (4.2, NR)

Subgroup: prior systemic treatment

Efficacy evaluable set By IRC assessment	Treatment naïve (n=24)	Previously treated (n=37)
Interim ORR, n (%) [95% CI]	13 (54.2) [32.8, 74.5]	17 (46.0) [29.5, 63.1]
Interim DCR, n (%) [95% CI]	23 (95.8) [78.9,99.9]	34 (91.9) [78.1, 98.3]
Interim DoR, months (95% CI)	6.8 (3.8, NR)	NR (6.9, NR)

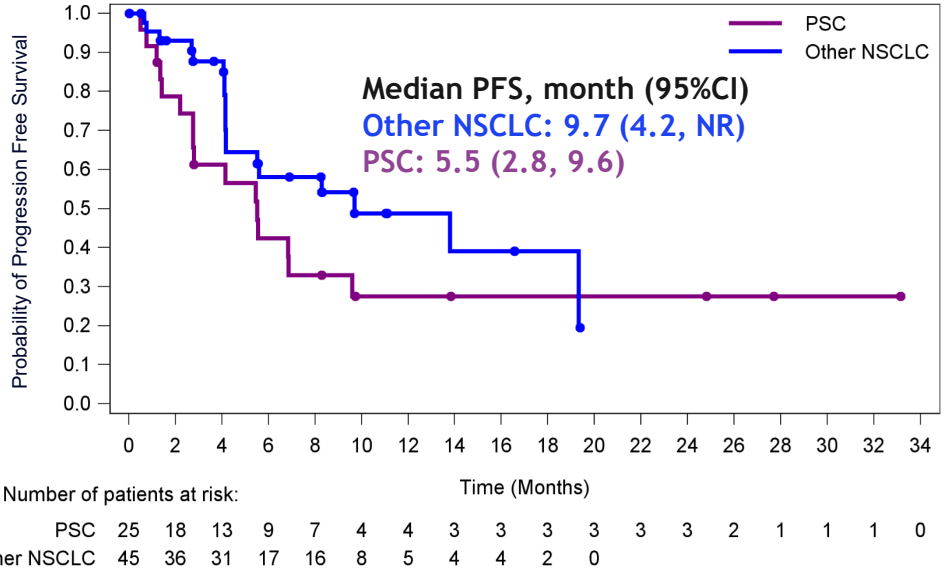
Full analysis set By IRC assessment	Treatment naïve (N=28)	Previously treated (N=42)
Interim ORR, n (%) [95% CI]	13 (46.4) [27.5, 66.1]	17 (40.5) [25.6, 56.7]
Interim DCR, n (%) [95% CI]	23 (82.1) [63.1, 93.9]	35 (83.3) [68.6, 93.0]
Interim DoR, months (95% CI)	6.8 (3.8, NR)	NR (6.9, NR)

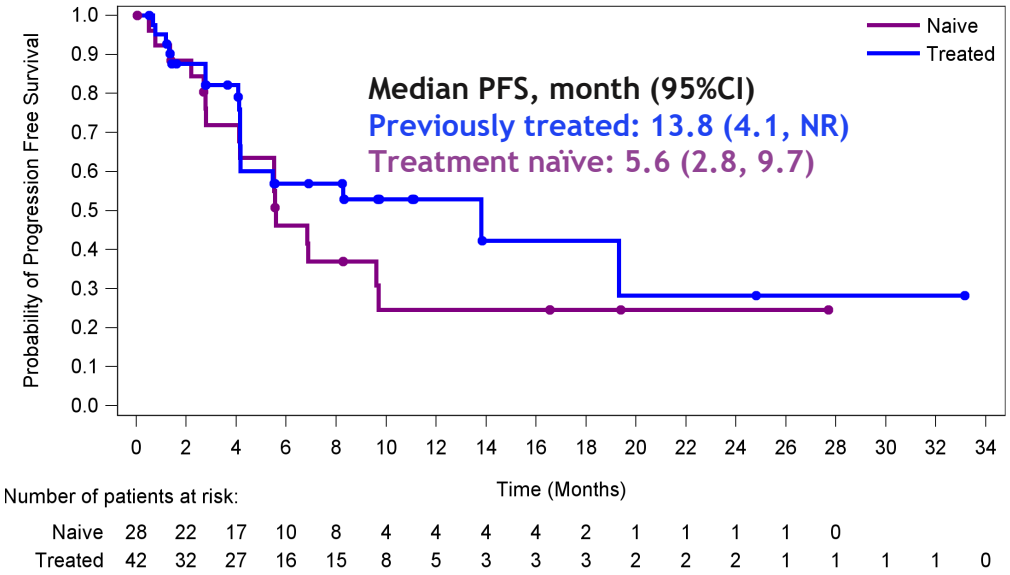
ORR: objective response rate; DCR: disease control rate; DoR: duration of response; IRC: independent review committee. NR: Not reached.

Progression-free survival assessed by IRC & overall survival

As of 31 Mar 2020, PFS and OS data were both not mature.

- Median PFS was 6.9 months (95% CI 4.2, 19.3) with maturity of 50.0%.
- Median OS was 14.0 months (95% CI: 9.7, NR) with maturity of 45.7%.





- PFS of clinical significance both among PSC and other NSCLC subgroups.
- PSC with more progressive disease behavior than other type of NSCLC; PSC resistant to chemotherapy (historically, PFS<3 months)[1,2].

- Promising PFS was observed among previously treated subgroup.
- In the treatment naïve subgroup, nearly half of pts were with PSC (46.4%, 13/28), which reflected in the PFS of this subgroup.

1. Vieira T, et al. J Thorac Oncol. 2013;8(12):1574-7; 2. Ung M, et al. Clin Lung Cancer. 2016;17(5):391-7.

Savolitinib has acceptable tolerability in METex14+ NSCLC pts

*Related AEs (overall rate ≥ 15%)	Total N=70	
	Any Grade n (%)	Grade ≥3 n (%)
Any AE	69 (98.6)	29 (41.4)
Peripheral edema	38 (54.3)	5 (7.1)
Nausea	31 (44.3)	0
Aspartate aminotransferase increased	26 (37.1)	9 (12.9)
Alanine aminotransferase increased	26 (37.1)	7 (10.0)
Vomiting	17 (24.3)	0
Hypoalbuminemia	16 (22.9)	0
Decreased appetite	13 (18.6)	0
Blood bilirubin increased	12 (17.1)	0
Asthenia	11 (15.7)	0
Hypoproteinemia	11 (15.7)	0

*Related: probably related and possibly related.
Treatment emergent adverse event were presented; graded by CTCAE 4.03.

