

Improving life for advanced liver cancer (HCC) patients  
Fostrox – The first oral, liver-targeted treatment for advanced HCC

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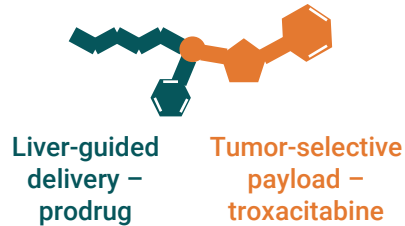
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# Fostrox (fostroxacitabine bralpamide)

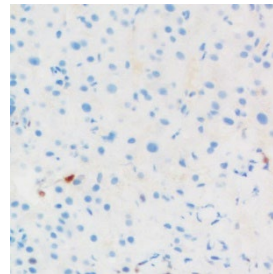
## The first oral, liver-targeted treatment tailored for HCC

Oral, liver-activated small molecule inducing DNA damage in tumor cells, sparing healthy liver cells<sup>3</sup>

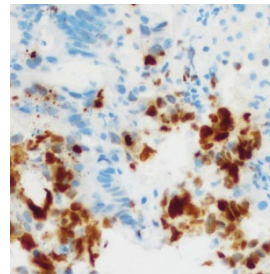
Unique, liver-targeted approach in HCC



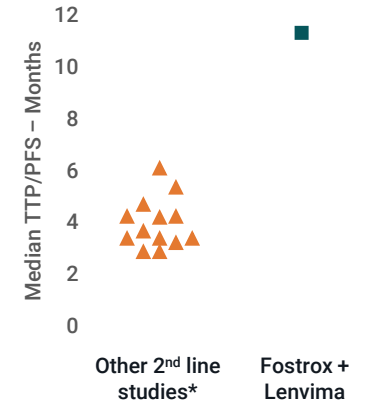
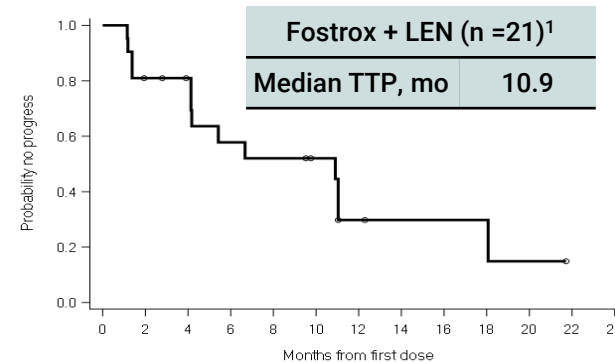
No DNA damage in healthy liver tissue



DNA damage in tumor tissue



10.9 months time to progression, substantially better than SoC<sup>1,2</sup>



\*see slide 20 for details regarding individual study data

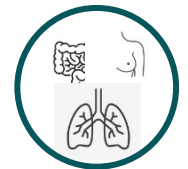
Absence of effective treatment options in 2<sup>nd</sup> line enables first-to-market opportunity for fostrox + Lenvima



- No 2<sup>nd</sup> line treatments approved in advanced HCC
- Global phase 2b start H1 '25
- Designed to enable breakthrough designation and support accelerated approval process

Market opportunity in 2<sup>nd</sup> line HCC >\$2.5bn, with significant upside potential

>\$2.5bn



2<sup>nd</sup> line HCC market by 2030, fastest growing cause of cancer death in US<sup>4</sup>

Significant upside in liver metastasis from other solid tumors

<sup>1</sup>Chon et al., ESMO, 2024, Poster 986

<sup>2</sup>Based on data from previous 2L phase 3 HCC studies with Stivarga, Cyramza & Cabometyx and investigator initiated prospective & retrospective 2L studies with Lenvatinib

<sup>3</sup>Evans et al ASCO GI, 2021

<sup>4</sup>Ma et al., Cancer, June 15, 2019; 2089-2098

# Medivir management team



**CEO**  
**Jens Lindberg**

- > 25 years of experience from pharmaceutical industry with focus on late-stage development & commercialization in Oncology of drugs like Tagrisso, Lynparza, Imfinzi and Iressa
- Other experience includes interim CEO for Sedana Medical AB and Director Investor Relations at AstraZeneca.
- Member of the Board of Braincool AB.



