



MEDIVIR Q3 REPORT 2023 & FOSTROX DEVELOPMENT UPDATE

MEDIVIR

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Today's presenters



Jens Lindberg
CEO



Dr. Pia Baumann
CMO



Magnus Christensen
CFO



Dr. Jeff Evans

- Professor of Translational Cancer Research, University of Glasgow.
- Lead of the Glasgow Experimental Cancer Medicine Centre (ECMC) and National Clinical Lead of the NHS Scotland Cancer Research Network.
- Investigator in the fostrox clinical development program & member of Medivir's Scientific Advisory Board.






Financial summary Q3, 2023











Consolidated Income Statement, summary (SEK m)

	Q3		Q1 - Q3		Full year
	2023	2022	2023	2022	2022
Net turnover	0.8	1.1	3.2	2.1	4.4
Other operating income	0.2	0.8	1.1	1.6	1.8
Total income	1.0	2.0	4.3	3.8	6.2
Other external expenses	-18.1	-11.1	-52.4	-53.3	-69.1
Personnel costs	-5.8	-3.9	-19.5	-16.0	-20.7
Depreciations and write-downs	-0.7	-0.7	-2.1	-1.9	-2.6
Other operating expenses	-0.4	-0.9	-1.0	-1.3	-1.2
Operating profit/loss	-24.1	-14.6	-70.6	-68.7	-87.4
Net financial items	0.5	-0.2	1.6	-1.9	-1.4
Profit/loss after financial items	-23.6	-14.8	-69.1	-70.7	-88.8
Tax	-	-	-	-	-
Net profit/loss for the period	-23.6	-14.8	-69.1	-70.7	-88.8

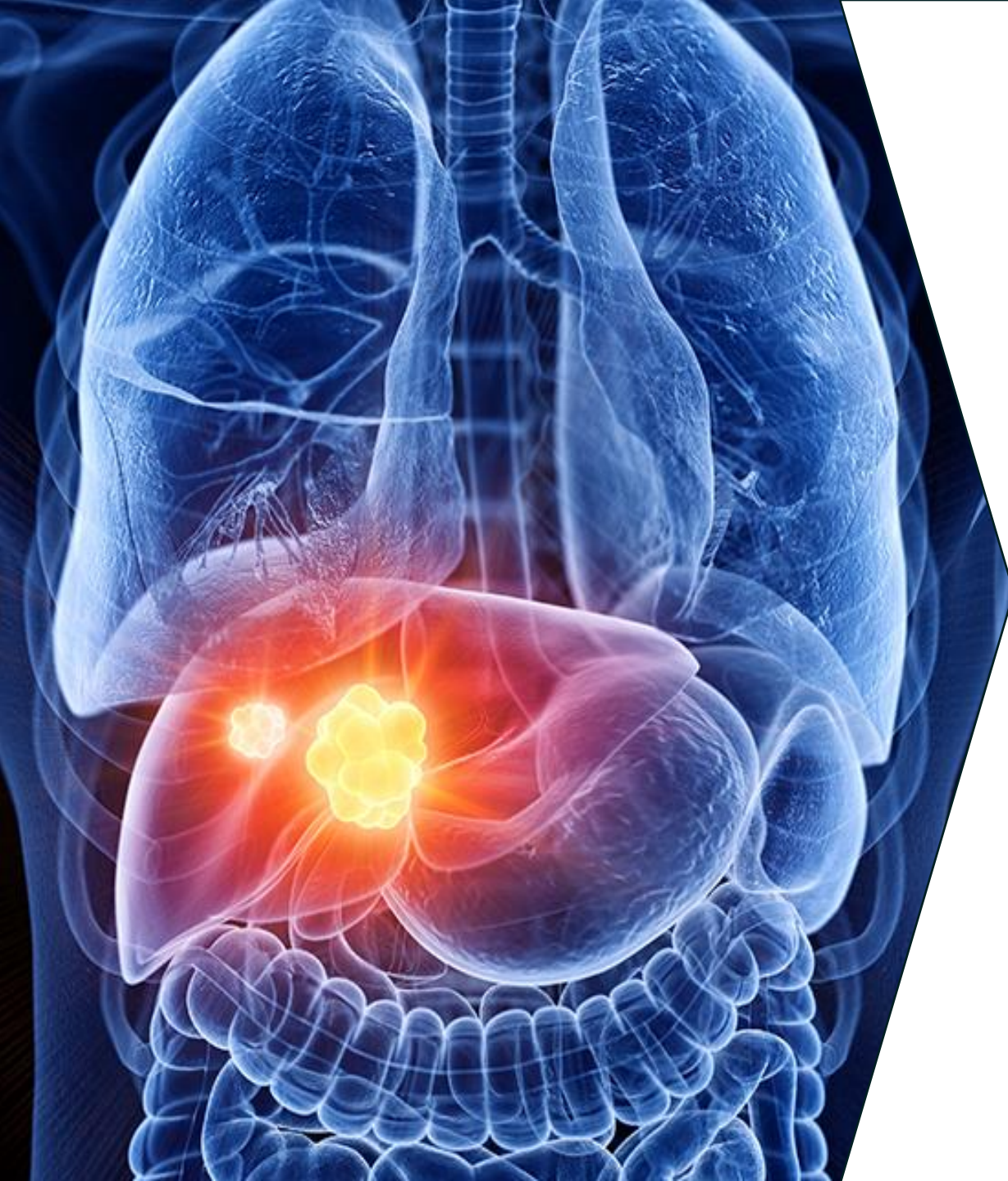
- Net turnover for Q3 was SEK 0.8 million
- Operating loss for Q3 was SEK -24.1 million
- Cash flow from operating activities for Q3 was SEK -21.0 million
- Cash balance end of Q3 was SEK 61.1 million

Broad pipeline with focus on in-house program fostrox

IN-HOUSE PROGRAM – FOSTROX								
PROJECT	DISEASE AREA	PATIENT POPULATION	PRE-CLIN	PH 1	PH 2	PH 3	NEXT EVENTS	
Fostrox	HCC	Monotherapy (Proof-of-Concept)					<ul style="list-style-type: none"> Fostrox + Lenvima data read-out Fostrox + Lenvima ph 2b initiation 	
		Fostrox + Lenvima						
		Fostrox + Keytruda						

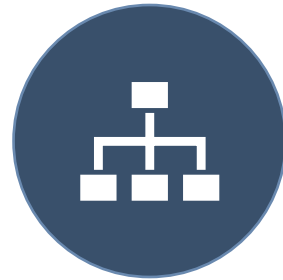
PARTNERING PROGRAMS								
PROJECT	PARTNER	DISEASE AREA	PRE-CLIN	PH 1	PH 2	PH 3	MARKET	POTENTIAL NEXT EVENT(S)
Xerclear	GSK	Herpes						<ul style="list-style-type: none"> Partnered – Reg. in China
Remetinostat	TBD	CTCL/BCC/ SCC						<ul style="list-style-type: none"> Partnering
MIV-711	TBD	Osteoarthritis						<ul style="list-style-type: none"> Partnering
Birinapant	IGM	Solid tumors						<ul style="list-style-type: none"> Partnered – Dose selection & initiation of dose expansion
TNG348	Tango	Cancer						<ul style="list-style-type: none"> Partnered – Phase I start in H1 2024
USP-7	Ubiquigent	Cancer						<ul style="list-style-type: none"> Partnered – Partnering agreement for Ubiquigent
MET-X	INFEX	Infection						<ul style="list-style-type: none"> Partnered – Phase I start 2023/2024

Completed
Ongoing
Planned



Fostrox + Lenvima[®] update

Phase 1b/2a data update & comparison with SoC



HCC today & tomorrow

Fostrox + Lenvima in a future clinical context



Fostrox moving forward

Target segment & path to get there with speed

Fostrox + Lenvima – Key take-aways from today's update



Fostrox + Lenvima shows consistently improved efficacy compared with Lenvima alone



Continued development for fostrox + Lenvima in 2nd line HCC with Accelerated Approval intent 2027

