Swedish biotech focused on development of innovative treatments for cancer

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MEDIVIR AB

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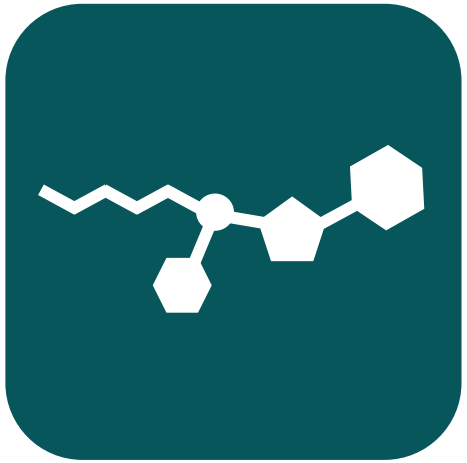
Medivir - A Swedish biotech focused on development of innovative treatments for cancer



Clear priority for unique, liver targeted chemotherapy inducing tumor selective cell death in high unmet need cancer

Active partnering strategy for additional value creation across product portfolio

Promising signs of clinical benefit for fostrox + Lenvima combination, 1st complete response

Phase 2a arm with fostrox in combination with Lenvima® now **fully recruited**

Promising signals of clinical benefit for fostrox + Lenvima, including 1st complete response & majority of patients achieving clinical benefit

Longest running patient **still on treatment after ~13 months**, with sustained tumor shrinkage

Patent application for fostrox in **China approved**, key component to enable partnering discussions in Asia

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Fostroxacitabine bralpamide (fostrox)

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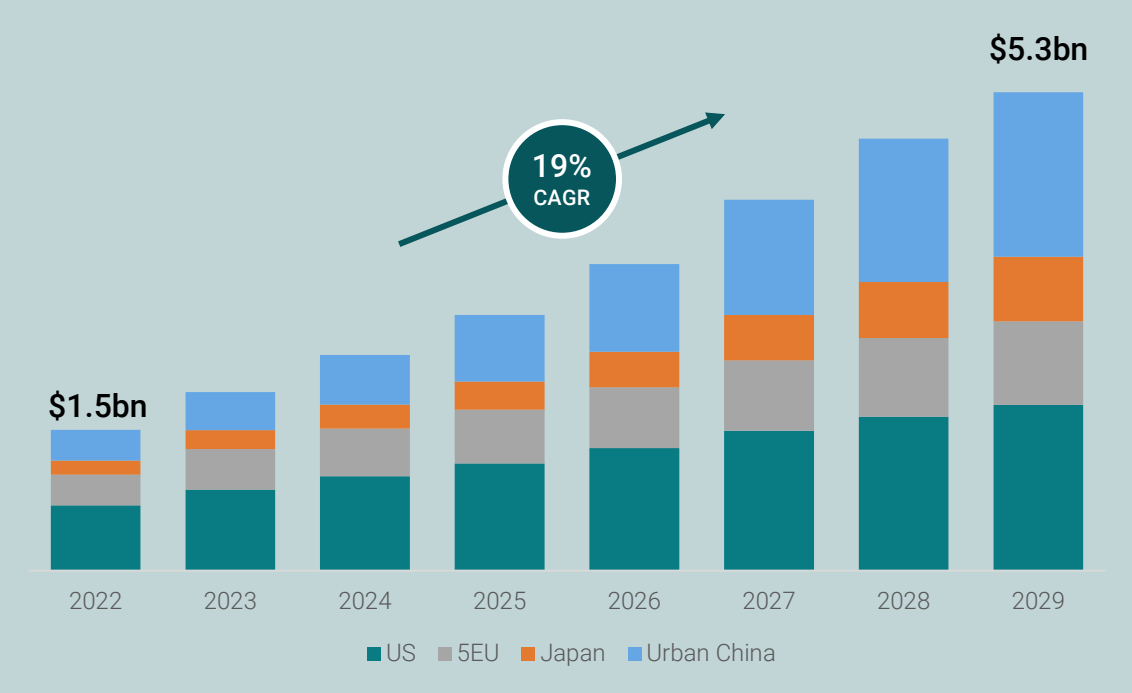
HCC (primary liver cancer) is a significantly growing market, partially driven by the increasing obesity pandemic

HCC market estimated to grow at ~20% per year



Despite recent advancements, unmet need is still high

- Liver cancer incidence & mortality are increasing; HCC being the third leading cause of cancer death worldwide[1,2]
- 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 respectively[3]
- HCC is the fastest increasing cause of cancer-related death in the USA[4,5]
- HCC rapid market growth is primarily driven by combination therapies and treatment in earlier lines