**CMO**  
**Dr. Pia Baumann**

- MD PhD with a specialist degree in medical & radiation oncology at Karolinska Institute/University hospital.
- Substantial experience in drug development in the cancer field.
- > 25 years of clinical work at Karolinska and pharmaceutical/biotech companies, including AstraZeneca, BMS, Takeda, Incyte and ARIAD



**CFO**  
**Magnus Christensen**

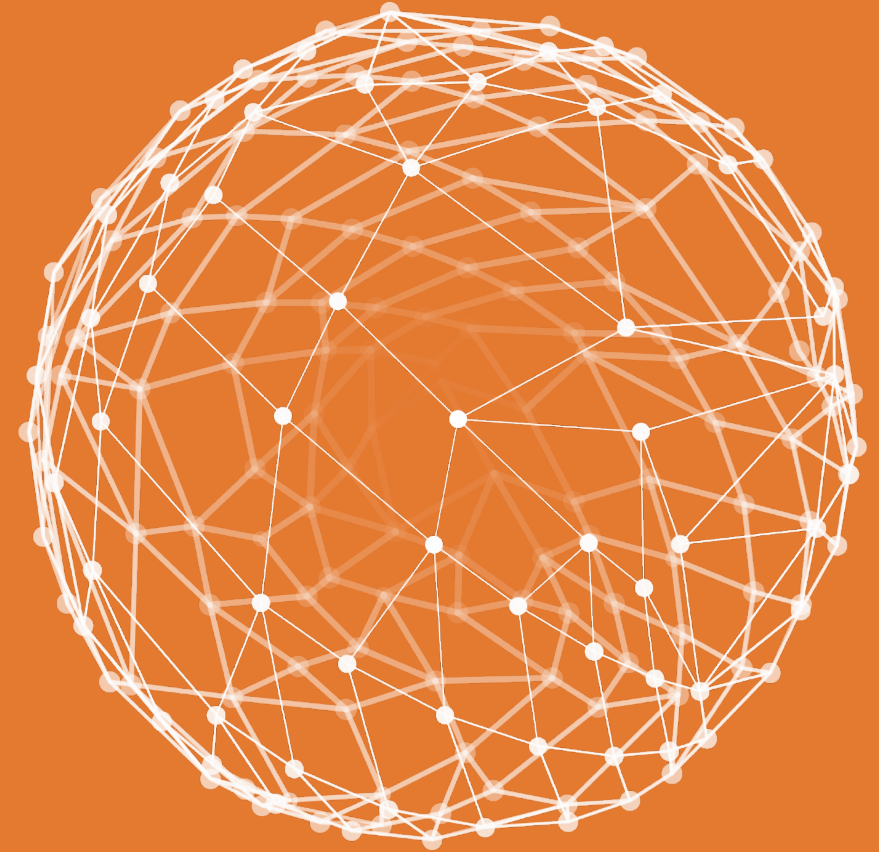
- > 25 years of experience in finance.
- Interim CEO at Medivir, May 2021-January 2022.
- Former CFO at O'Learys Trademark AB.
- Experience of working in listed-, private equity- and private companies.
- Member of the Board of PMD Device Solutions AB.