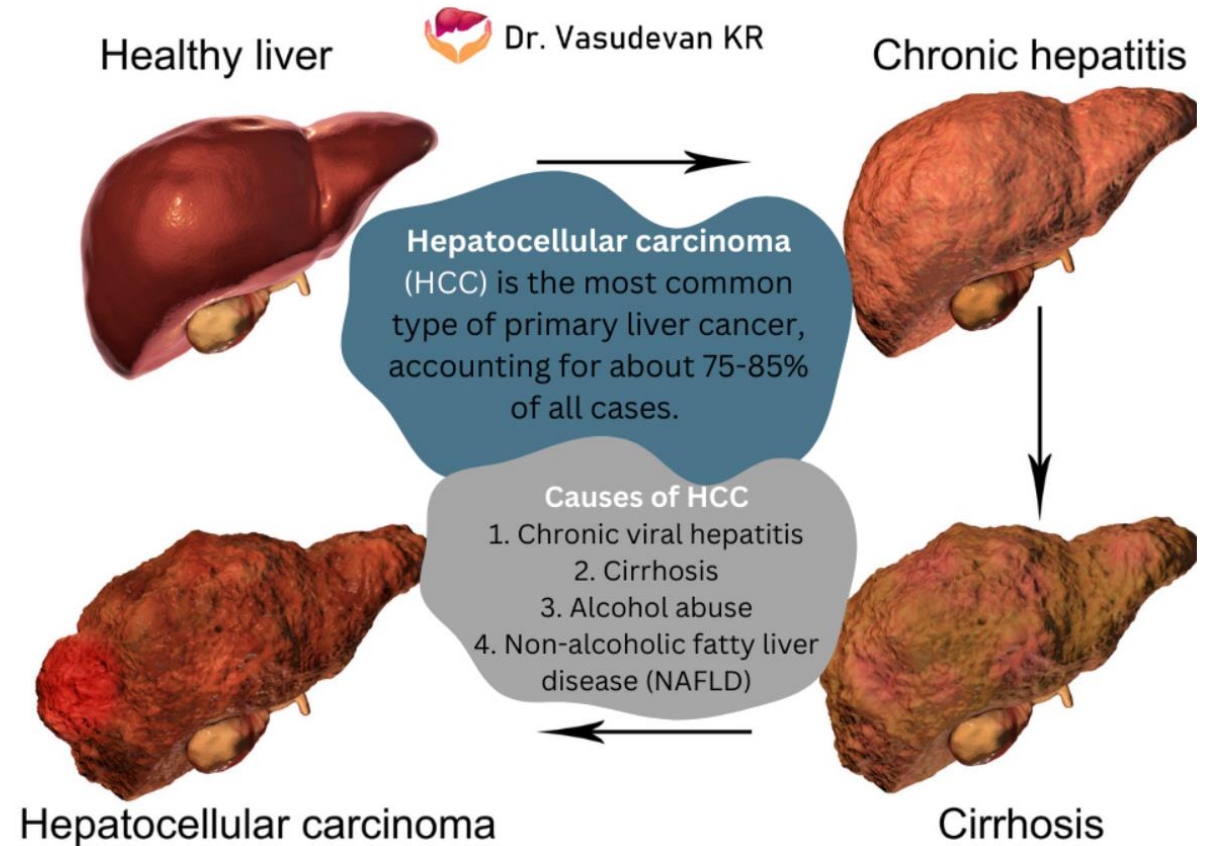


2nd line HCC post Tecentriq[®] + Avastin[®] lacks approved treatments & is a market valued at ~\$2.5bn annually

Fostrox + Lenvima – HCC background and phase 1b/2a clinical data in 2nd line HCC

Advanced hepatocellular carcinoma (HCC) is an underserved disease with high need of new treatment options

- HCC is an underserved disease where only surgery and liver transplantation provides hope of long-term survival^{1,2}
- The majority (80%) are diagnosed with advanced HCC with a 5-y survival < 20%^{1,2}
- Cirrhosis is the cause of HCC and the major hindrance for tolerating the treatment of HCC^{1,2}
- Despite recent advances in treatment of advanced HCC, only a minority experience longer term benefit and death rates remain high³



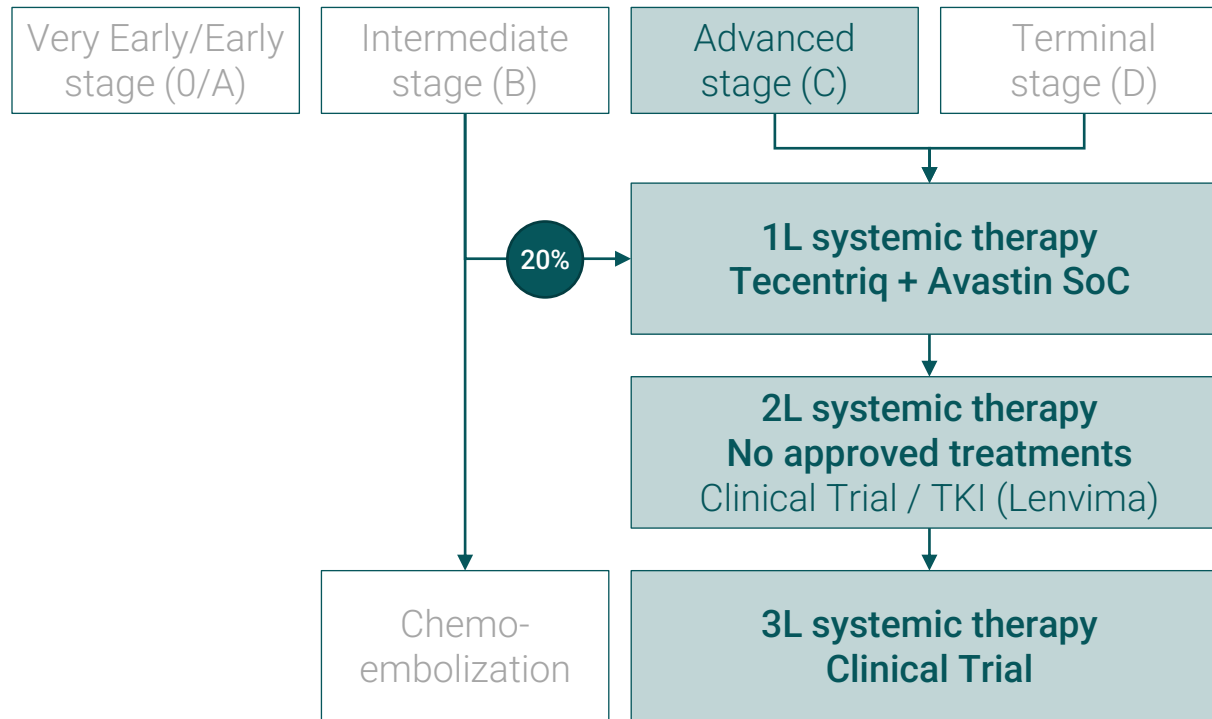
¹ Senthilnathan et al., Hepatology, 2012 May; 55(5): 1432-1442

² Llovet et al., Nature Reviews Gastroenterology & Hepatology, Vol 20, Aug 2023, 487-503

³ Llovet et al. Nature Reviews Gastroenterology & Hepatology 2023. 487–503

HCC – current preferred treatment algorithm provides opportunity for fostrox

HCC Treatment Algorithm

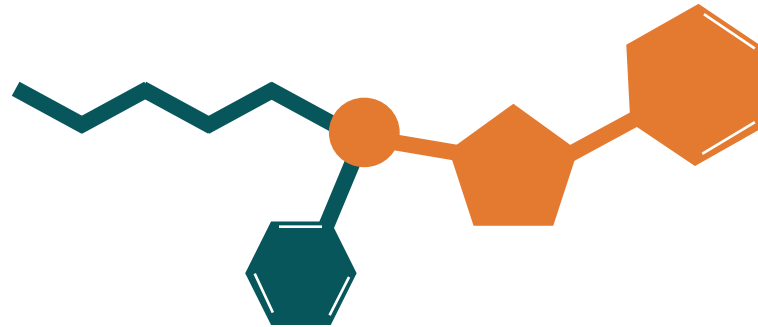


- IV chemotherapy currently not used in HCC, primarily due to systemic side effect challenges
- Need for liver-targeted treatment that does not impact vital liver functions

Fostrox – unique, liver targeted treatment inducing tumor selective cell death without impacting vital liver functions

Pro-drug tail

Pro-drug approach enables oral administration and achieves >100-fold liver targeted exposure vs traditional IV chemotherapy¹



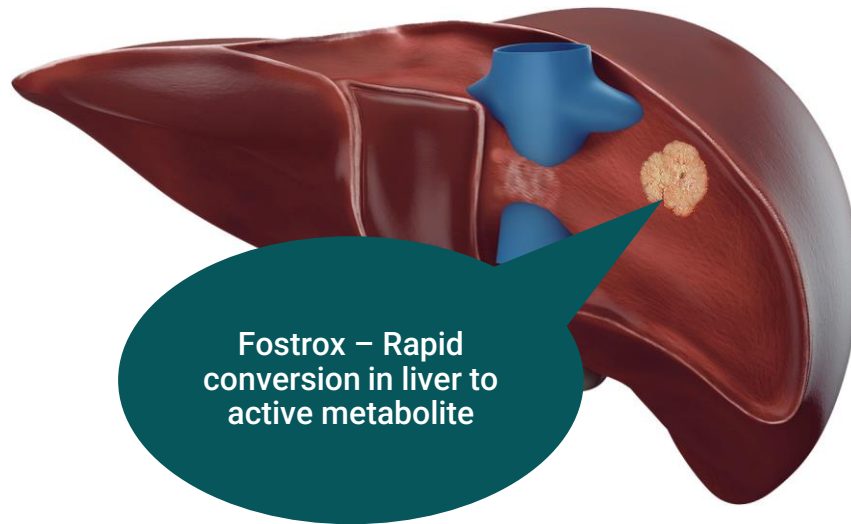
Active substance - troxacitabine

Cytotoxic with high cell killing selectivity of tumor cells, sparing normal cells

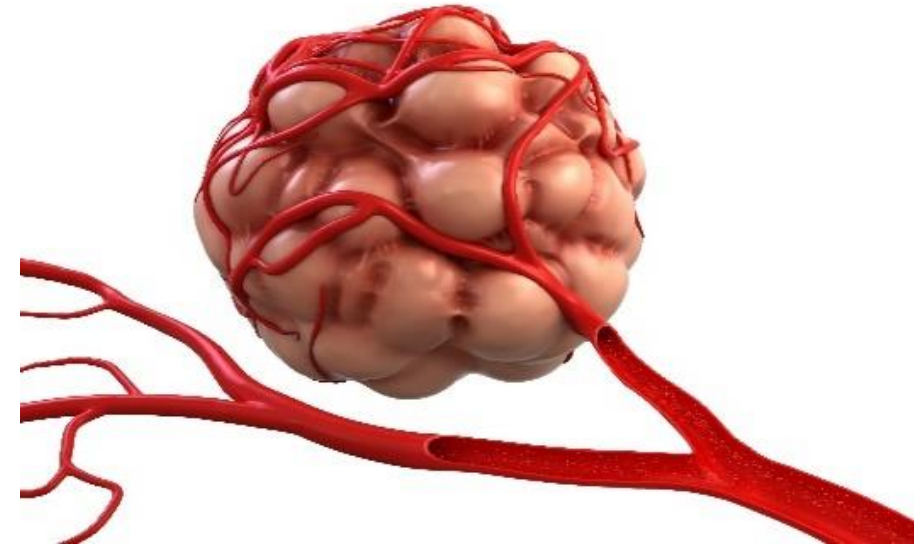
Fostrox use of differentiated MoA in HCC; provides synergistic combination possibility with Lenvima (TKI)

