



Medivir AB

Bringing smart chemotherapy to primary liver cancer (HCC)

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Jens Lindberg, CEO

MEDIVIR

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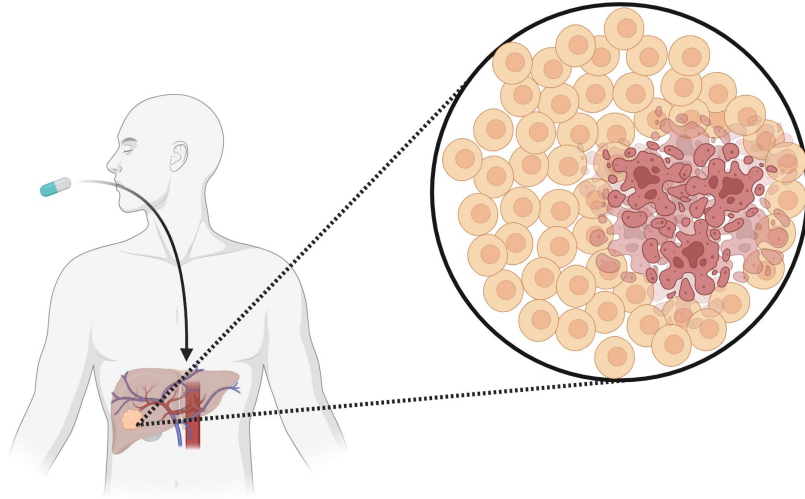
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Fostrox – a smart chemotherapy with a unique, liver targeted & tumor selective treatment of HCC

Nucleotide prodrug, enabling oral administration & liver targeting



>100-fold liver targeted exposure vs traditional chemotherapy¹

Promising signals of clinical benefit supports accelerated approval path

- **First-in-class with OD designation** in EU & US
- **Fostrox + Lenvima provides additional clinical benefit** to Lenvima alone
- Pivotal phase IIb with **Accelerated Approval intent 2027/2028**
- First-to-market opportunity in target population with **annual market value of ~\$2.4bn in 2028***

Medivir – Oncology pipeline with in-house developed lead program in phase 2 & 3 out-licensed oncology programs

Fostrox



Proprietary, in-house developed lead program based on proven technology

- Smart chemotherapy delivering cell-killing activity selectively to the liver tumor
- Orphan Drug Designation granted in USA and EU
- Promising clinical benefit with first-to market opportunity 2027

Partnering programs



Out-licensed oncology programs with potential upside without further investment

- 3 out-licensed oncology programs; ongoing discussions for additional out-license
- Birinapant (IGM Biosciences) currently in phase 1 dose escalation with IGM-8444
- TNG348 (Tango Therapeutics) to enter phase 1 in H1 2024

Fostrox initial focus in 2L HCC where no treatments are approved and expected clinical benefit is low

Advanced stage HCC Treatment Algorithm

1L systemic therapy

Immunotherapy combination

- Only ~30% of patients respond to treatment¹
- Estimated time to progression ~6.5 months¹



2L systemic therapy

No approved treatments –
off-label Lenvima preferred

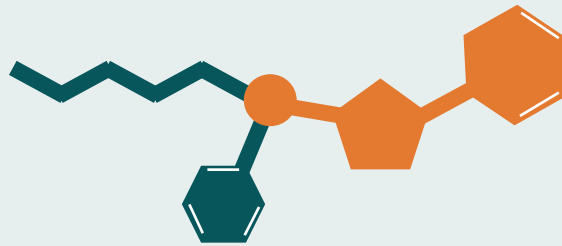
- **Only ~5-10% of patients respond to treatment²**
- **Estimated time to progression ~3.5 months²**
- Fostrox + Lenvima, the only novel combination in development

¹ Finn et al., N Engl J Med 2020; 382:1894-1905

² Based on previous 2nd line HCC studies with kinase inhibitors

Fostrox – liver targeted, smart chemotherapy

Proven prodrug
technology



Active substance -
troxacitabine

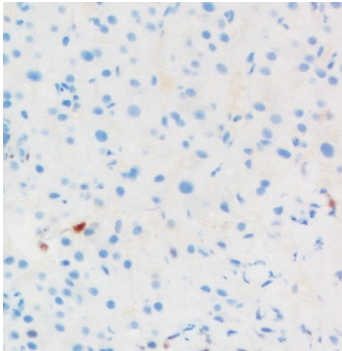
1. Oral administration
2. Targeted (>100-fold) liver exposure vs IV chemotherapy¹
3. Selective DNA damage in tumor vs normal liver tissue