Median treatment duration of 70 pts was 6.8 months (range 0.2 to 37.3); 62 pts received 600mg QD, 8 received 400 mg QD.

Treatment-related serious adverse events (SAE):

- 18 (25.7%) pts reported.
- Hepatic function abnormal (4.3%), drug hypersensitivity (2.9%) and pyrexia (2.9%) reported in ≥2 pts.
- One patient had treatment-related fatal SAEs (tumor lysis syndrome).

Treatment-related AEs leading to dose discontinuation:

- 10 (14.3%) pts reported.
- Drug-induced liver injury and drug hypersensitivity each reported 2 pts (2.9%).
- Others each reported in 1 pt.

Savolitinib treatment was tolerable in most patients; the safety profile was consistent with the prior observations and no new safety signal identified.

Conclusion: Savolitinib demonstrated promising anti-tumor activity and acceptable tolerability in METex14+ NSCLC patients

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Harnessing the power of Chinese Innovation

3 Savolitinib: Papillary Renal Cell Carcinoma

SAVOIR: a Phase III study of savolitinib vs sunitinib in patients with *MET*-driven papillary renal cell carcinoma (PRCC)

Toni K. Choueiri[1], Daniel Y.C. Heng[2], Jae Lyun Lee[3], Mathilde Cancel[4], Remy B. Verheijen[5], Anders Mellemgaard[5], Lone H. Ottesen[5], Melanie M. Frigault[6], Anne L'Hernault[5], Zsolt Szijgyarto[5], Sabina Signoretti[7], Laurence Albiges[8,9]

[1]Dana-Farber Cancer Institute and Harvard Medical School; [2]Department of Medical Oncology, Tom Baker Cancer Center, University of Calgary, Calgary, Canada; [3]Asan Medical Center and University of Ulsan College of Medicine, Seoul, South Korea; [4]CHU Bretonneau Centre, Tours University, France; [5]Oncology R&D, AstraZeneca, Cambridge, UK; [6]Oncology R&D, AstraZeneca, Boston, MA, USA; [7]Department of Pathology, Brigham and Women's Hospital, Boston, MA, USA; [8]Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, MA, USA; [9]Department of Cancer Medicine, Institut Gustave Roussy, Villejuif, France

Introduction

- PRCC is the most common type of non-clear cell RCC, accounting for approximately 15% of all RCC[1–3]
- As a subset of PRCC cases are *MET*-driven, MET inhibition may be an appropriate targeted treatment approach[1,2]
  - *MET* has been found to be associated with major chromosome-level alterations in PRCC[4]
- Savolitinib (AZD6094, HMPL-504, volitinib) is a potent and selective MET-TKI under investigation in several malignancies[5–7]
  - Preclinical data and Phase I studies have shown that savolitinib has promising activity in animal models of PRCC, and leads to partial responses in patients with *MET*-driven PRCC[8,9]
- In a single-arm Phase II study, savolitinib demonstrated antitumor activity in patients with *MET*-driven PRCC[10]
  - Partial responses were confirmed in 18% of patients with *MET*-driven PRCC vs none with *MET*-independent disease[10]
  - This Phase II trial justified the investigation of savolitinib in a randomized controlled trial of *MET*-driven, locally advanced or metastatic PRCC[10]
- **Here we report the results from the Phase III SAVOIR study (NCT03091192), which assessed savolitinib vs standard of care sunitinib in patients with *MET*-driven, locally advanced or metastatic PRCC**

1. Linehan et al. N Engl J Med 2016;374:135–145; 2. Akhtar et al. Adv Anat Pathol 2019;26:124–132; 3. Graham et al. Eur Urol Oncol 2019;2:643–648; 4. Albiges et al. Clin Cancer Res 2014;20:3411–3421; 5. Hua et al. Cancer Res. 2015;75(15 Suppl):CT305; 6. Jia et al. J Med Chem 2014;25:57:7577–7589; 7. Gavine et al. Mol Oncol 2015;9:323–333; 8. Schuller et al. Clin Cancer Res 2015;21:2811–2819; 9. Gan et al. Clin Cancer Res 2019;25:4924–4932; 10. Choueiri et al. J Clin Oncol 2017;35:2993–3001. PRCC, papillary renal cell carcinoma; RCC, renal cell carcinoma; TKI, tyrosine kinase inhibitor

SAVOIR study design

Open-label, randomized, Phase III trial (NCT03091192)

Patients with locally advanced or metastatic PRCC

Key inclusion criteria

- ≥18 years
- Central confirmation of a *MET*-driven tumor (chromosome 7 gain / *MET* or *HGF* amplification / *MET* kinase domain mutations)*
- Measurable disease
- Karnofsky Performance Status ≥80%
- Patients could have received prior systemic treatment in the advanced setting or be treatment-naïve#

Savolitinib
600 mg QD
(or 400 mg if <50 kg)

Randomized 1:1

Sunitinib
50 mg QD in 6-week cycles of 4 weeks on / 2 weeks off

RECIST 1.1 assessment every 6 weeks‡ until objective progressive disease

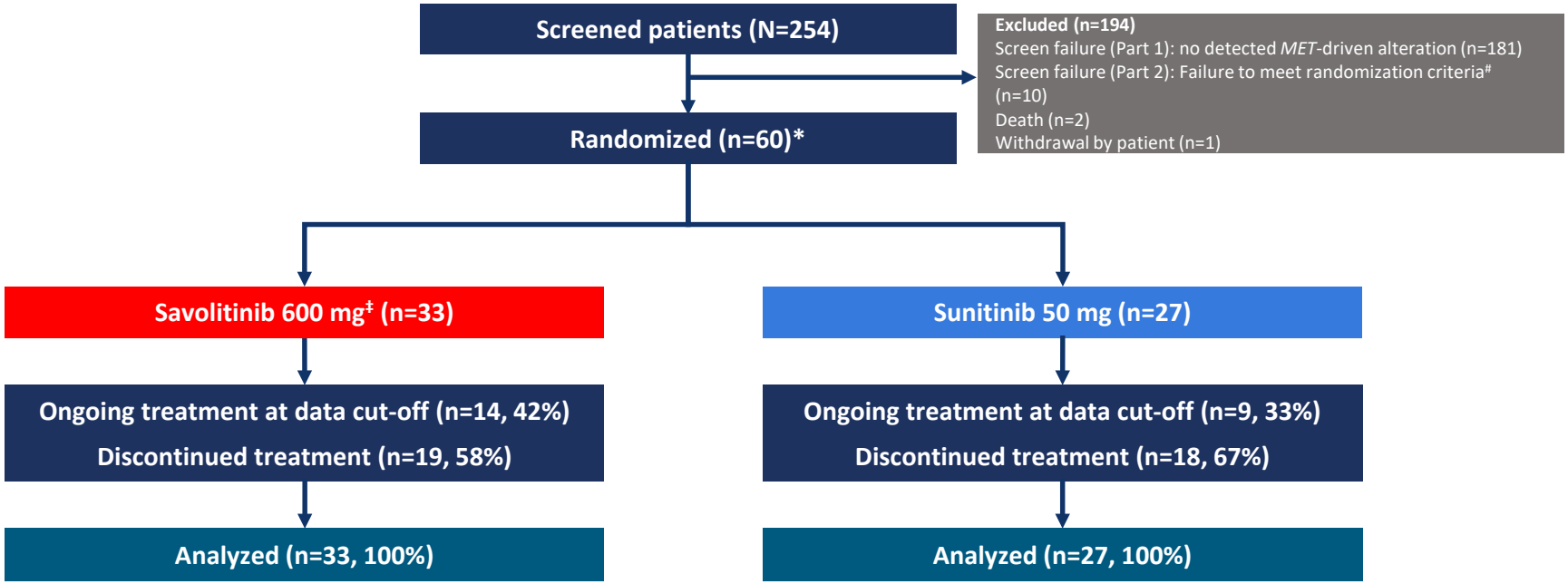
Approximately 360–450 patients were planned to be screened, in order to randomize ~180 patients