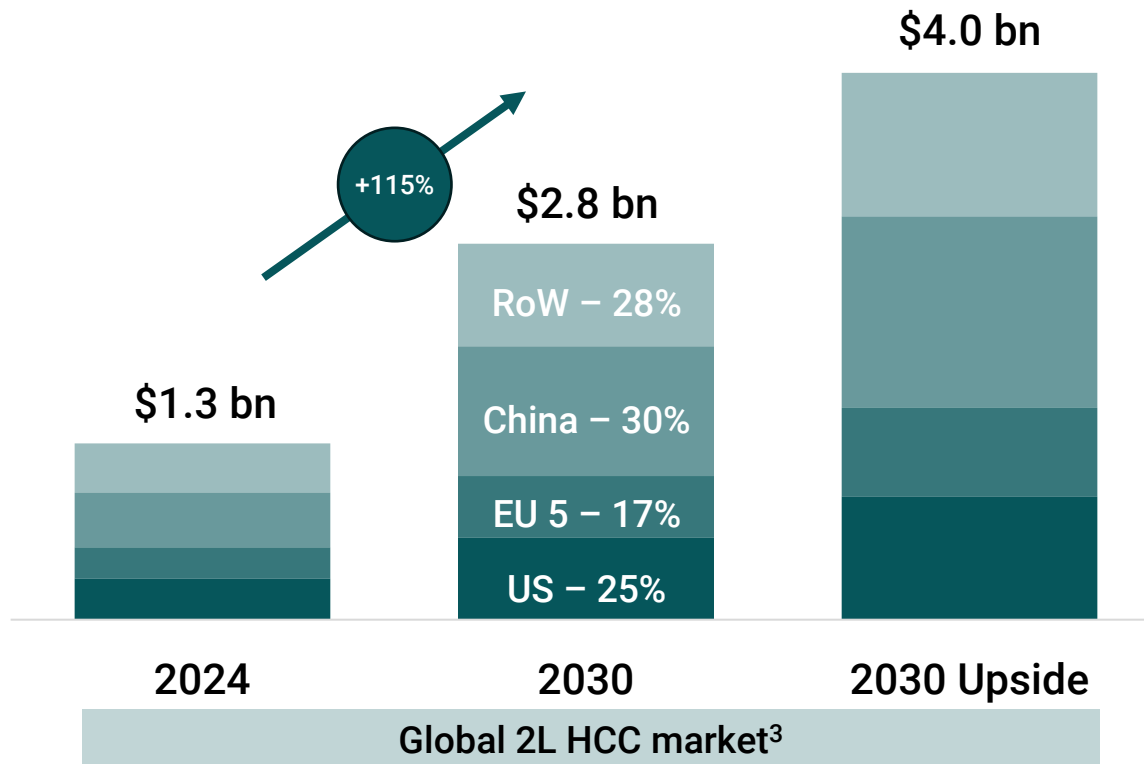
**CSO**  
**Fredrik Öberg**

- PhD in Medical Science & Adjunct professor at the Medical Faculty of Uppsala University.
- > 25 years of experience in cancer research.
- During the last 10 years focused on industrial drug discovery and development projects in oncology.
- He has published more than 50 scientific articles and holds several patents.

**First-to-market opportunity  
in 2<sup>nd</sup> line HCC market  
valued >\$2.5bn**



# 2<sup>nd</sup> line HCC – a large and growing commercial opportunity with significant need for new treatment options<sup>3</sup>



## Growth driven by:

- HCC to increase **+122% in the US** and **+82% in China<sup>2</sup>** by 2030, caused by fatty liver disease
- With improved 1L treatment, more patients will be **fit enough for 2L, 50% → 70%**
- New, approved treatment options increase average **treatment duration to 7 months** by 2030

## 2030 Upside:

- Average treatment duration increases to 10 months based on fostrox + Lenvima<sup>®</sup> study

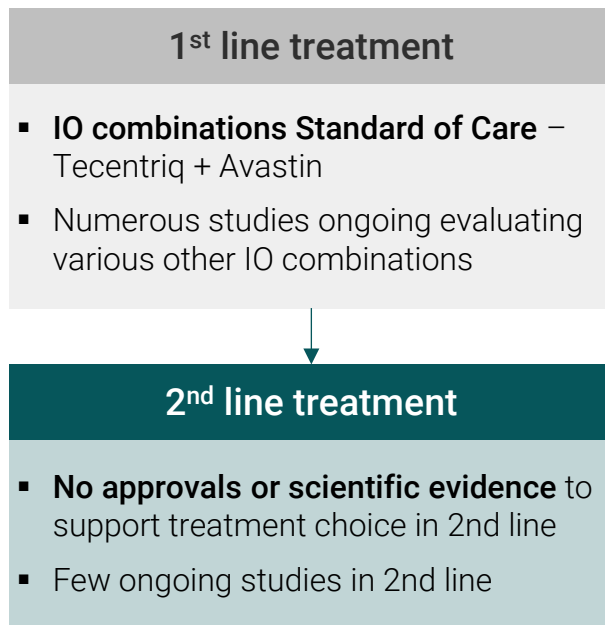
<sup>1</sup>Rumguy et al. Journal of Hepatology 2022

<sup>2</sup>Huang et al., Nature Reviews, Gastroenterology & Hepatology, Vol 18, 2021