Liver directed, cytotoxic prodrug

Angiogenesis inhibitor



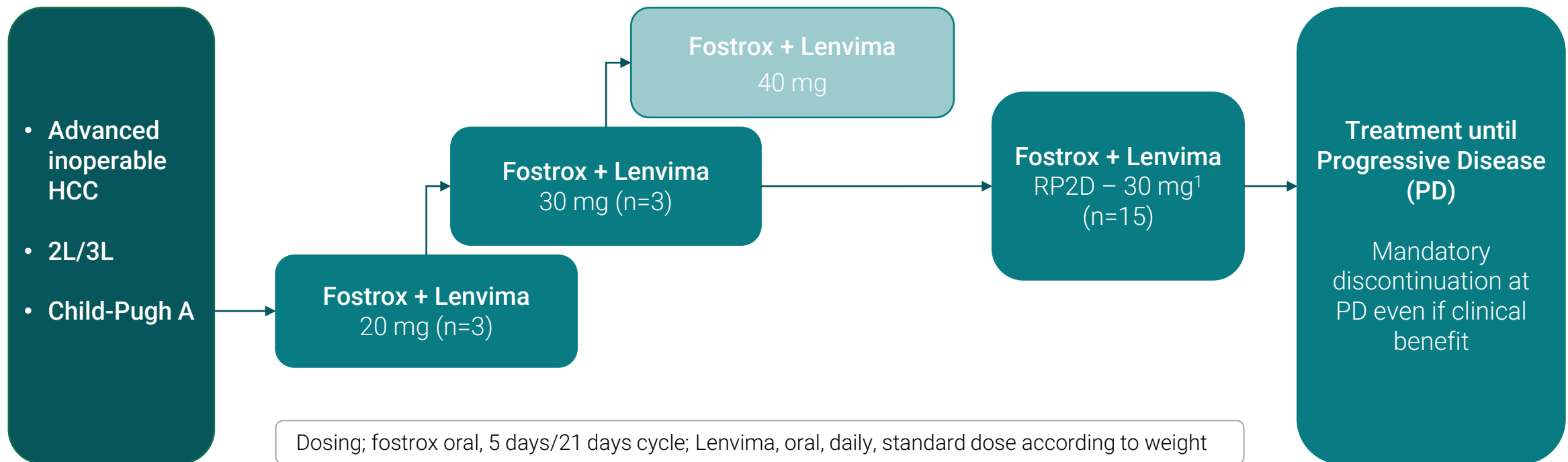
+



Lenvima induces lack of oxygen in tumors leading to increased activity of fostrox in the liver

Phase 1b/2a study fully recruited with >50% of patients still on treatment

Fostrox + Lenvima phase 1b/2a dose expansion study – 21 patients dosed



¹Maximal tolerated dose not reached with no DLTs reported. 30 mg selected with a focus on optimal dose ensuring balance between efficacy and tolerability

Majority of patients followed for ≥ 12 weeks (18 of 21), enabling a robust evaluation in 2L HCC

Phase 1b/2a – focus of today's data presentation

18 patients

- 15 sites in Spain, the UK, South Korea
- Primary Endpoint: Safety & tolerability
- Secondary endpoints: ORR, DCR, PFS
- All followed for ≥ 12 weeks

Response evaluation

- **CT or MRI every 6 weeks**
 - Investigator review RECIST 1.1
 - Independent review RECIST 1.1
 - Independent review mRECIST

Key patient characteristics (18 patients)

- 100% progressed (tumor growth) on prior treatment
- 82% had Tecentriq/Avastin in 1st line
- 65% enrolled in Asia and 35% in Europe

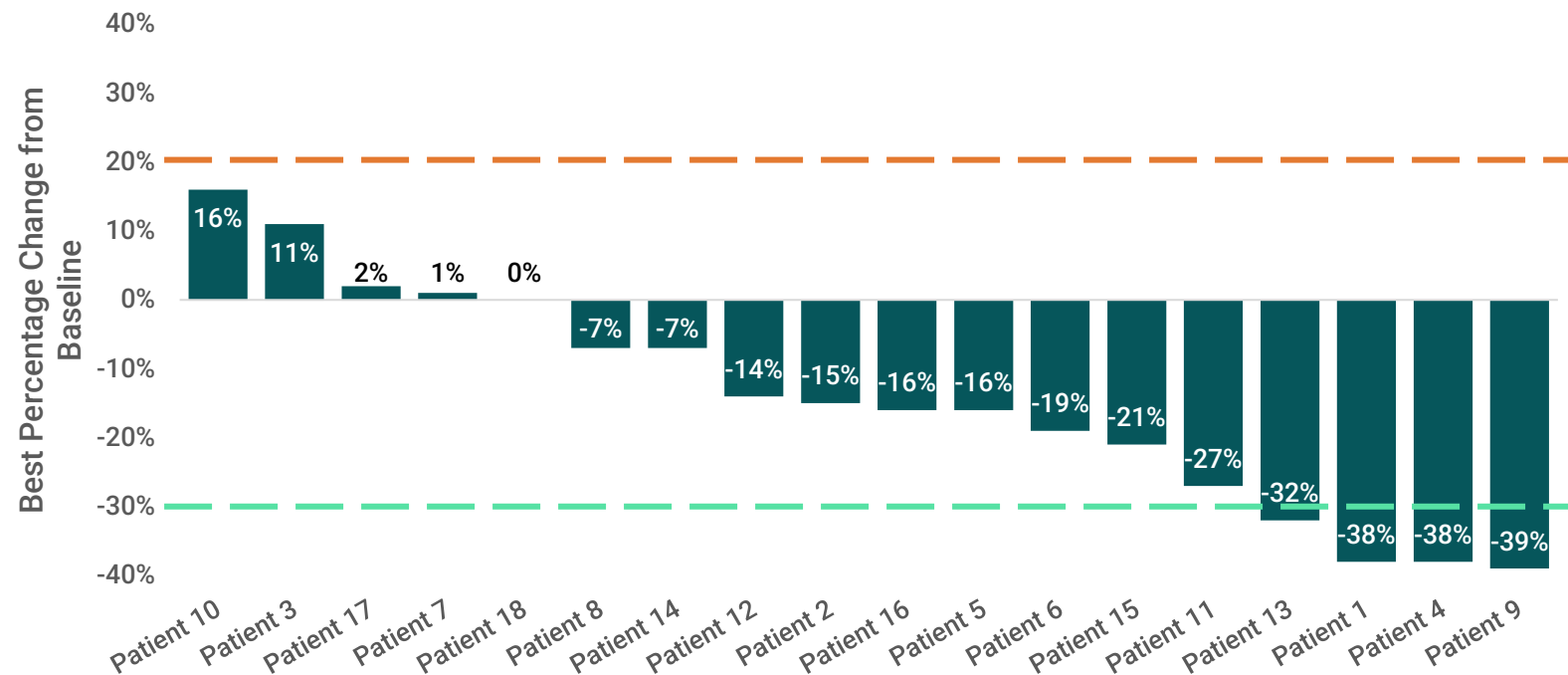
Improved clinical benefit across key efficacy endpoints in latest interim update of fostrox + Lenvima

Investigator review ¹ (RECIST 1.1)	Fostrox + Lenvima (n=18)	
Overall response rate (ORR)	22%	<ul style="list-style-type: none"> • Study ongoing, data continues to mature as >50% of patients still on treatment • Improved response rate since previous update (ORR 17%) • Time to progression continues to increase since previous update (4.5 months)
Disease Control Rate (DCR) at 6 weeks	78%	
DCR at 12 weeks	72%	
Median Time to Progression (TTP)	4.9 months	

¹Preliminary results from Investigator review (18 patients with a minimum of 12 weeks follow-up)

22% Overall Response Rate (ORR); more than two third of patients with tumor reduction* (Investigator review RECIST 1.1)

Best % change from baseline in target lesion size (n=18)