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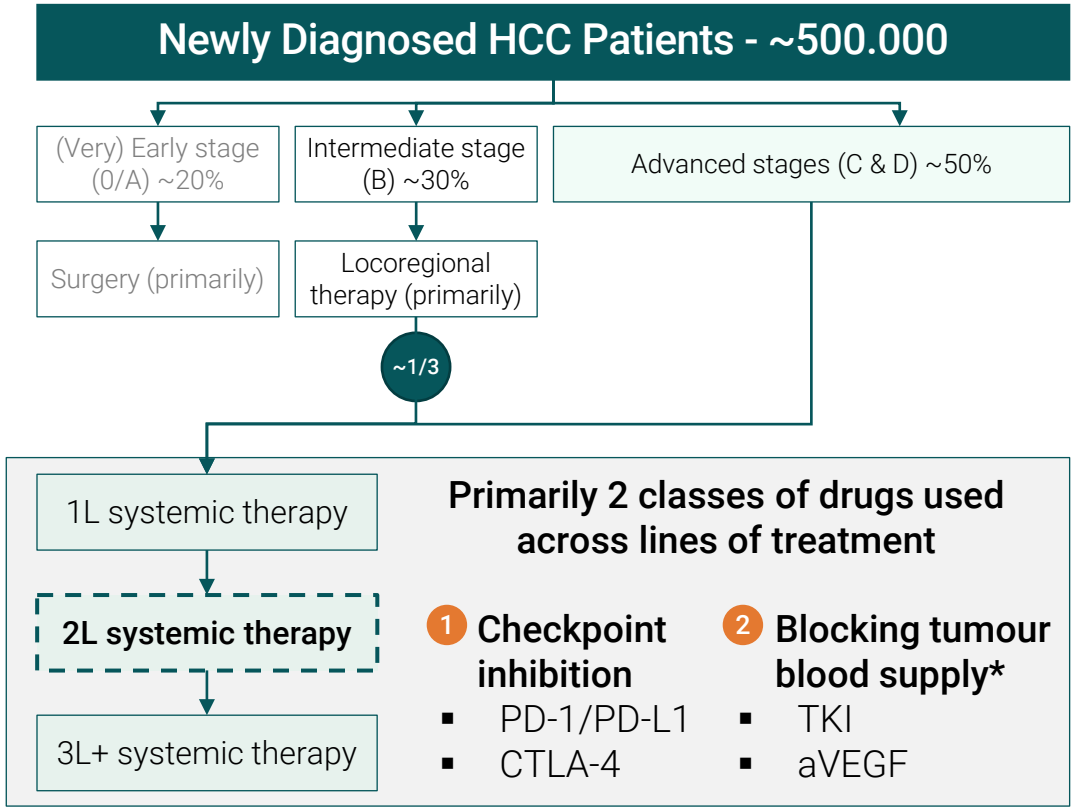
Source: GlobalData 2021

Limited treatment options in HCC with primarily 2 classes of drugs used; patients not able to benefit from chemotherapy



Traditional IV chemotherapy not used in HCC

1. Doses required to achieve sufficient liver exposure & clinical benefit cause unacceptable tolerability
2. HCC patients extra sensitive to liver toxicity due to primary tumor burden & underlying liver disease (cirrhosis)
3. General detoxifying mechanisms in hepatocyte-derived cancer cells, e.g. deaminases, cause inactivation of many cytotoxic compounds locally

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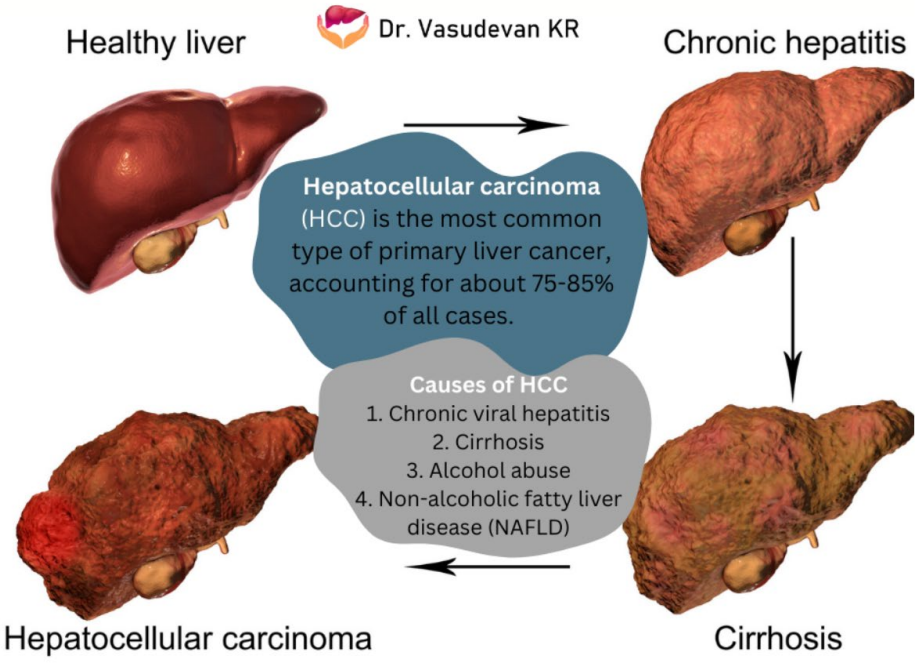
Source: Kantar Health & Global Data, 8 major markets