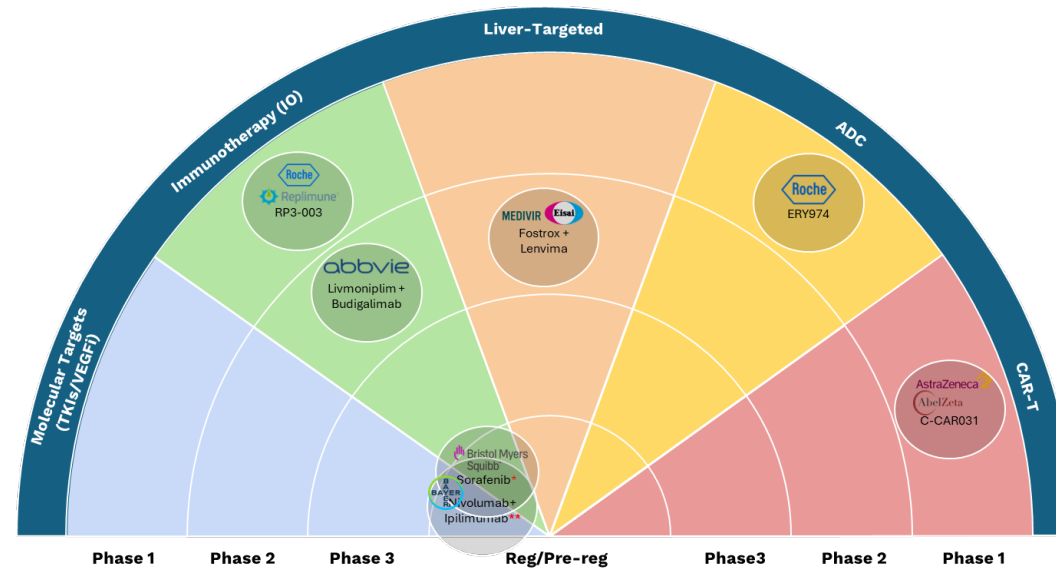
<sup>3</sup>GlobalData 2021 and internal analysis

# Absence of effective treatment options in 2<sup>nd</sup> line HCC

Treatment algorithm – major need for new 2<sup>nd</sup> line options



Competitive landscape in 2<sup>nd</sup> line HCC highlights lack of novel mechanisms in development with fostrox + Lenvima at the forefront



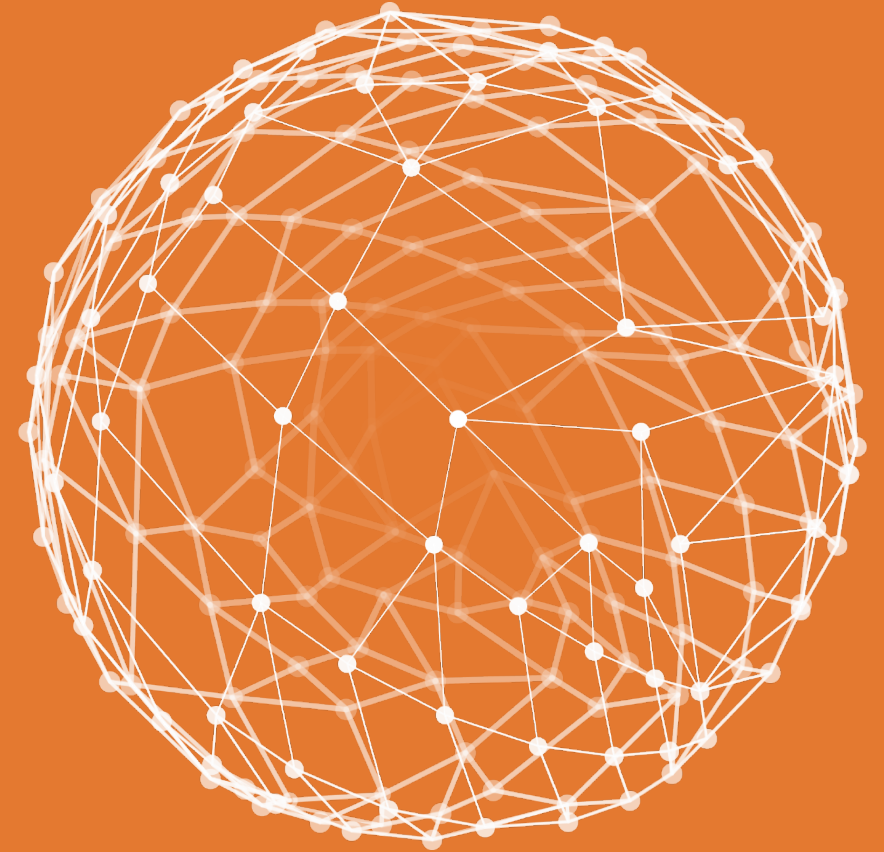
“We are becoming greedy, trying to have 8 different regimens in the 1L setting and none of us know what to do after.”