After external data on predicted PFS with sunitinib in patients with *MET*-driven disease became available, study enrollment was closed early[1]

- **Primary endpoints:** PFS by BICR
- **Secondary endpoints**: OS and ORR by BICR, safety and HRQoL

1. Albiges et al. ASCO; May 29–31, 2020; presented here: abstract e19321; 2. Frigault et al. AACR 2018;78:4541–4541.
*In the absence of co-occurring *FH* or *VHL* mutations.[2] #Patients were excluded if they had previously received sunitinib or a MET inhibitor. ‡Follow-up every 12 weeks after first year. BICR, blinded independent central review; HRQoL, health-related quality of life; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PRCC, papillary renal cell carcinoma; QD, once daily; RCC, renal cell carcinoma; RECIST, Response Evaluation Criteria in Solid Tumors

SAVOIR patient disposition



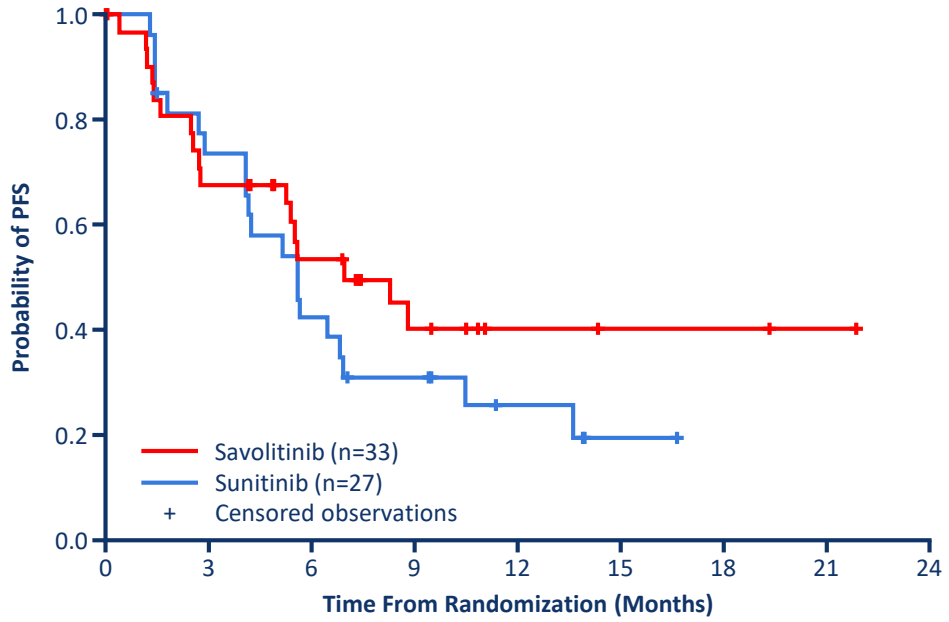
Data cut-off August 19, 2019.
*Enrollment was stopped before reaching target 180 patients due to external data on predicted PFS with sunitinib in patients with *MET*-driven disease becoming available. #Patients who had *MET*-driven alteration in Part 1 screening but did not fulfil eligibility criteria for the main study in Part 2 screening, and therefore were not randomized. ‡Patients in the savolitinib group were to receive 600 mg of savolitinib, or 400 mg of savolitinib if they weighed <50 kg; all patients in this group received 600 mg savolitinib. PFS, progression-free survival

SAVOIR patient baseline characteristics

Demographic characteristics	Savolitinib 600 mg (N=33)	Sunitinib 50 mg (N=27)
Age, median (range), years	60 (23, 78)	65 (31, 77)
Sex: male / female, n (%)	29 (88) / 4 (12)	17 (63) / 10 (37)
Race: white / black / Asian / other, n (%)	29 (88) / 1 (3) / 2 (6) / 1 (3)	23 (85) / 1 (4) / 3 (11) / 0
IMDC risk group*: poor / intermediate / favorable, n (%)	4 (12) / 22 (67) / 7 (21)	3 (11) / 17 (63) / 7 (26)
Line of therapy, n (%)		
1st line	28 (85)	25 (93)
≥ 2nd line with prior VEGF-TKI	3 (9)	0
≥ 2nd line without prior VEGF-TKI	2 (6)	2 (7)
Karnofsky Performance Status: 100% / 90% / 80%, n (%)	11 (33) / 15 (45) / 7 (21)	4 (15) / 16 (59) / 7 (26)
SAVOIR clinical trial assay-specific *MET*-driven (BICR)#, n (%)		
MET amplification‡	1 (3)	1 (4)
HGF amplification‡	1 (3)	0
MET mutation†	2 (6)	3 (11)
Chromosome 7 gain§	30 (91)	26 (96)

Data cut-off August 19, 2019. *Calculated from IVRS. #Patients can be counted in more than one subtype group for *MET*-driven by SAVOIR clinical trial assay. ‡Amplification of ≥6 copies (in diploid genome). †*MET* kinase domain mutations (allele frequency >5%). §Gain of 1 copy above ploidy of the genome. BICR, blinded independent central review; IMDC, Independent Data Monitoring Committee; IVRS, interactive voice response system; VEGF-TKI, vascular endothelial growth factor receptor tyrosine kinase inhibitor