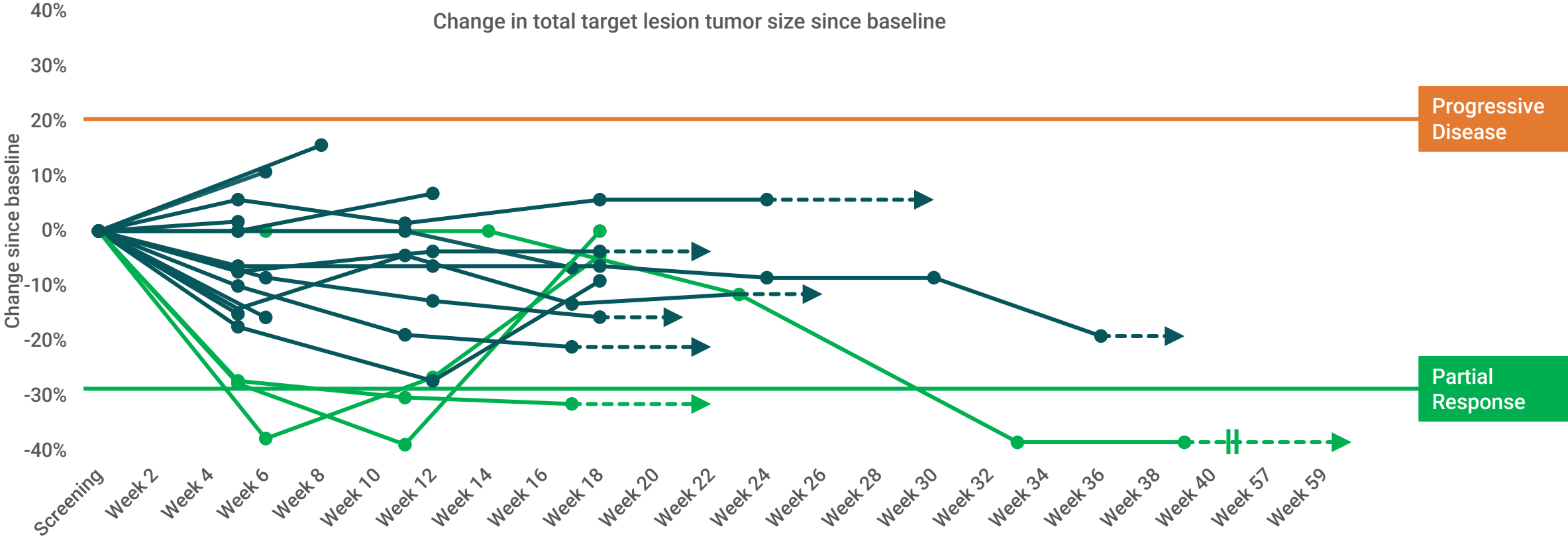
3 additional patients; all with ≥6 weeks follow-up & stable disease

Fostrox + Lenvima n=18

ORR	22%
Partial Response, PR	22%
Stable disease, SD	56%
DCR	78%
Progressive Disease, PD	22%
Tumor reduction	72%

*Preliminary results from Investigator review (18 patients with a minimum of 12 weeks follow-up)

Early & durable anti-tumor activity with longest running patient still on treatment after 14 months* (Investigator review RECIST 1.1)



*Preliminary results from Investigator review (18 patients with a minimum of 12 weeks follow-up)

Good safety & tolerability profile with fostrox + Lenvima* and lower than expected dose modifications

Discontinuation and dose modifications

Only 10%

of patients discontinue due to fostrox adverse events

> 65%

of patients remain on fostrox starting dose

< 50%

of Lenvima patients require dose modification (in monotherapy or other combinations around 62-66%)

Encouraging safety with Fostrox + Lenvima

- No unexpected new safety events
- Adverse events transient and manageable
- Most common grade ≥ 3 related to fostrox:
 - Neutropenia 36% (no febrile, 3 pts with Gr 4)
 - Thrombocytopenia 18% (no bleeding, 1 pt with Gr 4)
- Lenvima related side effects in line with expectations

*Unclean data, 21 pts, cut-off date Aug 31, 2023, both drug-related and unrelated AEs

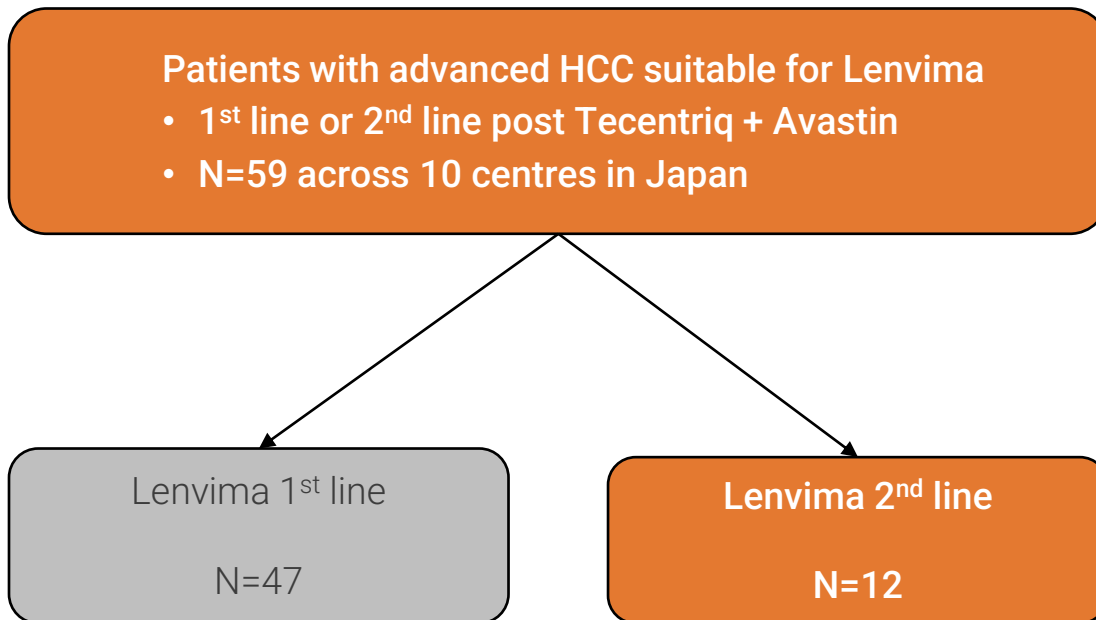
Independent review of phase 1b dose escalation cohorts shows 50% ORR with 1 complete response (CR)

Phase 1b fostrox + Lenvima dose escalation cohorts¹; Independent Review – mRECIST

- 1 of 6 patients achieved Complete Response (CR), no signs of viable tumor
 - Achieving complete tumor response is rare in a 2nd line HCC population
- 2 patients showed Partial Response (PR) for an Overall Response Rate (CR+PR) of 50%
- 2 patients had Stable Disease (SD) for a Disease Control Rate (CR+PR+SD) of 83%

The first, prospective study to evaluate clinical efficacy & safety of Lenvima in 2nd line HCC

Non-randomised, open-label, multi-center study evaluating Lenvima in 1st & 2nd line HCC patients¹



Primary Endpoint:

- Safety & tolerability

Secondary endpoints:

- ORR
- PFS
- OS

Treatment until progression or lack of clinical benefit with Lenvima

CT/MRI assessment; 4 weeks after 1st lenvima dose, then every 8 weeks

¹Kobayashi et al., Clinical Cancer Research, Oct 5, 2023 online

Indirect comparison; similar patient characteristics in fostrox + Lenvima study & Lenvima study in 2nd line HCC

Key patient characteristics	Fostrox + Lenvima ² (n=18)	Lenvima ¹ (n=12)
2 nd line/3 rd line patients*	83% / 17%	100% / 0%
ECOG status (0/1)	67% / 33%	92% / 8%
Extrahepatic metastases	≥56%	42%
Max intrahepatic tumor ≥50 mm	44%	42%
AFP ≥400 ng/ml	≥44%	42%

*Fostrox + Lenvima study allowed 3rd line patients to be included

¹Kobayashi et al., Clinical Cancer Research, Oct 5, 2023 online

²Phase Ib/IIa Fostrox + Lenvima, (n=18, all patients with minimum 12 weeks follow-up)

Indirect comparison; Fostrox + Lenvima study with comparable tolerability, no new safety events vs Lenvima study

Safety & tolerability	Fostrox + Lenvima ² (n=18)	Lenvima ¹ (n=12)
≥ Grade 3 AEs	61%	67%
Dose modifications Lenvima	50%	92%
Discontinuations due to AEs	17%	25%

¹Kobayashi et al., Clinical Cancer Research, Oct 5, 2023 online

²Phase Ib/IIa Fostrox + Lenvima, (n=18, all patients with minimum 12 weeks follow-up)

Fostrox + Lenvima study shows consistently improved clinical benefit compared with Lenvima study alone

Indirect comparison – Independent review (mRECIST)	Fostrox + Lenvima ² (n=6)	Lenvima ¹ (n=12)
CR	17%	0%
ORR	50%	17%
DCR (at 6 weeks)	83%	75%

Indirect comparison – Investigator Review (RECIST 1.1)	Fostrox + Lenvima ³ (n=18)	Lenvima ¹ (n=12)
ORR	22%	17%
DCR (at 6/4 weeks)	78%	83%
DCR (at 12 weeks)	72%	58%*
DCR (at 18/20 weeks**)	50%	25%*

*Data only reported as mRECIST (Local Review)

¹Kobayashi et al., Clinical Cancer Research, Oct 5, 2023 online

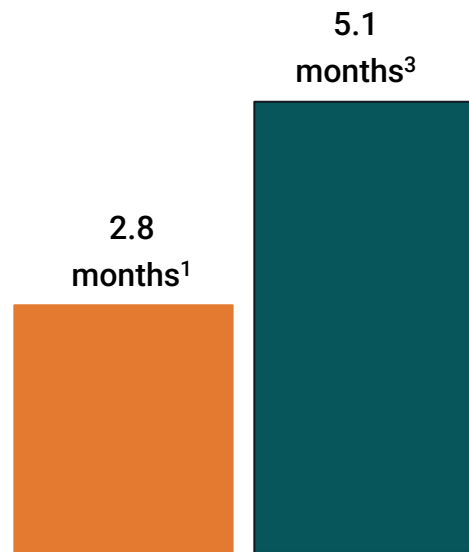
²Phase 1b fostrox + Lenvima, data cut-off May 19, 2023

³Phase 1b/2a fostrox + Lenvima, (n=18, all patients with minimum 12 weeks follow-up)

Indirect comparison of Progression free survival (PFS)/Time to progression (TTP) reinforces improved clinical benefit