If I had my way, the focus should really be on 2L treatment and beyond”

Rachna T Schroff, University of Arizona Cancer Center  
Late Breaking Abstract session at ESMO, September 2024

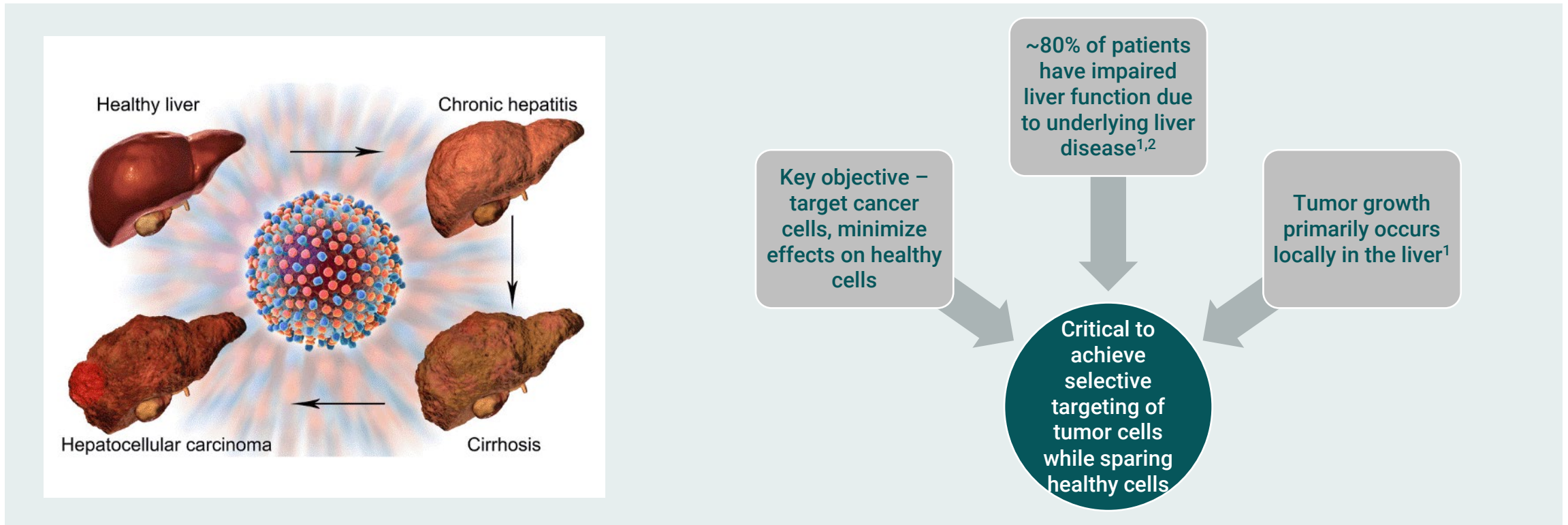
\*Sorafenib was the first approved 1st-line treatment for HCC. Although approved for 2nd-line use, guidelines recommend against it due to a lack of evidence showing efficacy after immunotherapy combinations.  
\*\*Nivolumab + Ipilimumab were approved for patients post-sorafenib but are now moving into 1st line HCC treatment (positive phase III, awaiting approval ([source](#))).