SAVOIR progression-free survival



Number of Patients at Risk										Number Randomized/ Number of Events
Savolitinib	33	21	15	8	4	3	3	1	0	33/17
Sunitinib	27	19	11	7	4	1	0	0	0	27/20

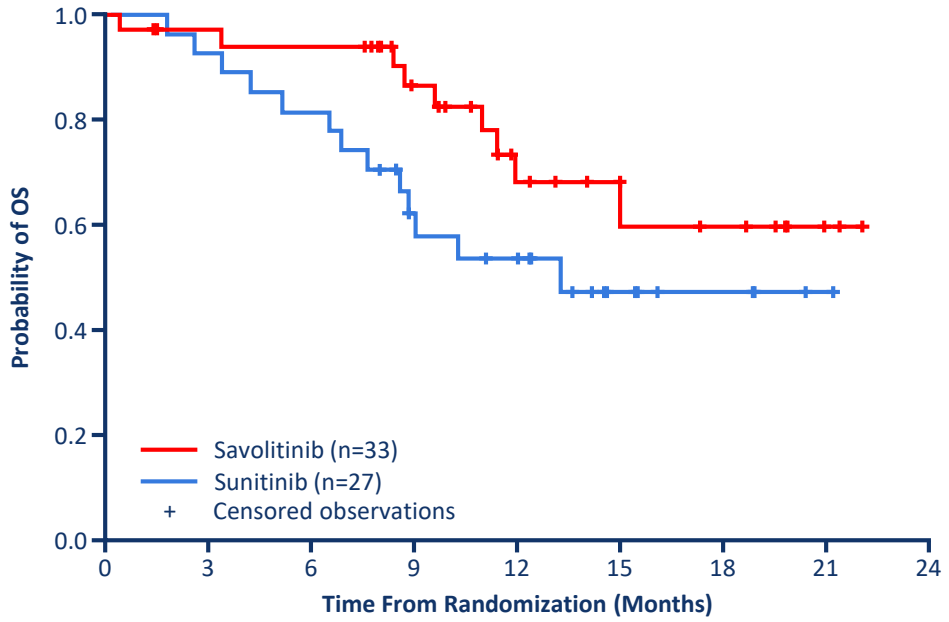
Median PFS by BICR in months (95% CI)
Savolitinib 7.0 (2.8, NC)
Sunitinib 5.6 (4.1, 6.9)

HR (95% CI): 0.71 (0.37, 1.36)
Log-rank two-sided *P*-value: 0.313

PFS reported for sunitinib was in range with previous studies[1,2]

Data cut-off August 19, 2019.
1. Albiges et al. J Clin Oncol 2018;36:3624–3631; 2. Ravaud et al. Ann Oncol 2015;26:1123–1128. BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; NC, not calculated; PFS, progression-free survival

SAVOIR overall survival



Number of Patients at Risk										Number Randomized/ Number of Events
Savolitinib	33	31	30	22	13	7	6	2	0	33/9
Sunitinib	27	25	22	14	10	5	3	1	0	27/13

Median OS by BICR in months (95% CI)
Savolitinib NC (11.9, NC)
Sunitinib 13.2 (7.6, NC)

HR (95% CI): 0.51 (0.21, 1.17)
Log-rank two-sided *P*-value: 0.110

Data cut-off August 19, 2019.
BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; NC, not calculated; OS, overall survival

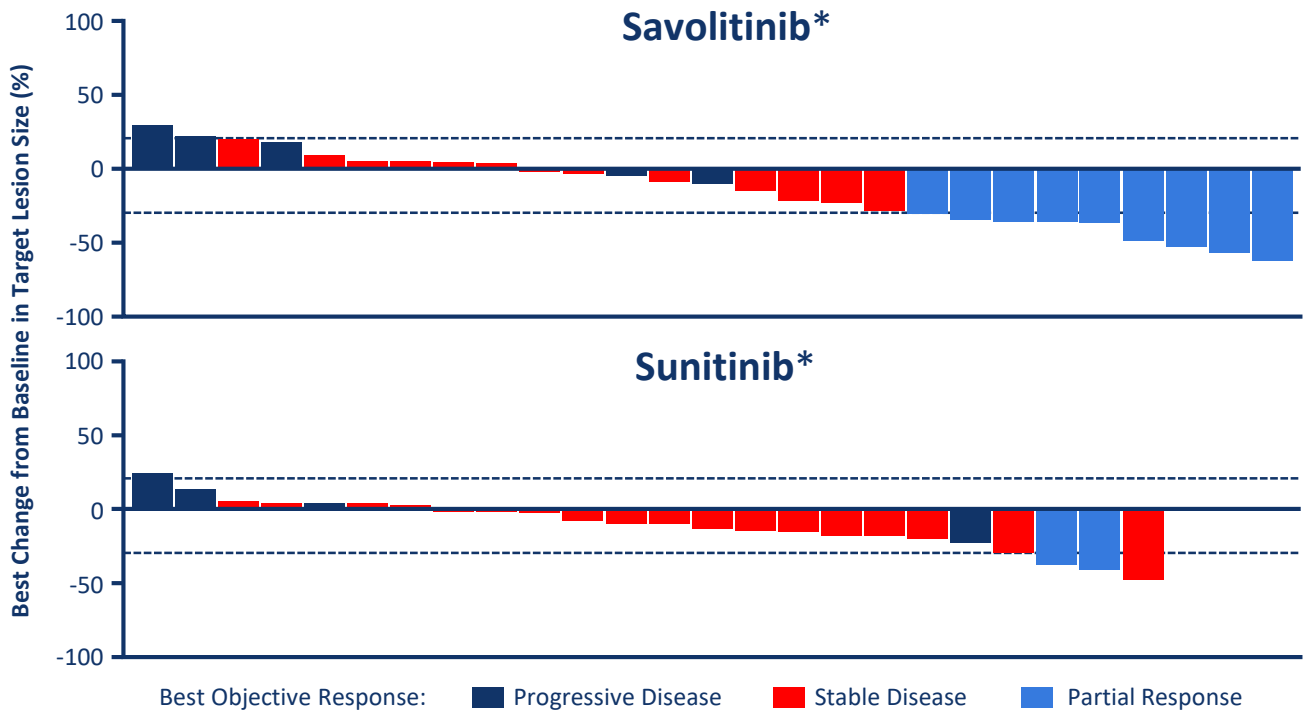
SAVOIR antitumor activity

Endpoint, n (%) [95% CI]	Savolitinib (N=33)	Sunitinib (N=27)
ORR by BICR,* *All partial responses*	9 (27) [13.3, 45.5]	2 (7) [0.9, 24.3]
Disease control rate by BICR,# At 6 months At 12 months	 16 (48) [30.8, 66.5] 10 (30) [15.6, 48.7]	 10 (37) [19.4, 57.6] 6 (22) [8.6, 42.3]