Median PFS/TTP*

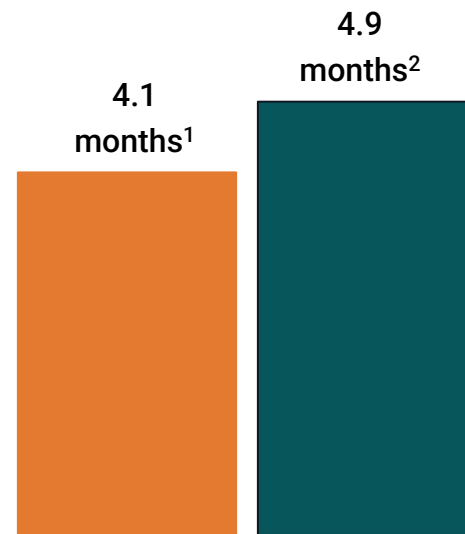
■ Lenvima (PFS) ■ Fostrox + Lenvima (TTP)



Independent Review (RECIST 1.1)

Median PFS/TTP*

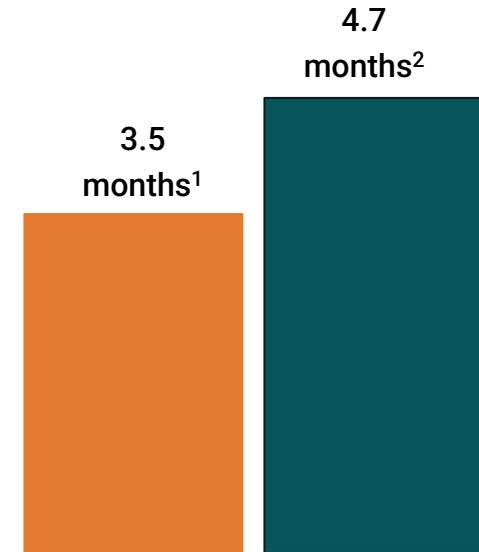
■ Lenvima (PFS) ■ Fostrox + Lenvima (TTP)



Investigator Review (RECIST 1.1)

Median Treatment Duration

■ Lenvima ■ Fostrox + Lenvima



Treatment Duration

¹Kobayashi et al., Clinical Cancer Research, Oct 5, 2023 online

²Phase Ib/IIa Fostrox + Lenvima, (n=18, all patients with minimum 12 weeks follow-up)

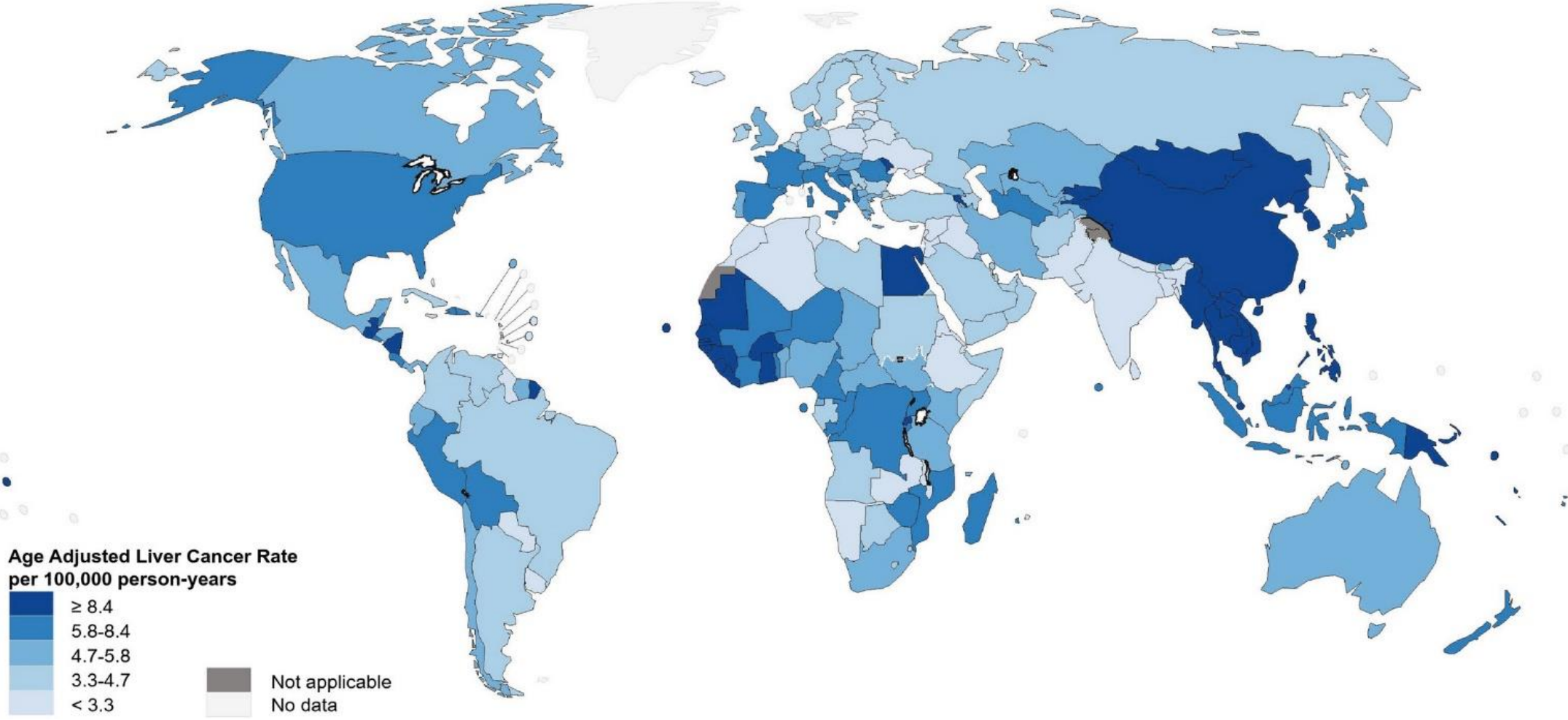
³Phase Ib Fostrox + Lenvima, data cut-off May 19, 2023

HCC treatment today & tomorrow;

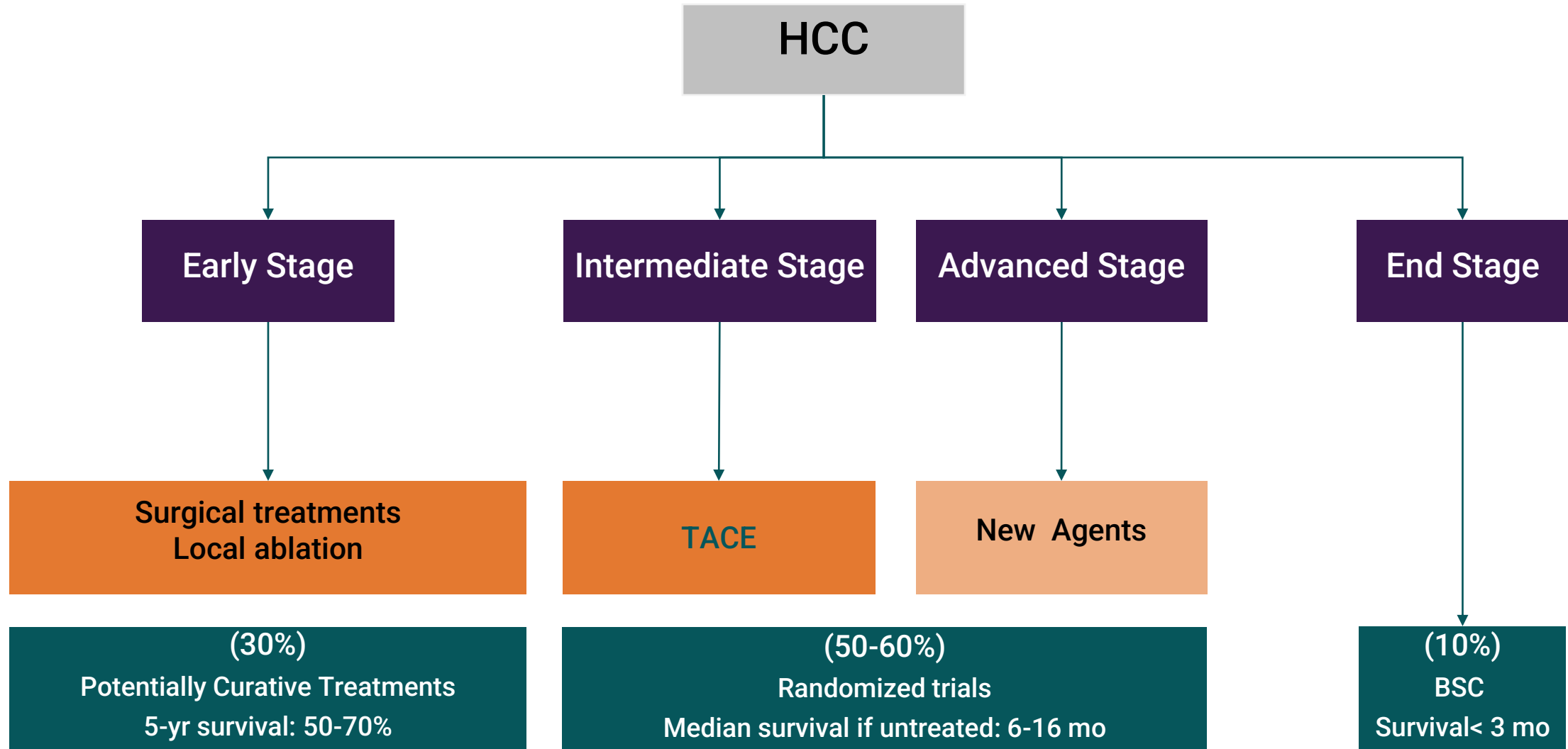
Fostrox + Lenvima in a future clinical context