Fostrox – Patient biopsies confirming selective DNA damage & cell death in tumor cells while sparing normal liver tissue

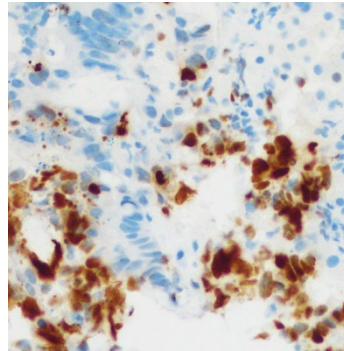
Tumor selective induction of DNA-damage¹

Cytotoxic in tumor tissue but not in normal liver tissue²

Normal liver tissue

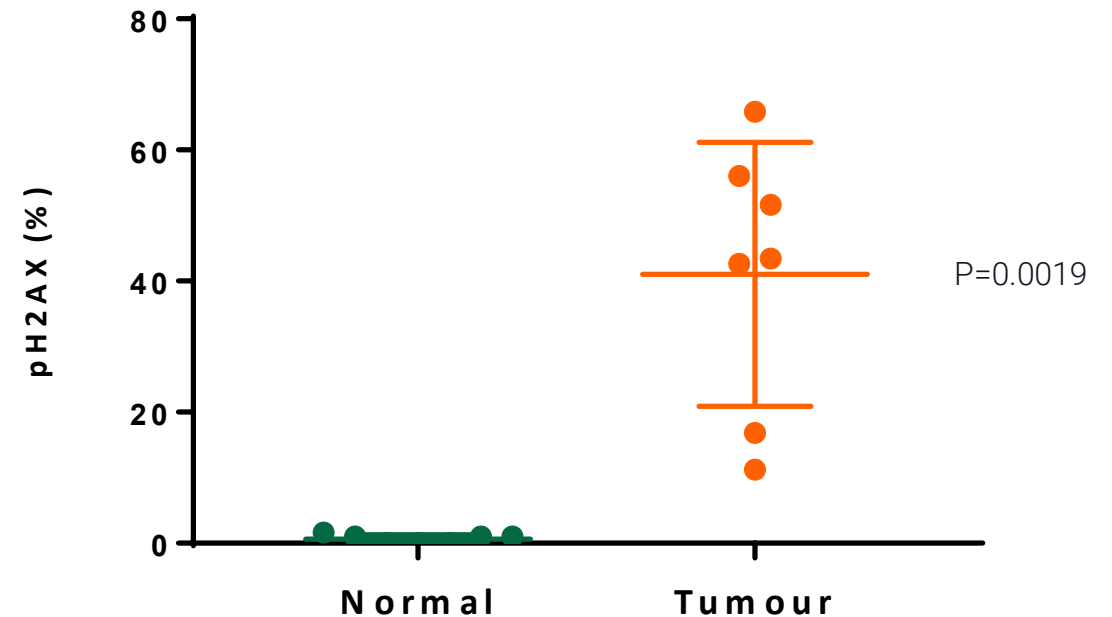


Tumor tissue



Fostrox-induced DNA-damage indicated by pH2AX immuno-histochemistry (IHC) staining of liver biopsy from phase 1b monotherapy