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 other treatments[1,2]
- Progression in HCC is unique as it primarily occurs locally in the liver[1]
- TACE & other local therapies show minimal long-term benefit and negatively impacts 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

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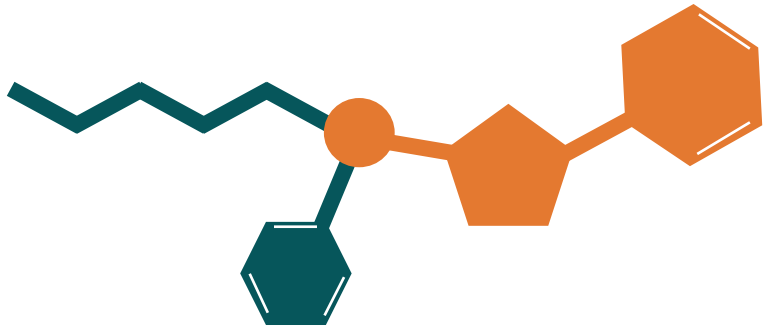
Fostrox – Combination of proven mechanisms

Pro-drug tail

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



Active substance - troxacitabine

2. Cytotoxic with high cell killing selectivity of tumor cells, sparing normal cells
3. Unnatural L-nucleoside structure to avoid resistance mechanisms

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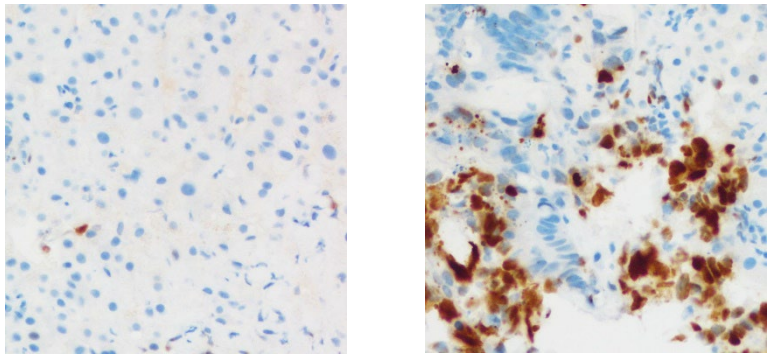
Fostrox – Patient biopsies in phase 1 with DNA damage & cell death in HCC tumour cells while sparing normal liver tissue

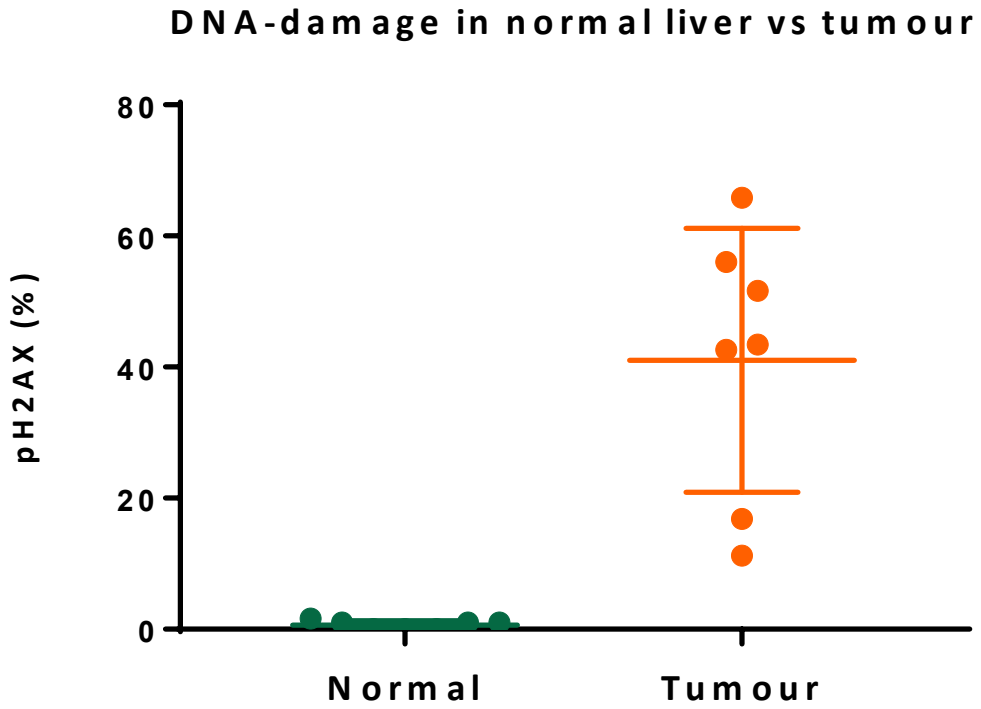
Tumour selective induction of DNA-damage[1]