- As of the data cut-off, no responding patients in the savolitinib group had disease progression, compared with 1 of 2 responding patients in the sunitinib group; response rate reported for sunitinib was in range with previous studies[1,2]
- It was not possible to calculate median DoR from the data as there were too few events
- Three responders on savolitinib were followed for >6 months after onset of response

Data cut-off August 19, 2019.
1. Albiges et al. J Clin Oncol 2018;36:3624–3631; 2. Ravaud et al. Ann Oncol 2015;26:1123–1128. *Response did not need confirmation. #Disease control rate = complete response + partial responses + stable disease at time point.
BICR, blinded independent central review; CI, confidence interval; DoR, duration of response; NC, not calculated; ORR, objective response rate

Best percentage change from baseline in target lesion size



Patients who experienced any tumor shrinkage
Savolitinib: n=18, 67%
Sunitinib: n=17, 71%

Data cut-off August 19, 2019. *Savolitinib n=27; sunitinib n=24. Target lesion size, best percentage change waterfall plot by BICR. Nine patients (savolitinib n=6; sunitinib n=3) were not included in the target lesion size plot: no target lesions present at baseline that were selected as target lesions for the purpose of BICR assessment n=7 (savolitinib n=5; sunitinib n=2); no post-baseline target lesion assessment captured n=2 (savolitinib n=1; sunitinib n=1). BICR, blinded independent central review

SAVOIR safety summary

Patients with an event, n (%)	Savolitinib 600 mg (N=33)	Sunitinib 50 mg (N=27)
Any AE	30 (91)	27 (100)
Possibly causally related to treatment	22 (67)	25 (93)
Any AE grade ≥3	14 (42)	22 (81)
Possibly causally related to treatment	8 (24)	17 (63)
Any AE leading to death	0	3 (11)
Possibly causally related to treatment	0	1 (4)
Any AE leading to dose interruption of treatment	9 (27)	15 (56)
Any SAE	8 (24)	8 (30)
Possibly causally related to treatment	4 (12)	4 (15)
Any SAE leading to treatment discontinuation	3 (9)	2 (7)
Possibly causally related to treatment*	2 (6)	2 (7)
Received post-discontinuation disease-related therapy	12 (36)[#]	5 (19)[#]

Data cut-off August 19, 2019.
*Possible treatment related SAEs that led to discontinuation were: ascites, increased alanine aminotransferase and increased aspartate aminotransferase for savolitinib; and thrombocytopenia and aggravated condition for sunitinib. [#]These values reflect the number of patients who received ≥1 post-discontinuation disease-related anticancer therapy; subjects could receive more than one type of anticancer therapy. AE, adverse event; SAE, serious adverse event

Most common adverse events independent of causality

AEs*, n (%)	Savolitinib 600 mg (N=33)		Sunitinib 50 mg (N=27)	
	All	Grade ≥3	All	Grade ≥3
Any AE	30 (91)	14 (42)	27 (100)	22 (81)
Anemia	2 (6)	0	12 (44)	4 (15)
Nausea	2 (6)	0	9 (33)	0
Decreased appetite	1 (3)	0	8 (30)	1 (4)
Palmar-plantar erythrodysesthesia syndrome	0	0	7 (26)	0
Thrombocytopenia	0	0	7 (26)	2 (7)
Diarrhea	0	0	6 (22)	1 (4)
Hypertension	1 (3)	0	6 (22)	4 (15)
Edema peripheral	11 (33)	0	3 (11)	0
Alanine aminotransferase increased	8 (24)	5 (15)	3 (11)	2 (7)
Aspartate aminotransferase increased	8 (24)	4 (12)	5 (19)	2 (7)
Dyspnea	7 (21)	1 (3)	4 (15)	0

Data cut-off August 19, 2019.
*≥20% in either treatment group.
AE, adverse event

Conclusions

- Although patient numbers and follow-up were limited, savolitinib demonstrated encouraging efficacy and an improved safety profile vs sunitinib
- Patients receiving savolitinib experienced fewer grade ≥3 AEs and required fewer dose modifications than those receiving sunitinib, and there were fewer treatment-related AEs of any grade in the savolitinib group
- More patients from the savolitinib arm received a subsequent therapy
- Overall, in SAVOIR, early termination of recruitment precludes definitive conclusions from being drawn due to the small dataset. However, based on the emerging data, further investigation of savolitinib as a treatment option for *MET*-driven PRCC is warranted

AE, adverse event; PRCC, papillary renal cell carcinoma

Acknowledgments

Thanks to all the patients and their families

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In press at JAMA Oncology

JAMA Oncology | **Original Investigation**

ONLINE FIRST

May 29, 2020

Efficacy of Savolitinib vs Sunitinib in Patients With *MET*-Driven Papillary Renal Cell Carcinoma

The SAVOIR Phase 3 Randomized Clinical Trial

Toni K. Choueiri, MD[1]; Daniel Y. C. Heng, MD[2]; Jae Lyun Lee, MD[3]; Mathilde Cancel, MD[4]; Remy B. Verheijen, PhD[5]; Anders Mellemgaard, MD[5]; Lone H. Ottesen, MD[5]; Melanie M. Frigault, PhD[6]; Anne L'Hernault, PhD[5]; Zsolt Szijgyarto, PhD[5]; Sabina Signoretti, MD[7]; Laurence Albiges, MD[8,9]

» Author Affiliations | Article Information

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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).*

4 Surufatinib

Efficacy and safety of Surufatinib in United States Patients with Neuroendocrine Tumors

American Society of Clinical Oncology, 2020

Presented by Arvind Dasari, MD

Dasari A [1], Li D [2], Sung M [3], Tucci C [4], Kauh J [4], Kania M [4], Paulson S [5]

[1] MD Anderson Cancer Center, Houston, TX, USA, [2] City of Hope Comprehensive Cancer Center and Beckman Research Institute, Duarte, CA, USA, [3] Tisch Cancer Institute at Mount Sinai, New York, NY, USA, [4] Hutchison MediPharma International Inc., Florham Park, NJ, USA, [5] Baylor Sammons Cancer Center, Dallas, TX, USA.

Introduction

- Surufatinib is a novel, oral, targeted inhibitor of tyrosine kinases VEGFR1, 2, & 3, FGFR1, and CSF-1R.

- Two randomized placebo controlled phase 3 trials in advanced neuroendocrine tumor (NET) patients are complete. Both trials stopped per a pre-planned interim analysis showing superior efficacy of surufatinib over placebo.