Dr. Jeff Evans

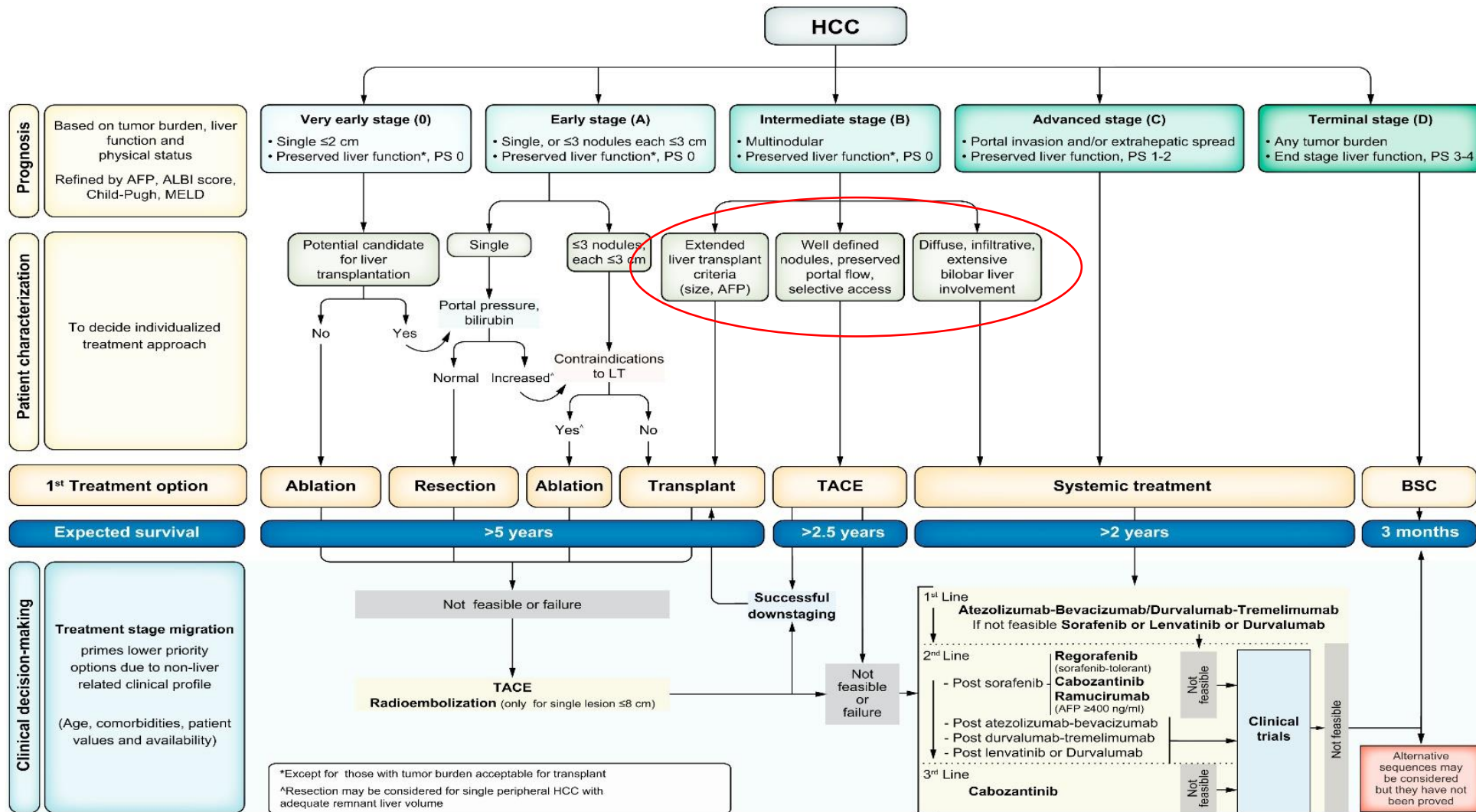
Epidemiology of Hepatocellular Carcinoma



Where we have come from (before 2008)



BCLC staging and treatment strategy in 2022



Systemic Therapy uHCC

First Line

Atezoliumab +
Bevacizumab

Durvalumab +/-
Tremelimumab

Lenvatinib

Sorafenib

Second Line

Sorafenib
Lenvatinib
Cabozantinib

Sorafenib
Cabozantinib
Ramucirumab

Ipi +
Nivo

Cabozantinib
Ramucirumab
Regorafenib

Regorafenib

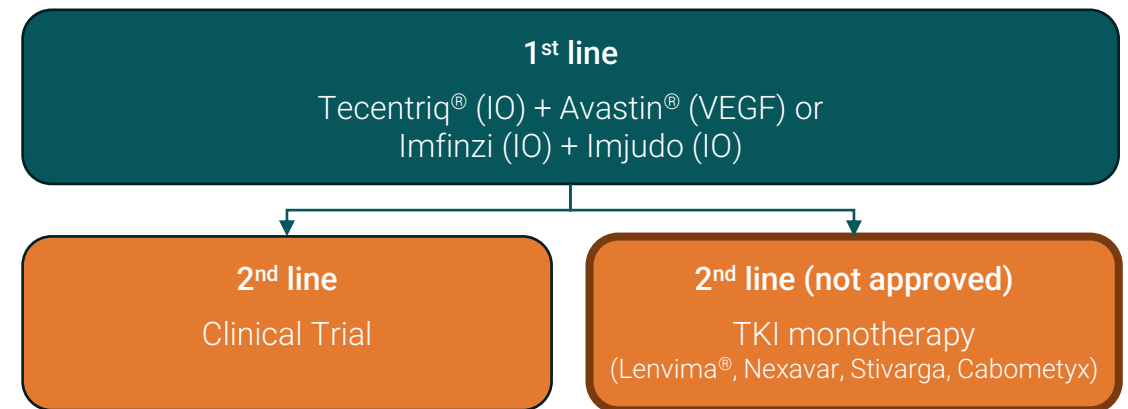
Regorafenib

While significant advances have been made in the 1st line HCC, high unmet need remains in 2nd line

No approved systemic 2nd line treatment options post 1st line standard of care (SoC)

- 1st line SoC in HCC: immunotherapy combinations
- 2nd line treatments lack regulatory approval in this setting
- 2nd line treatment in clinical practice is therefore based on:
 - Clinical trials
 - Drugs approved post previous 1st line SoC (Nexavar)
 - Drugs approved or shown benefit in 1st line
 - Drugs recommended in treatment guidelines

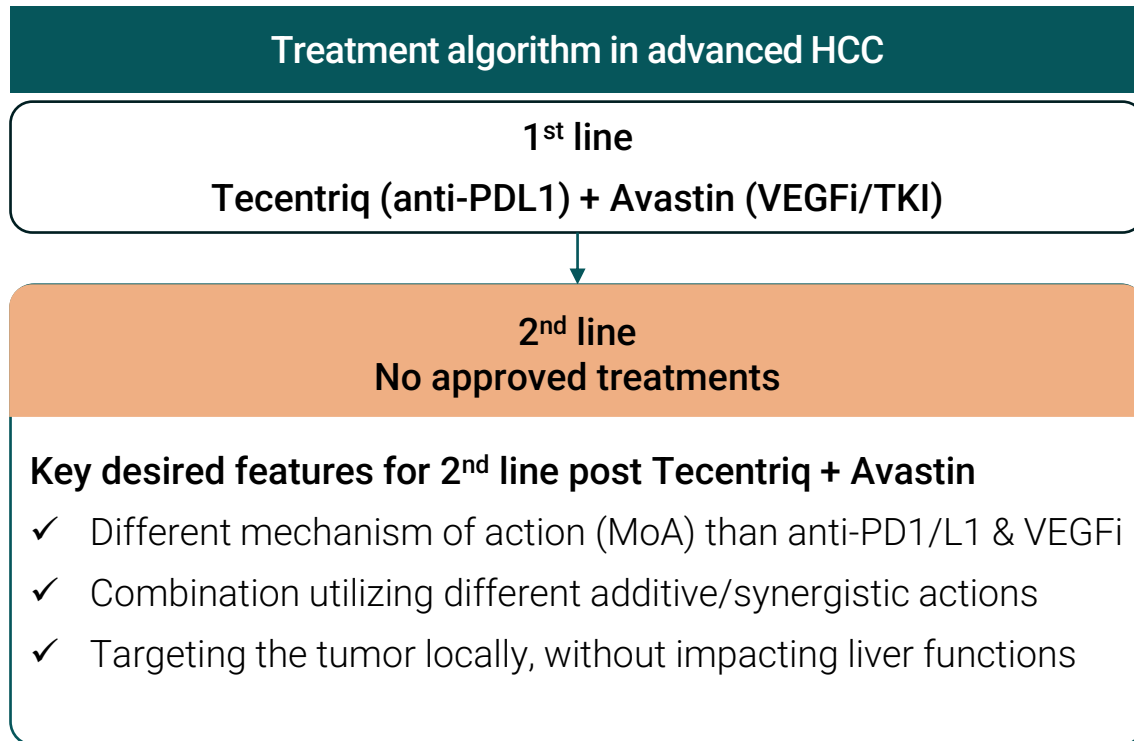
Treatment guidelines* highlights significant unmet medical need in 2nd line advanced HCC



Key unmet medical needs

- Combinations using different mechanisms of action (MoA) in 2nd line compared to 1st line
 - Targeting the tumor locally without impacting liver functions

Fostrox + Lenvima: novel combination in development aligned with current and future 2nd line HCC SoC