Normal liver tissue **Tumour tissue**



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

Cytotoxic in tumor tissue but not in normal liver tissue[2]



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[1]Öberg F et al, ESMO, 527P, 2021
[2]Öberg F. et al, EASL PO-221, 2022

Fostrox – *a novel combination partner in HCC; promising clinical benefit in ongoing 2L study*

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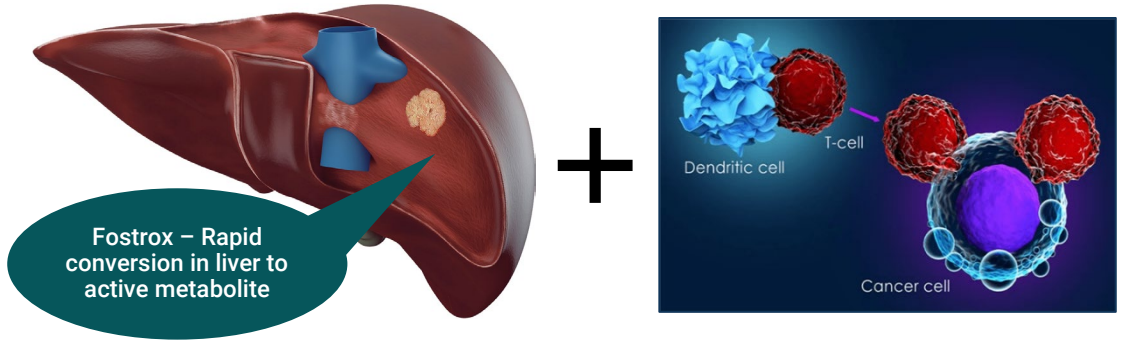
Fostrox – A unique, differentiated MoA in HCC inhibiting DNA replication; strong potential for combinations

Fostrox + stimulation of immune system (PD-1)

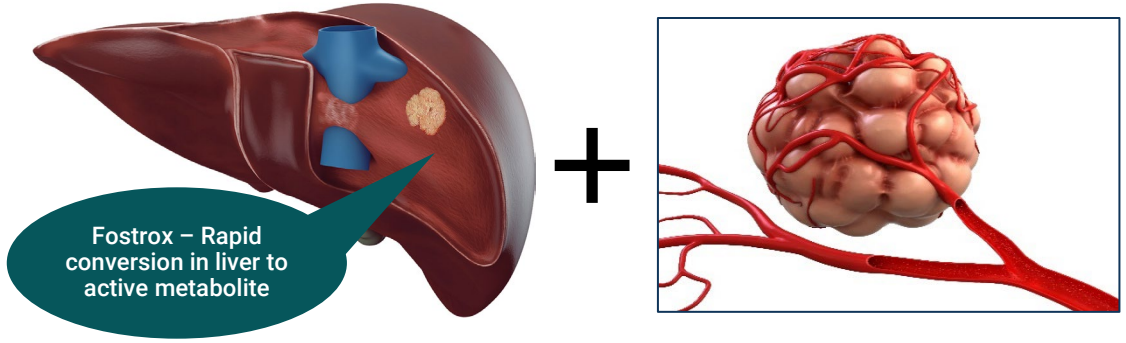


"Fostrox induces DNA damage and tumor cell death, potentially leading to **increased tumor antigen presentation and increased immune response"**

Drugs that stimulate the immune system:

- Keytruda (PD-1)
- Tezentriq (PD-L1)
- Opdivo (PD-1)

Fostrox + blocking blood supply to tumor (TKI/VEGF-R*)



"TKI´s induce lack of oxygen in tumors which increases PGK1, **the enzyme responsible for cleaving fostrox into its active metabolite"**

TKIs (tyrosine kinase inhibitors):

- Lenvima (Multi-TKI)
- Nexavar (Multi-TKI)
- Avastin (VEGF-R)