  ↗ SANET-ep (NCT02588170)
  Demonstrated superior efficacy in pts with advanced extra-pancreatic neuroendocrine tumors (epNET).
  - ☐ Median progression free survival 9.2 vs. 3.8 months (HR: 0.334; 95% CI: 0.223, 0.499; p<0.0001).

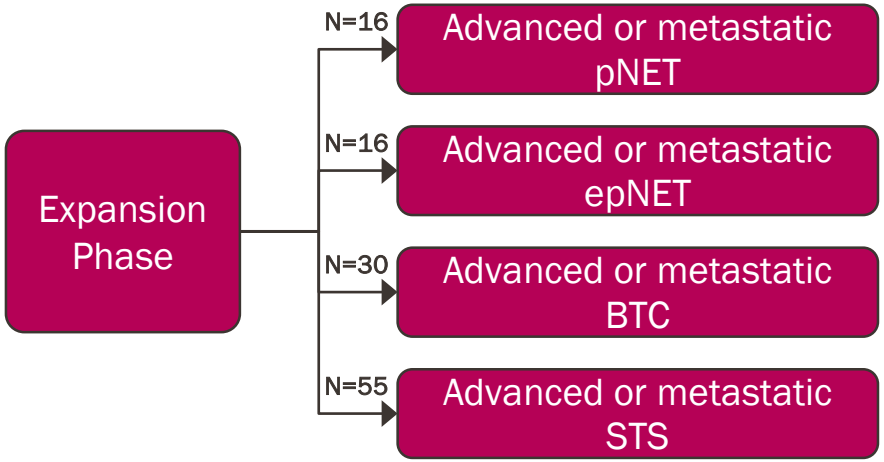
  ↗ SANET-p (NCT02589821)
  Demonstrated superior efficacy in pts with advanced pancreatic neuroendocrine tumors (pNET)[1].
  - ☐ Results pending disclosure at upcoming scientific conference.

- We report data from the ongoing US trial in patients with NETs to demonstrate similar efficacy and safety in a US population.

[1] https://www.chi-med.com/surufatinib-phase-iii-sanet-p-study-achieved-primary-endpoint/

Methods

- A dose escalation/expansion study (NCT02549937) was conducted to evaluate and confirm the effects of surufatinib in US patients.
- Dose escalation was completed and the MTD/RP2D was determined to be 300mg QD.
  - ↗ Equivalent to previous trials conducted in China.
- The primary objective of the expansion cohorts was to evaluate anticancer activity in patients with select indications including pNETs and epNETs.



Primary Endpoint:
Progression Free Survival (PFS)

Secondary Endpoints:
Objective Response Rate (ORR), Disease Control Rate (DCR), Time to Response (TTR), Duration of Response (DOR), Safety, PK

Exploratory Endpoints:
Overall Survival (OS), Tumor marker evaluation

MTD = maximum tolerated dose; RP2D = recommended Phase 2 dose; BTC = biliary tract cancer; STS = soft tissue sarcoma.

Anti-tumor Activity

- As of 21-Apr-2020, 32 patients with heavily pre-treated progressive NETs (median prior lines of treatment: 3; range 1-8).
- 15 patients remain on active treatment – 5 pNET pts (31%) and 10 epNET patients (63%).
- An objective response rate of 18.8% was observed in pNET patients
- No epNET patients have yet achieved a cPR (1 unconfirmed PR)

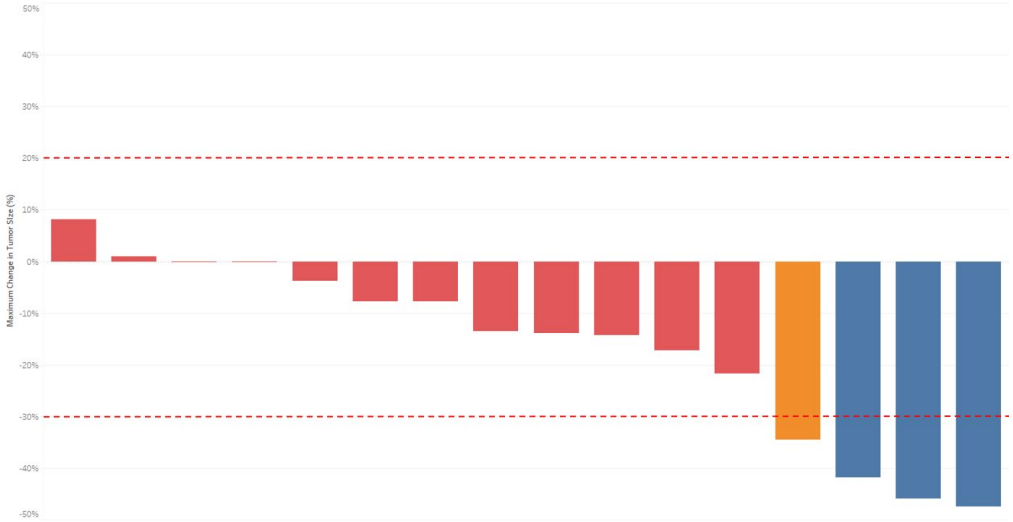
Best Tumor Assessment	pNET, n=16 n (%)	epNET, n=16 n (%)
Complete Response (CR)	0	0
Partial Response (PR)	3 (18.8)	0
Stable Disease (SD)	13 (81.2)*	16 (100)⁺
Progressive Disease (PD)	0	0
Objective Response Rate (ORR)	18.8%	0%
Disease Control Rate (DCR)	100%	100%
Median Duration of Treatment	7.1 months Range (2.0-17.5)	4.9 months Range (1.0-10.2)