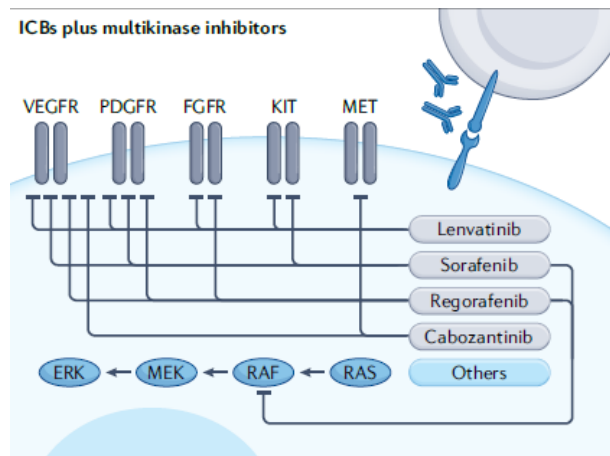


Ongoing studies in 2nd line HCC post Tecentriq + Avastin

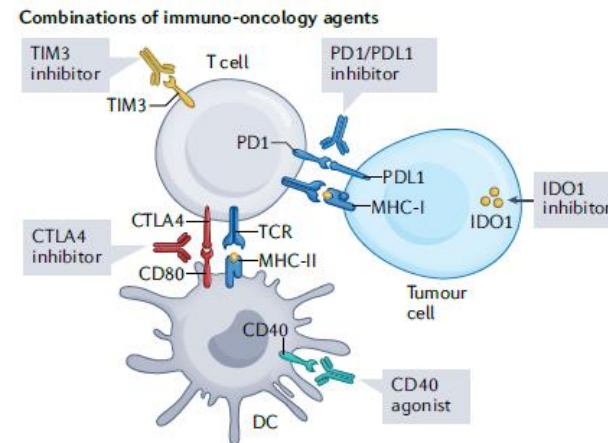
	Fostrox + Lenvima	TKI monotherapy	IO combinations
Different MoA	✓	✓	
Synergistic actions	✓		✓
Targeting tumor locally	✓		

Standard of care treatment - synergy in mechanism of action – how could fostrox provide further benefit

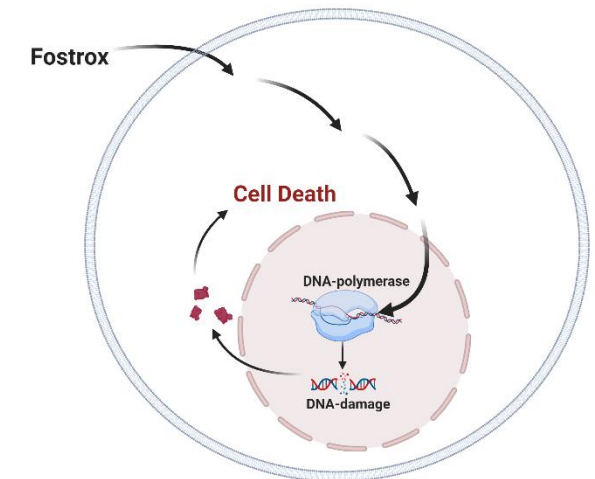
Inhibiting growth factor signaling



Blocking negative immune-checkpoints

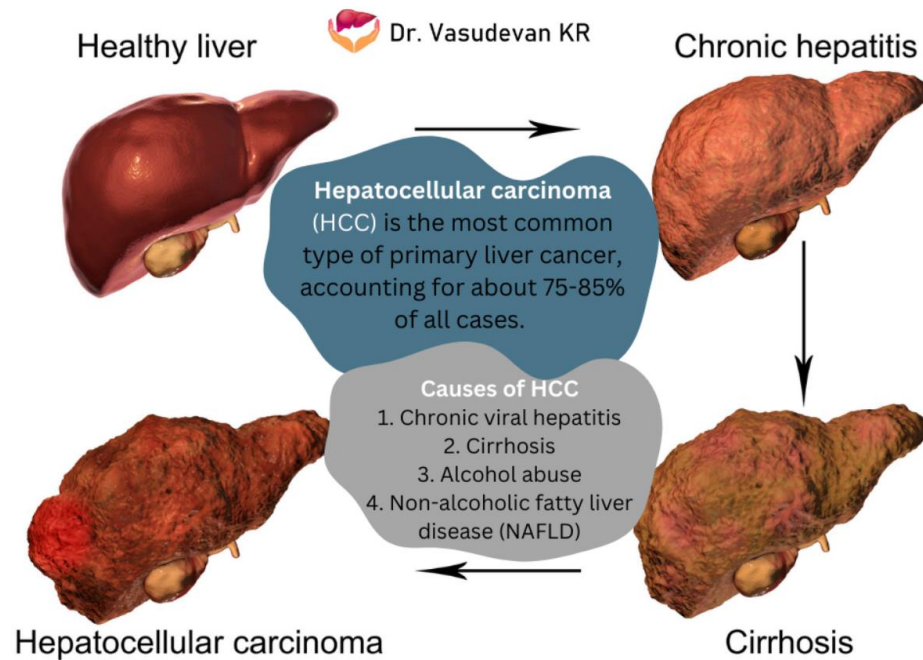


Inducing DNA-damage and cell death



- Current systemic therapy in advanced HCC uses multikinase inhibitors (MKIs), or combines inhibition of VEGF (bevacizumab) plus PD-L1 checkpoint inhibition (atezolizumab), or two different checkpoint inhibitors; PD-L1 (durvalumab) and CTLA4 (tremelimumab)
- **Fostrox adds a third unique mechanism with the potential to synergize with current standard of care**

Cancer in the liver is different; controlling the primary tumor in the liver is critical in HCC



Up to 80%

of HCC patients has an underlying cirrhosis in the liver, negatively impacting ability to tolerate anti-tumor treatments^{1,2}



Progression in HCC is unique as it primarily occurs locally in the liver¹



TACE & other local therapies show minimal long-term benefit and by damaging vessel/non-tumour tissue, reduces normal liver function^{3,4}

¹ Senthilnathan et al., Hepatology, 2012 May; 55(5): 1432-1442

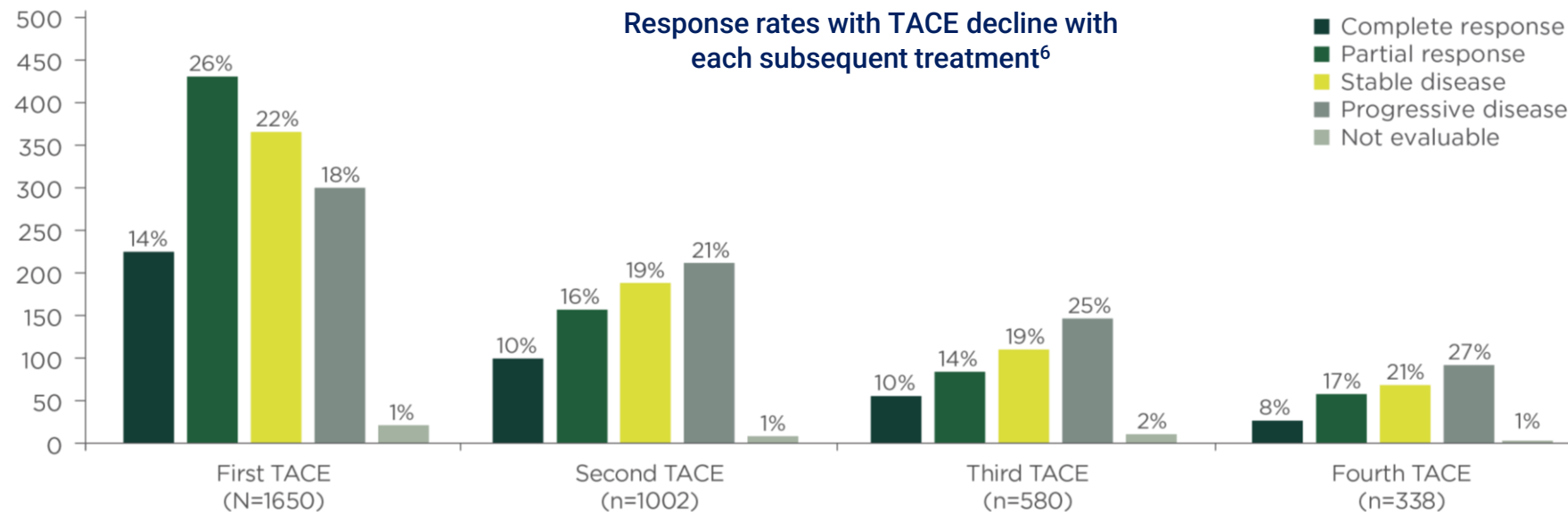
² Llovet et al., Nature Reviews Gastroenterology & Hepatology, Vol 20, Aug 2023, 487-503

³ Galle PR et al. J Hepatol 2017;67:173-183.