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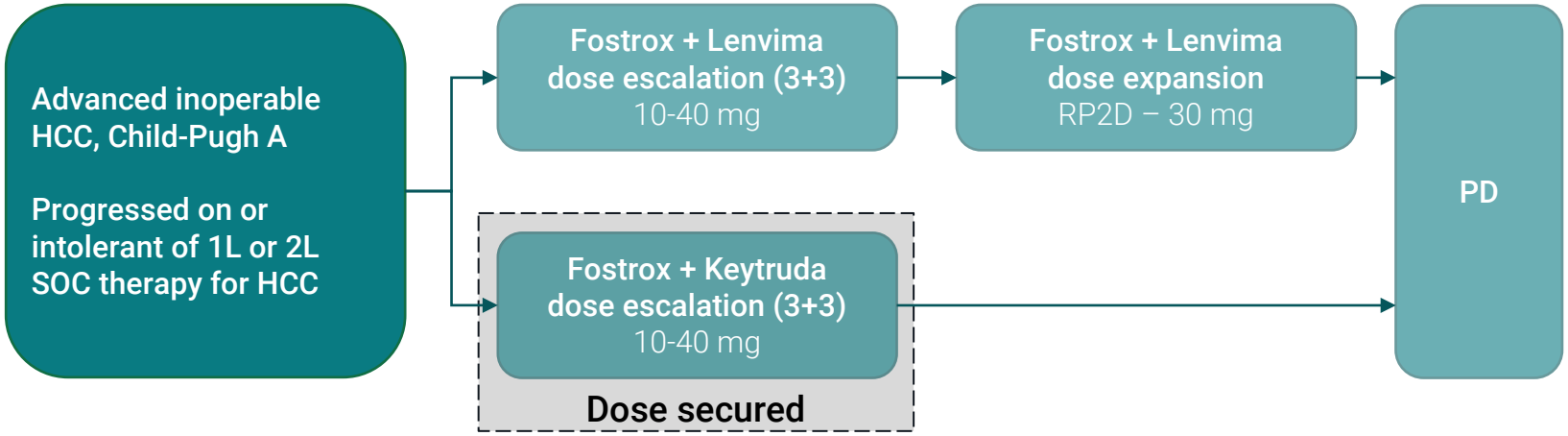
*Some of these drugs are multifunctional and have additional functions

Fostrox + Lenvima (TKI) combination chosen in 2L HCC and dose secured in fostrox + Keytruda (PD-1) arm

Phase 1b/2a dose escalation & dose expansion combination study*



Phase 1b/2a 2nd & 3rd line study

Primary end-point: Safety & tolerability
Secondary end-points: ORR, DCR, PFS
First subject-in: Q4 2021

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*Currently ongoing at 15 sites in UK, Spain & Korea

All patients in fostrox + Lenvima arm experienced tumor growth on previous 1L treatment, majority on SoC Tecentriq + Avastin

Key patient characteristics (first 17 patients)

Region, Asia / Europe	65% / 35%
Etiology HCC, viral / non-viral	65% / 35%
Prior Tecentriq - Avastin in 1L	**82%**
Known prior local therapy (TACE)	65%
PD (tumor growth ≥ 20%) on prior treatment	**100%**
Starting dose fostrox, 20mg / 30mg	18% / 82%

Update on previously reported sample patients

1

Female
Caucasian
56 years
Hepatitis C

- Progressed on 1L Tecentriq + Avastin after 5 months
- **Still on treatment for ~13 months** with sustained tumor shrinkage >30% (PR)
- Fostrox dose cohort – 20 mg

2

Male
Asian
71 years
Non-viral

- Progressed on 1L Tecentriq + Avastin after 1.5 months
- **Stable Disease for 7 months** with fostrox monotherapy
- Fostrox dose cohort – 30 mg

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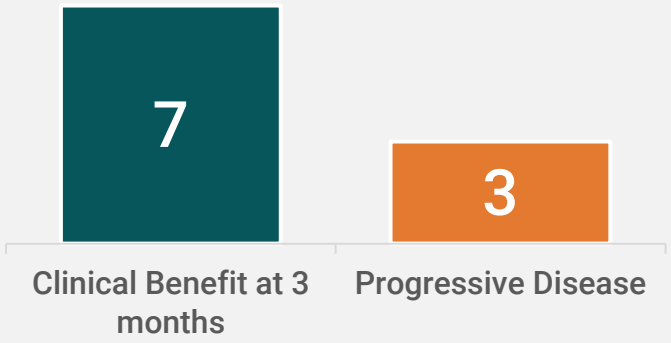
Promising tumor control for fostrox + Lenvima in both local & central review, majority of patients achieving clinical benefit

Local review[1]

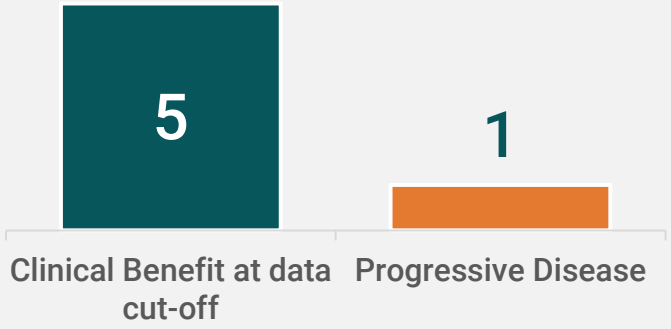
- First 10 patients in phase 1b/2a
- Scans reviewed by local oncologist & radiologist