**One pNET patient had an unconfirmed PR*
⁺One epNET patient had an unconfirmed PR

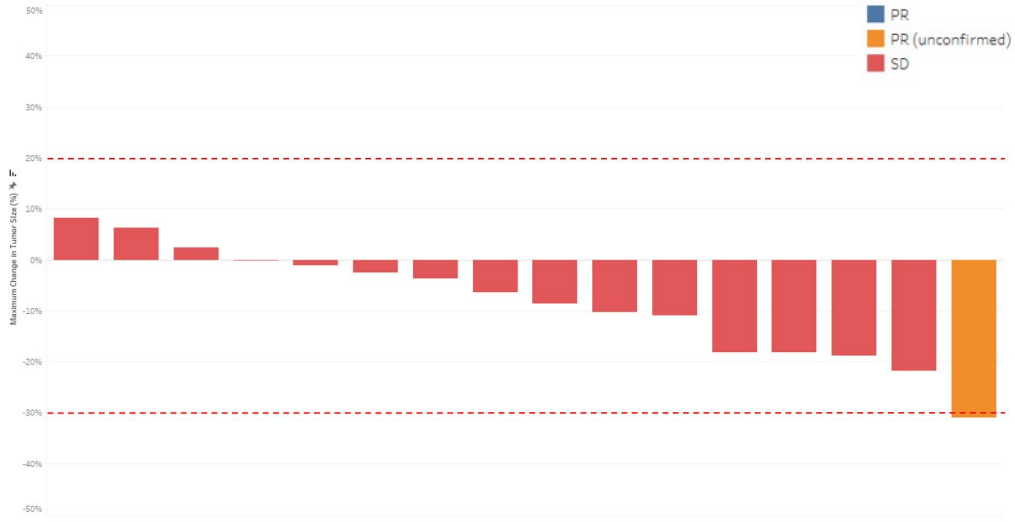
Anti-tumor Activity
Maximum Change in Tumor Size (%)

- Surufatinib shows clinical efficacy irrespective of prior lines of therapy, including everolimus or sunitinib (median prior lines of treatment: pNET: 4; epNET: 2)
- Tumor growth was controlled in all NET patients