DNA-damage in normal liver vs tumour

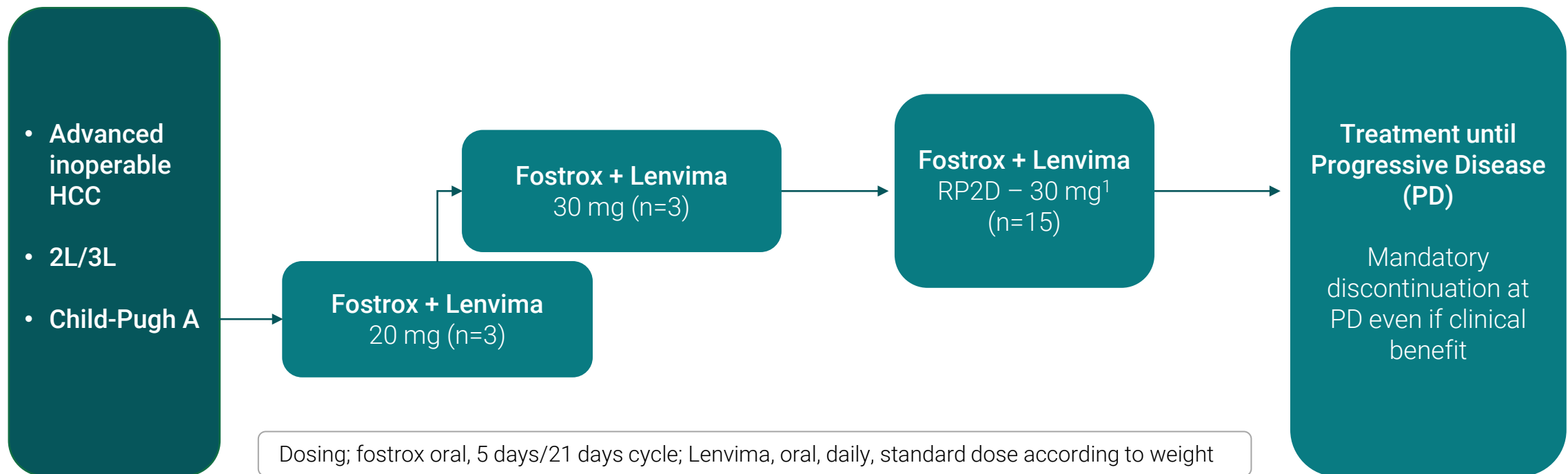


¹Evans et al ASCO GI, 2021

²Öberg F. et al, EASL PO-221, 2022

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

Previous studies in 2nd line HCC confirm difficult-to-treat population

RECIST 1.1	Efficacy Benchmarks TKIs – previous 2 nd line studies ¹
Overall response rate (ORR)	~10%
Clinical Benefit Rate (CBR/DCR)	~60%
Median Progression-free Survival/Time to Progression	~3.5 months

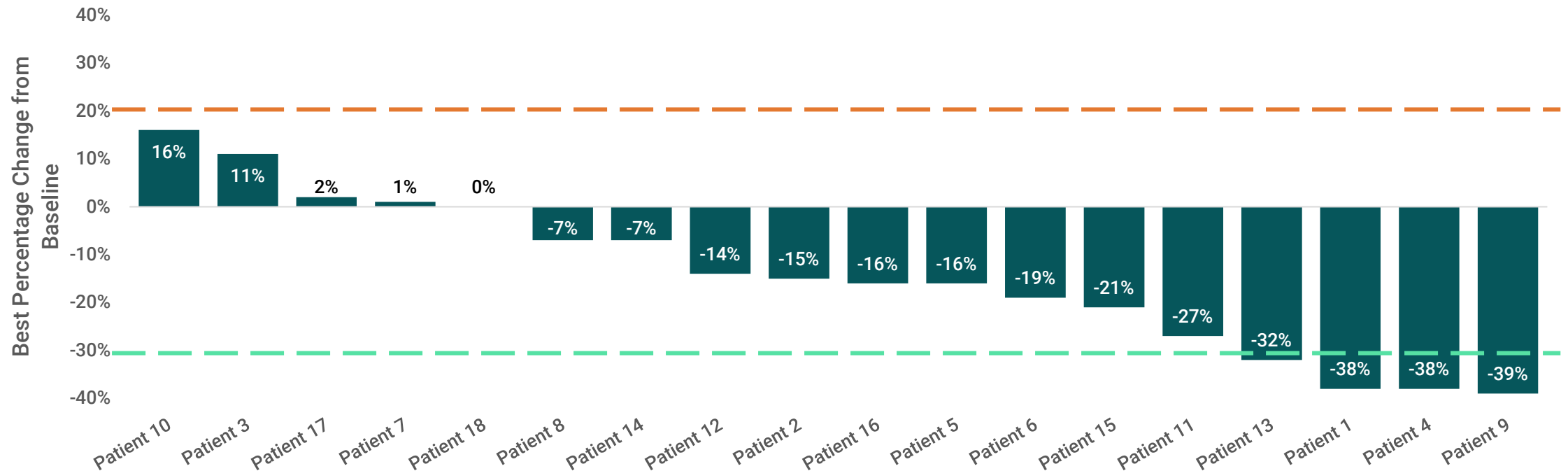
Fostrox + Lenvima compares favourably with benchmarks in 2nd line HCC

RECIST 1.1	Efficacy Benchmarks TKIs – previous 2 nd line studies ¹	Fostrox + Lenvima* (n=18)
Overall response rate (ORR)	~10%	22%
Clinical Benefit Rate (CBR/DCR)	~60%	78%
Median Progression-free Survival/Time to Progression	~3.5 months	4.9 months

*Preliminary 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 at 1st evaluation

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

Lenvima monotherapy data in 2nd line HCC confirms significant unmet medical need

RECIST 1.1	Lenvima ¹ (n=12) Independent & investigator review	Fostrox + Lenvima ² (n=18) Investigator review
ORR	8-17%	
Clinical Benefit Rate (at 12 weeks)	58%*	
Median Progression-free Survival/Time to Progression	2.8-4.1 months	
Median Treatment Duration	3.5 months	