- **2 partial response; tumor ↓ ≥ 30%**
- **5 stable disease**

Central review[2]

- All patients in phase 1b (6)
- Scans reviewed by independent radiologist



- **1 complete response**
- **2 partial response; tumor ↓ ≥ 30%**
- **2 stable disease**

[1]Preliminary results from local reads
[2]Data cut-off 17 September, 2023

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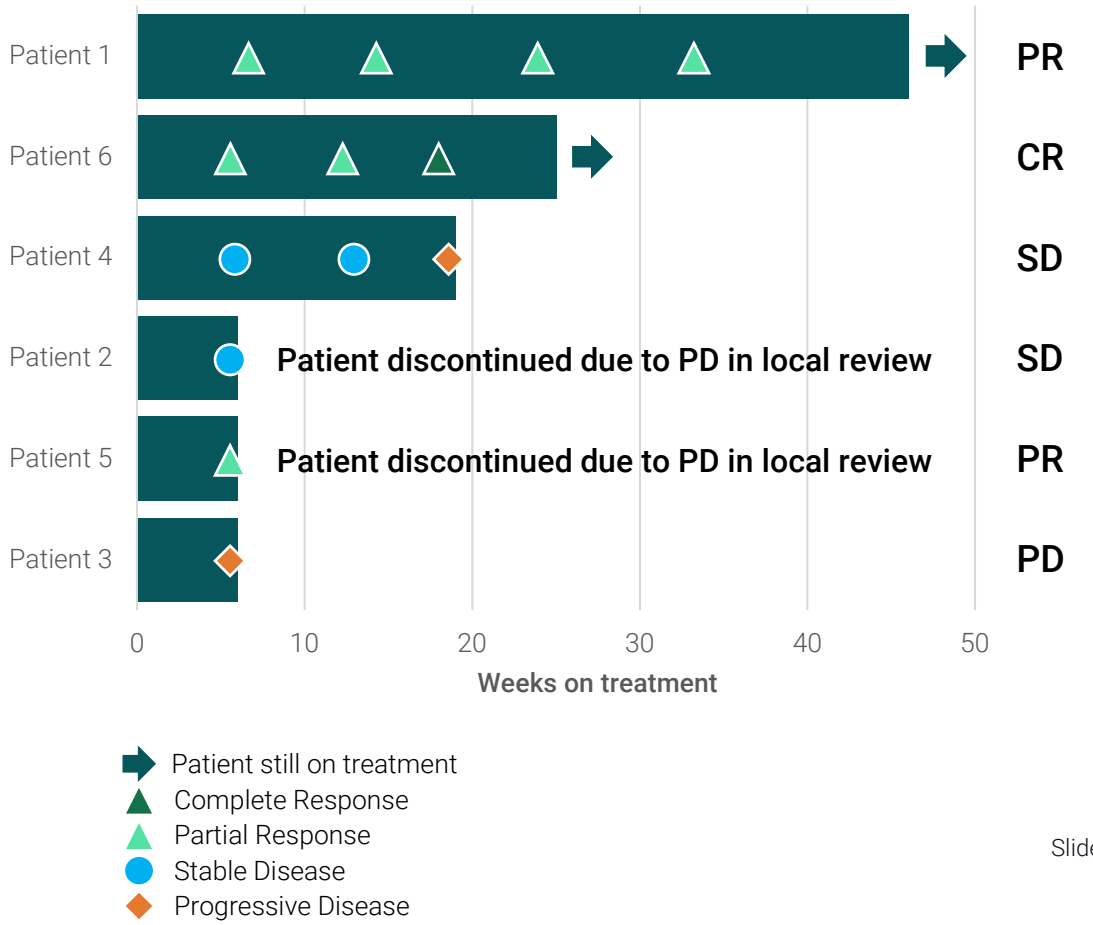
Central review – 1 complete & 2 partial response out of 6 patients in first interim data of phase 1b dose escalation cohorts

Independent review by radiologist – mRECIST



Improved response assessment with independent review

- 1 complete response (mRECIST), all signs of viable tumor in the liver absent by 3rd scan, and 2 partial response
- 5 out 6 patients achieved clinical benefit; stable disease or better
- 2 out of 3 patients with progressive disease, local review, were subsequently reviewed as partial response or stable disease by independent review

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Low response rates & short time to progression across 2L HCC studies; indicating significant unmet medical need

Study name	Treatment	Median PFS[1] (mts)	ORR[1] mRECIST/ RECIST	Grade 3/4 TRAEs	D/C rate
RESORCE	Regorafenib	**3,1**	**11% / 7%**	50%	10%
CELESTIAL	Cabozantinib	**5,2**	**NR / 4%**	68% (all cause)	16%
REACH-2 (AFP>400)	Ramucirumab	**2,8**	**NR / 5%**	NR	11%
Retrospective 2L post Tecentriq + Avastin	Lenvima	**3,7**	**NR**	40%	13%
KEYNOTE 240/224	Pembrolizumab	**3,0**	**NR / 18,3%**	52%	17,2%