Best Response of Target Lesions: pNET

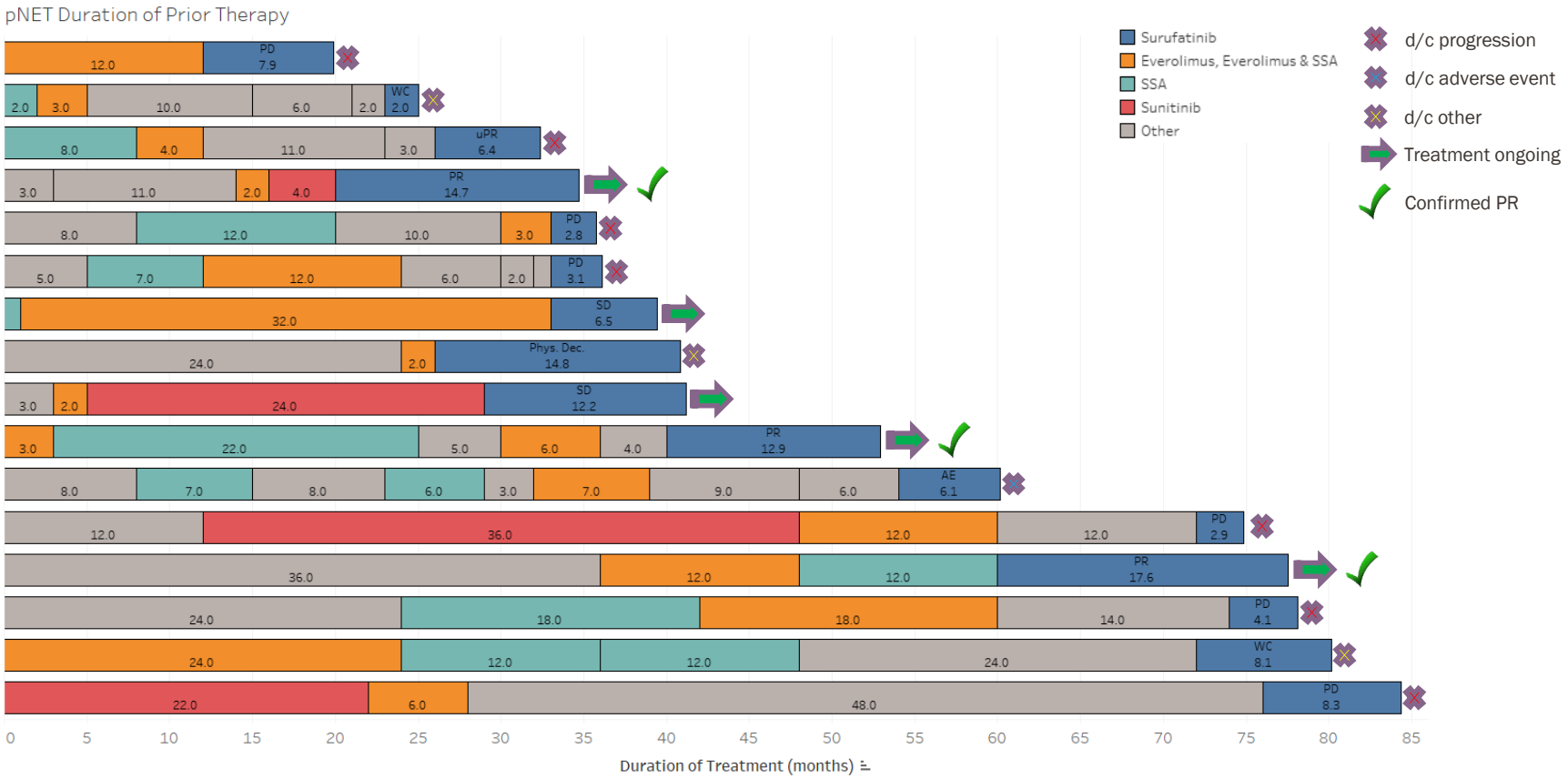


Best Response of Target Lesions: epNET



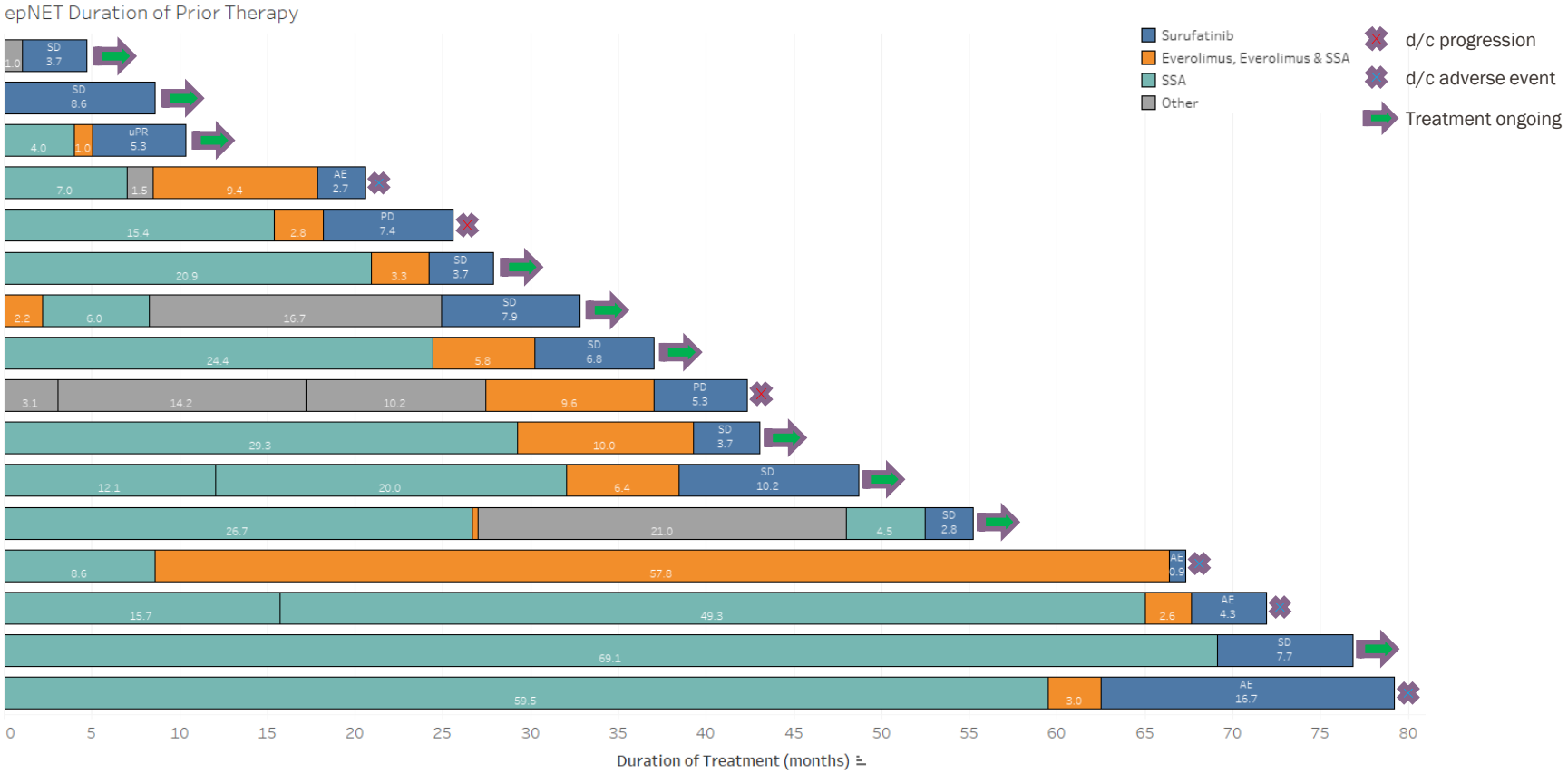
Anti-tumor Activity
Duration of Treatment pNET

- Surufatinib shows clinical efficacy irrespective of prior lines of therapy, including everolimus or sunitinib (median prior lines of treatment: 4)



Anti-tumor Activity
Duration of Treatment epNET

- Surufatinib shows clinical efficacy irrespective of prior lines of therapy, including everolimus (median prior lines of treatment: 2)



Safety Results

- The safety profile of surufatinib remains consistent with previously completed trials.
- 30 pts (93.8%) had reported at least one adverse event (AE), and 22 pts (68.8%) reported ≥ grade 3 AE's.
- 5 patients discontinued treatment due to AE (pNET: 1; epNET 4)

TEAEs >15%	pNET (N=16) n (%)		epNET (N=16) n (%)		Total (N=32) n (%)	
	Any Grade	≥ Grade 3	Any Grade	≥ Grade 3	Any Grade	≥ Grade 3
Hypertension	6 (37.5)	2 (12.5)	13 (81.3)	7 (43.8)	19 (59.4)	9 (28.1)
Fatigue	8 (50.0)	0	8 (50.0)	0	16 (50.0)	0
Proteinuria	3 (18.8)	0	13 (81.3)	1 (6.3)	16 (50.0)	1 (3.1)
Diarrhea	8 (50.0)	3 (18.8)	5 (31.3)	1 (6.3)	13 (40.6)	4 (12.5)
Abdominal pain	1 (6.3)	0	7 (43.8)	0	8 (25.0)	0
AST increase	4 (25.0)	0	4 (25.0)	0	8 (25.0)	0
Hematuria	3 (18.8)	1 (6.3)	5 (31.3)	1 (6.3)	8 (25.0)	2 (6.3)
Rash	2 (12.5)	0	6 (37.5)	0	8 (25.0)	0
Headache	2 (12.5)	1 (6.3)	4 (25.0)	0	6 (18.8)	1 (3.1)
ALT increase	2 (12.5)	0	3 (18.8)	0	5 (15.6)	0
Peripheral Edema	1 (6.3)	0	4 (25.0)	0	5 (15.6)	0
Platelet Count Decreased	1 (6.3)	0	4 (25.0)	0	5 (15.6)	0
Urinary Retention	0 (0)	0	5 (31.3)	1 (6.3)	5 (15.6)	1 (3.1)
Vomiting	3 (18.8)	0	2 (12.5)	1 (6.3)	5 (15.6)	1 (3.1)

Conclusions

- Surufatinib has demonstrated promising antitumor activity in US patients with progressive NETs
- A manageable safety profile has been seen and is comparable with the larger pool of surufatinib safety data
- PK and dose exposure data is consistent with collective pool of patients across the US and China[1]

Thank you to all of our patients, their families and participating site staff for their time and efforts in these trials

For questions and comments please contact:
Arvind Dasari, MD - ADasari@mdanderson.org
John Kauh, MD – Johnk@hmplglobal.com

[1] *Dasari A. et al., Comparison of Pharmacokinetic Profiles and Safety of Surufatinib in Patients from China and the United States. American Association of Cancer Research 2020*

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5 Conclusion and Q&A

Summary
Robust Efficacy in Challenging Patient Settings

Savolitinib in Exon 14 NSCLC

- **49.2% ORR**, 93.4% DCR & 6.9 mo PFS, **despite 36% PSC pts**.
  - Generally well tolerated and consistent with prior observations.
- **NDA accepted** by NMPA in May; AZ lung cancer team to launch.
- Evaluating global clinical development.

Savolitinib in PRCC (SAVOIR)

- Encouraging efficacy & an improved safety profile vs. sunitinib.
  - **27% vs 7%** ORR, OS hazard ratio 0.51, 42% vs 81% ≥Gr3 AEs.
- Evaluating **restart of global clinical** development.

Surufatinib in US NET Patients

- Show antitumor activity in US NET, with safety profile, PK and dose exposure data consistent across US and China patients.
- **Agreed with FDA at Pre-NDA mtg**: data from prior Phase IIIs + US data could form basis of **Fast Track rolling US NDA submission**, starting late 2020.

Q&A

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Thank you