* Data only reported as mRECIST

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

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

Fostrox + Lenvima compares very favourably with benchmarks in 2nd line HCC

RECIST 1.1	Lenvima ¹ (n=12) Independent & investigator review	Fostrox + Lenvima ² (n=18) Investigator review
ORR	8-17%	22%
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Median Progression-free Survival/Time to Progression	2.8-4.1 months	4.9 months
Median Treatment Duration	3.5 months	4.7 months

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

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

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

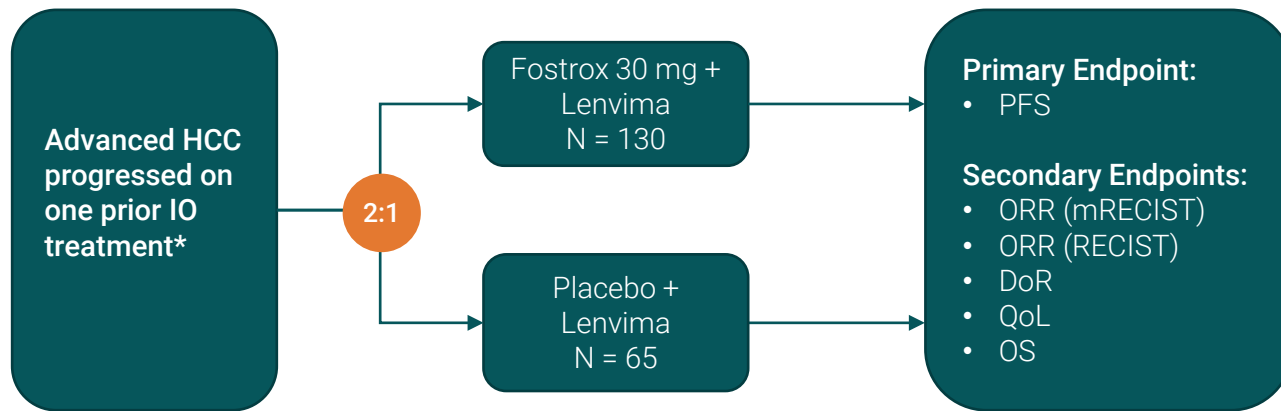
	Lenvima ¹ (n=12)	Fostrox + Lenvima ² (n=18)
≥ Grade 3 AEs	67%	61%
Dose modifications Lenvima	92%	50%
Discontinuations due to AEs	25%	17%

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

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

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

Phase IIb: randomized, double-blind study design



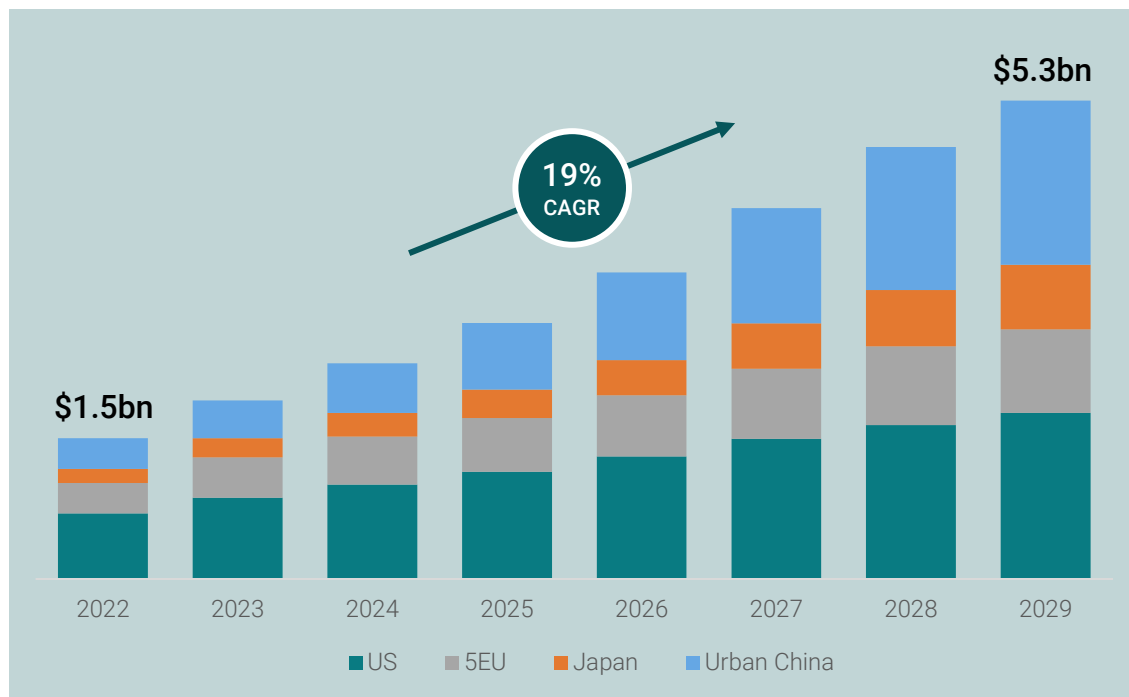
* PD within 12 mo on adjuvant IO combination counted as prior tx