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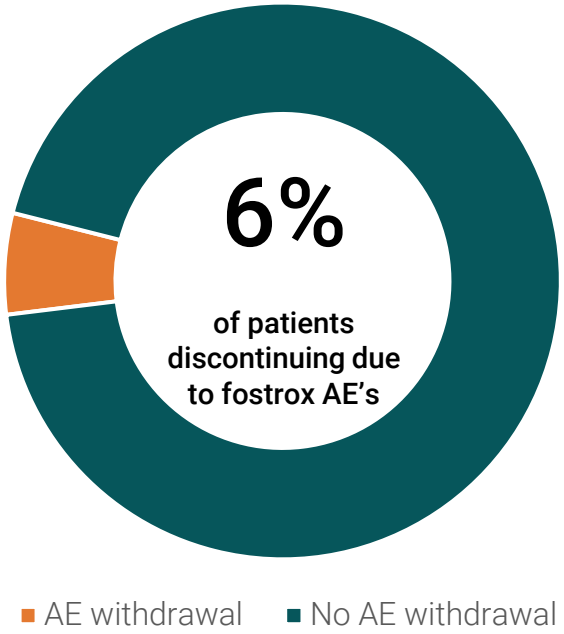
[1]PFS (Progression-free survival), ORR (Overall Response Rate), TRAEs (Treatment Related Adverse Events), D/C rate (Discontinued rate)
[2]Data from previous 2L phase 3 HCC studies with Stivarga, Cyramza, Cabometyx and Keytruda + retrospective 2L with Lenvima after Tecentriq + Avastin in 1L

Consistently good safety & tolerability profile for fostrox + Lenvima combination*; lower than expected need for dose reductions

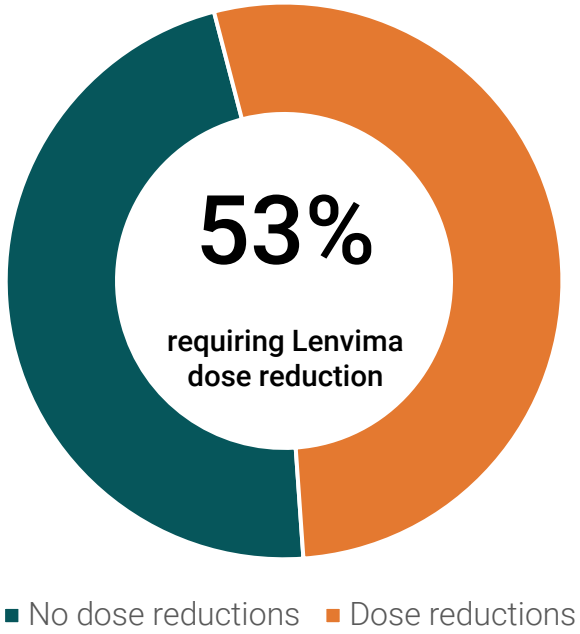
Only 1 exit due to fostrox side effects



Very encouraging tolerability profile

- No unexpected new safety events
- Adverse events manageable and transient with 2/3 patients on fostrox starting dose
- Lower need for dose reductions than expected for Lenvima
  - 62 – 66% dose reductions in previous monotherapy & combination studies

~50% requiring Lenvima dose reduction



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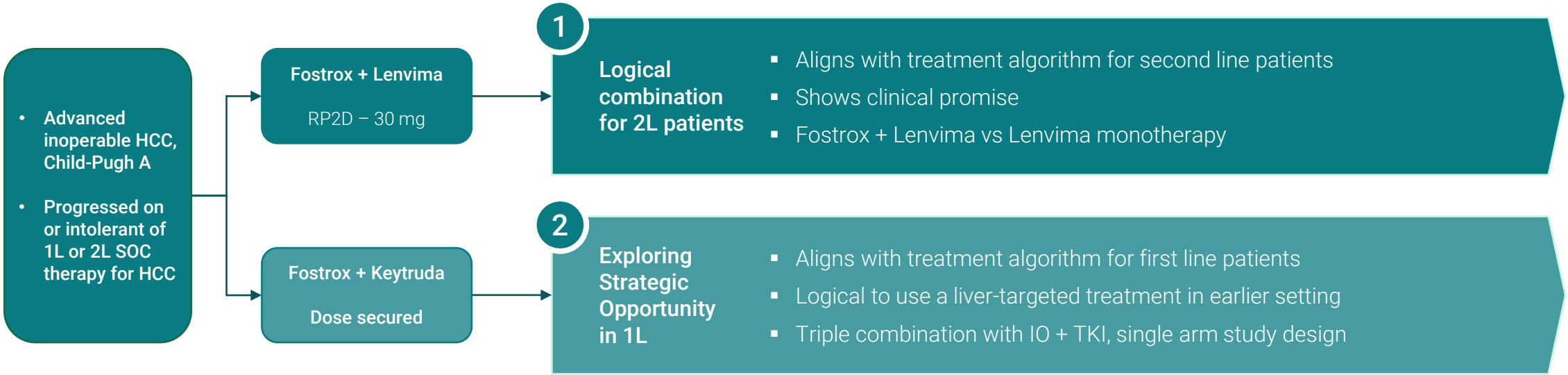
*First 17 patients