⁴ Peck-Radosavljevic M et al. Oral presentation at ILCA, 14-16th September 2018, London

TACE (local chemoembolization); a frequently used alternative to reduce primary tumor burden in HCC provides diminishing returns

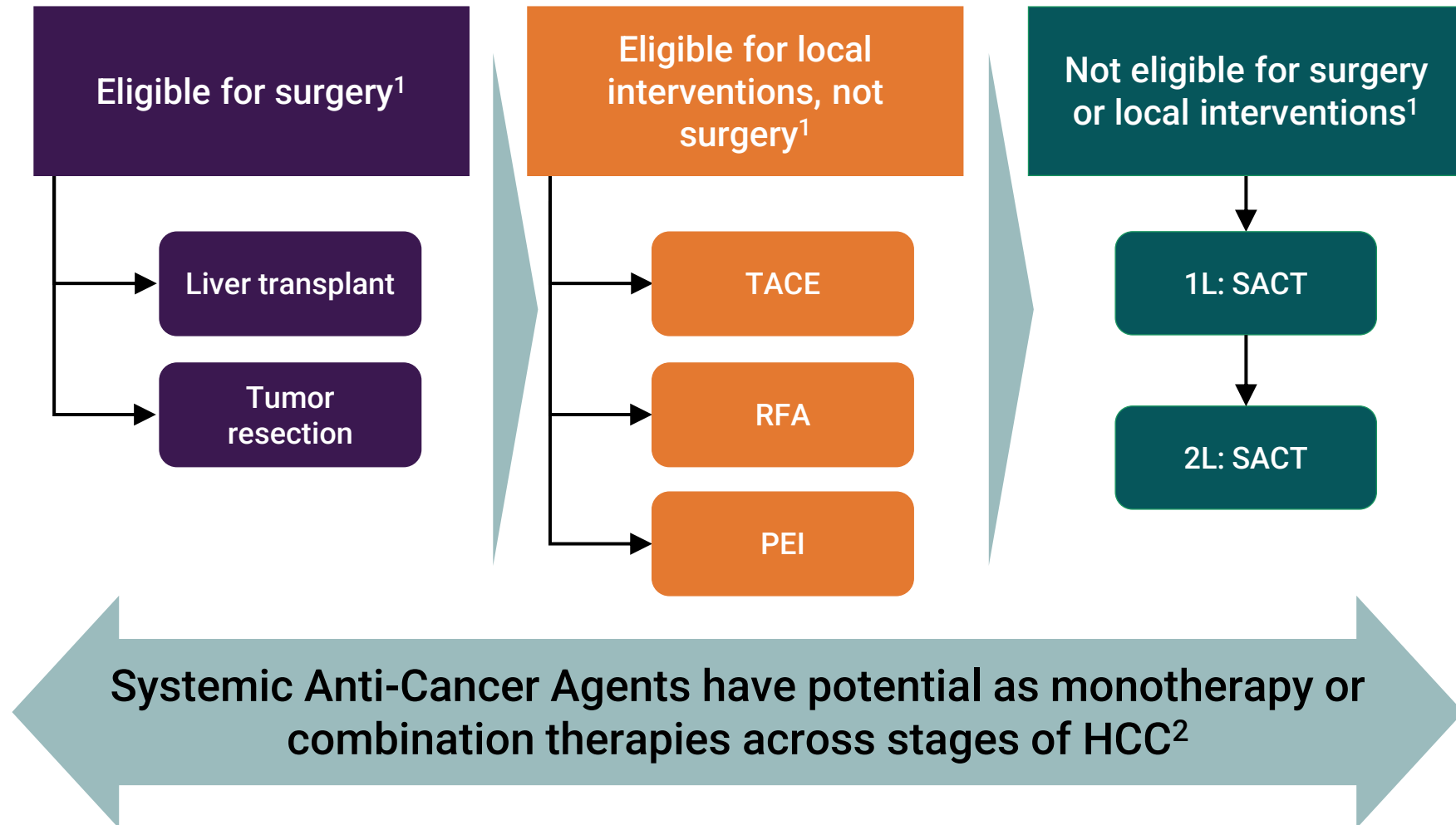
- TACE is the general standard of care for patients with intermediate-stage HCC (i.e. BCLC stage B)¹
- However, despite consensus between international guidelines on when to discontinue TACE,²⁻⁴ evidence suggests TACE is commonly overused,⁵ which may have real-world clinical implications including a decline in response rates with each subsequent TACE treatment⁶



Data are presented for the first 4 TACE procedures only; fewer than 15% of the total population received more than 4 TACE procedures.

Slide 34

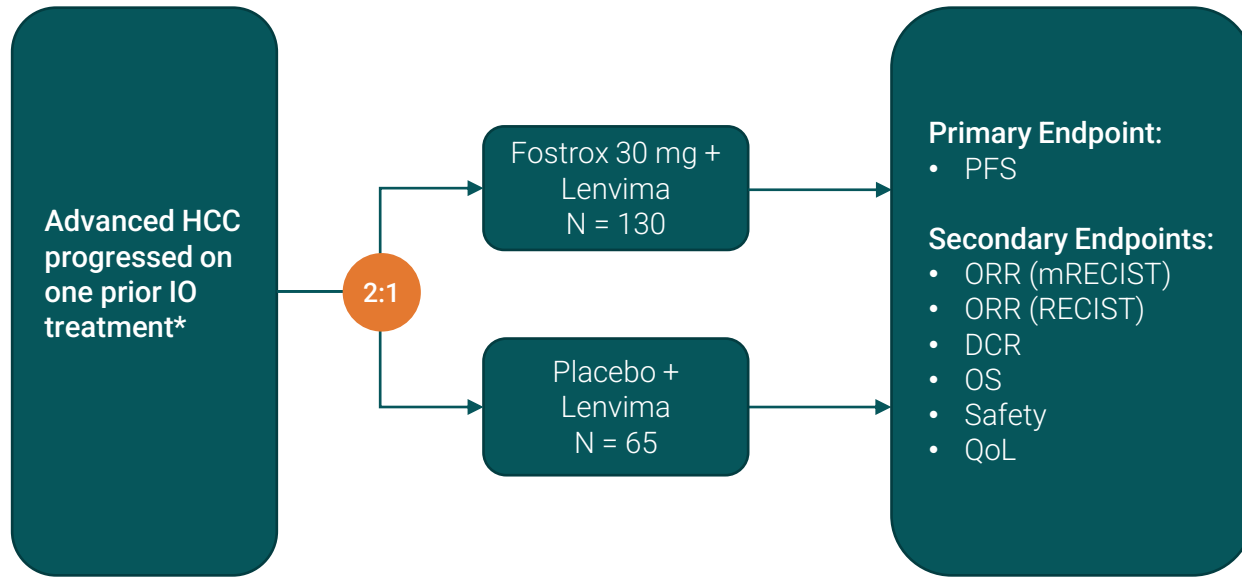
Potential of Systemic Anti-Cancer Agents (SACT) across the HCC landscape



**Pivotal phase 2b with Accelerated
Approval intent is the next appropriate step**

Pivotal phase 2b; randomized design with PFS as primary endpoint to enable accelerated approval 2027

Phase 2b: randomized, double-blind study design with Master Protocol for phase 2b & confirmatory phase 3



Key factors supporting accelerated approval process

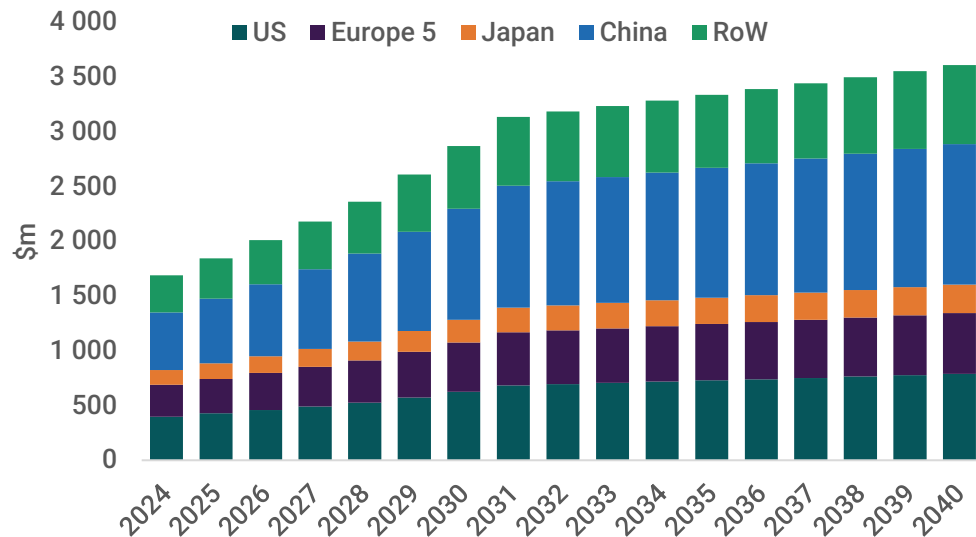
- ✓ Serious, orphan disease with high unmet medical need
- ✓ Promising clinical benefit & safety profile
- ✓ Randomized study design with PFS as primary endpoint
- ✓ Appropriate patient safety database

* PD within 12 mo on adjuvant IO combination counted as prior tx

**Fostrox – Major commercial
opportunity in a patient population
with no approved treatments**

First-to-market opportunity for fostrox in 2nd line HCC market worth \$2.4bn annually by 2028

Significant market growth* driven primarily by NASH/NAFLD induced HCC



*Source: GlobalData 2021 & internal analysis

As medical treatments improve, 2nd line treatment duration will increase significantly*

- 2L treated patients 2028**
 - US: ~7.500 | EU5: ~11.000 | JP: 5.000 | CN: ~38.000
- 2L treatment duration**
 - 2L patients assumed to be **treated for 7 months** on average
- Anticipated 2L competition 2028**
 - Base case – **no approved treatments post current 1L SoC** to compete with Fostrox + Lenvima
- Cost of therapy per month**
 - US - \$10.000 | EU - \$5.000 | JP - \$5.000 | CN - \$3.000

Summary

Fostrox + Lenvima – Potential to transform 2nd line HCC



Fostrox + Lenvima shows consistently improved efficacy compared with Lenvima alone



Continued development for fostrox + Lenvima in 2nd line HCC with Accelerated Approval intent 2027



2nd line HCC post Tecentriq[®] + Avastin[®] lacks approved treatments & is a market valued at ~\$2.5bn annually

Q/A

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Thank You!