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

HCC is a significantly growing market, likely to grow even faster with the increasing obesity pandemic

HCC market estimated to grow at ~20% per year



Despite recent advancements, unmet need is still high

- Incidence & mortality are increasing; HCC being the third leading cause of cancer death worldwide¹
- Anticipated additional growth as HCC caused by fatty liver disease is expected to increase dramatically by 2030, with increases of 82% & 122% in China & USA respectively²
- HCC is the fastest increasing cause of cancer-related death in the USA^{3,4}
- HCC rapid market growth is primarily driven by combination therapies and treatment in earlier lines

Source: GlobalData 2021

¹Rumguy et al. Journal of Hepatology 2022

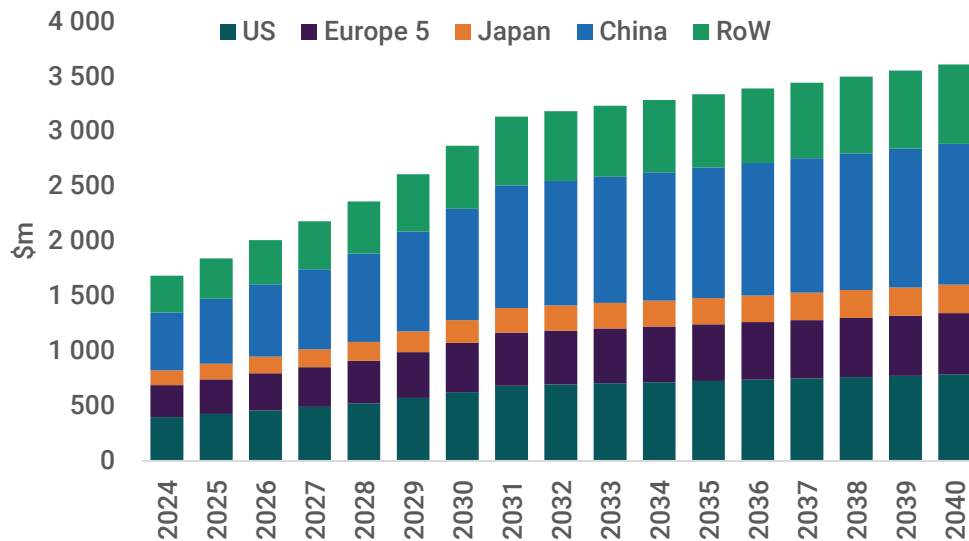
²Huang et al., Nature Reviews, Gastroenterology & Hepatology, Vol 18, 2021

³Llovet et al, Hepatology 2020

⁴Llovet et al, Nature Review 2021

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

Strategic evolution – Earlier treatment lines in HCC provides additional market opportunity of >\$5bn

Key reasons underpinning Rights Issue



Keep maximum speed and momentum in development program for fostrox



Patients in ongoing fostrox + Lenvima study staying longer on treatment and data has continued to improve with increased maturity



Improved clinical benefit supports raised ambition & plan to enable accelerated approval as early as 2027, which will require accelerating critical activities with regards to regulatory interactions, clinical preparations and CMC

Fostrox – a smart chemotherapy with a unique, liver targeted & tumor selective treatment of HCC, potential for accelerated approval 27/28



Fostrox + Lenvima shows consistently improved efficacy compared with Lenvima alone



Continued development for fostrox + Lenvima in 2nd line HCC with Accelerated Approval intent 2027/2028



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

Thank You!

Fostrox + Lenvima combination uniquely targets key needs in 2nd line HCC

Ongoing studies in 2nd line HCC post Tecentriq + Avastin

	Fostrox + Lenvima	TKI monotherapy	IO combinations
Different mechanism of action than 1 st line	✓	✓	
Combination treatment with potential for synergistic activity	✓		✓
Targeting tumor locally in the liver to minimize side effects	✓		