Exciting potential options for next phase of fostrox development

Potential options beyond ongoing phase 1b/2a



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Fostrox Scientific Advisory Council to support shaping the future development of fostrox

Dr. Richard Finn

- Professor of Medicine at the Geffen School of Medicine at UCLA Department of Medicine, Division of Hematology/Oncology.
- Director of the Translational Research Laboratory in the Division of Hematology/Oncology.
- PI of several, ground-breaking studies in HCC, including ImBrave 150 study.

Dr. Jeff Evans

- Professor of Translational Cancer Research in the School of Cancer Sciences, Univ. of Glasgow & honorary Consultant in Medical Oncology at Beatson West of Scotland Cancer Centre
- He is the Lead of the Glasgow Experimental Cancer Medicine Centre (ECMC) and National Clinical Lead of the NHS Scotland Cancer Research Network.
- He is an investigator in the fostrox clinical development program.

Dr. Arndt Vogel

- Managing senior consultant and Prof. in the Department of Gastroenterology, Hepatology and Endocrinology at Hannover Medical School.
- Member and chairman of Hepatobiliary Cancer Study Group of the AIO
- Member of the ESMO Guidelines Steering Committee and coordinator of the ESMO clinical practice guideline on the management of HCC and BTC.

Dr. Maria Reig

- Head of the BCLC and Liver Oncology Unit at Hospital Clinic of Barcelona in Spain.
- Her expertise and area of interest is the development of prognostic models for patients with liver cancer and evaluation of treatment options as well as new research about immune modulation and cancer emergence after antiviral treatment.
- She is an investigator in the fostrox clinical program.

Dr. Jeong Heo

- Professor of Internal Medicine at Pusan National University School of Medicine and Director of Gastroenterology and Hepatology at Pusan National University Hospital.
- Professor Heo has held a number of academic positions, university & hospital appointments and has been PI in many ph. I-IV clinical trials in hepatitis B, C and HCC.
- He is an investigator in the fostrox clinical program.

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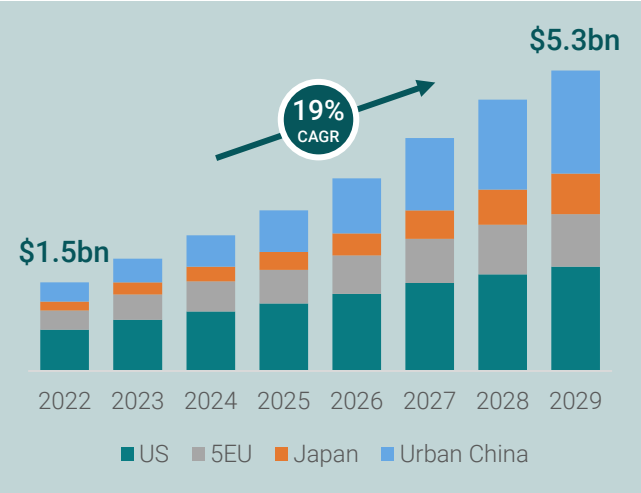
Fostrox – unique, liver targeted chemotherapy inducing tumor selective cell death in cancer patients with high unmet need

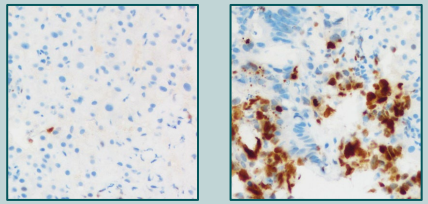
Significant unmet need & **commercial potential**



Selectively targets liver **cancer** cells, sparing normal tissue

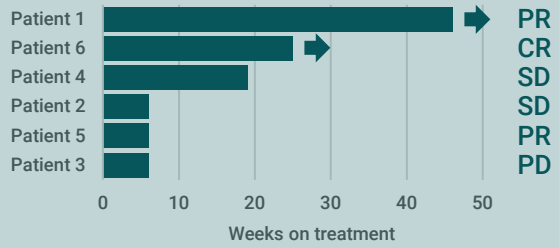
Pro-drug enables 100-fold increased liver targeted exposure…

…while selectively killing tumor cells



Promising signals of clinical benefit, **1st complete response**

- 1 of 6 with complete response (phase 1b)
- 2 partial responses & 2 stable disease
- Longest running patient at ~13 months



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