**Fostrox – tailored for the  
specific needs of HCC**





# Targeted treatment approach critical in liver cancer (HCC)

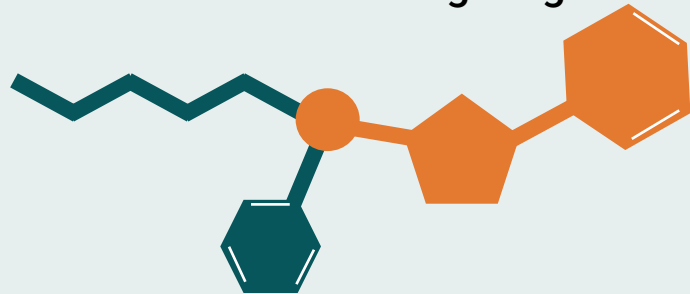


<sup>1</sup> Senthilnathan et al., Hepatology, 2012 May; 55(5): 1432-1442

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

# Fostrox – tailored for HCC to achieve targeted DNA damage in liver tumor cells with minimal impact on healthy liver cells

The same, proven & highly successful approach used in HCV to maximize liver-targeting<sup>2</sup>



Liver-guided delivery – prodrug

Tumor-selective payload – troxacitabine



Combining prodrug & payload enables oral administration & targeted (>100-fold) liver exposure vs IV chemotherapy<sup>1</sup>



Molecule stable in GI tract & in blood, rapidly activated by enzymes in the liver<sup>2</sup>



Payload selected as it causes DNA damage selectively in liver tumor cells, sparing healthy liver cells<sup>3,4,5</sup>

<sup>1</sup>Bethell, R. et al , SAT-123, EASL 2017

<sup>2</sup>Bethell, R. et al P-035, ILCA 2016

<sup>3</sup>Kukhanova, M et al J Biol Chem 1995

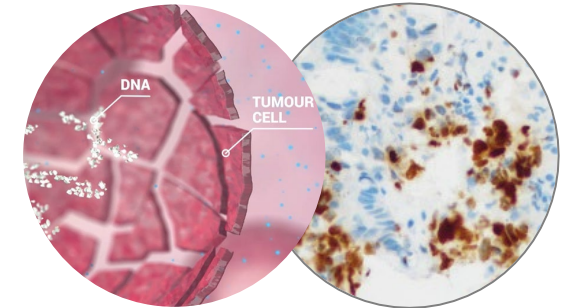
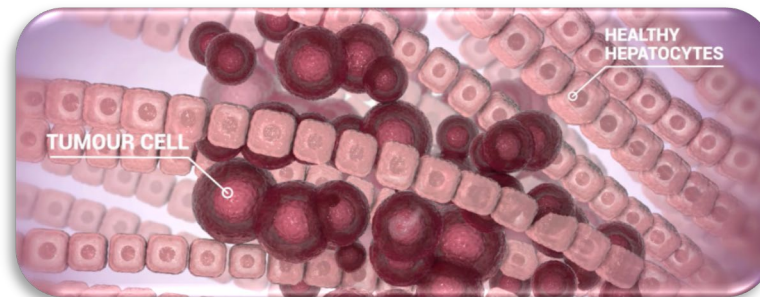
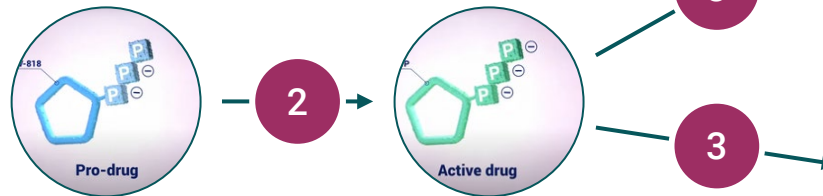
<sup>4</sup>Albertella, M. et al EASL Summit P01-05, 2018

<sup>5</sup>Öberg F. et al, EASL PO-221, 2022

# Fostrox MoA – tailored for HCC to achieve targeted DNA damage in liver tumor cells with minimal impact on healthy liver cells

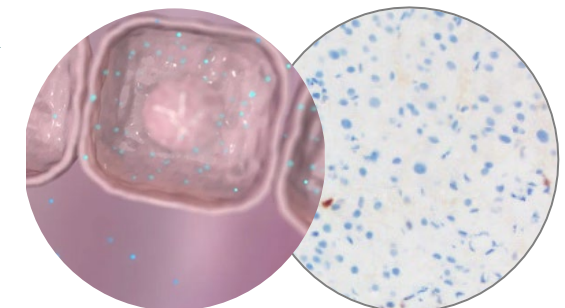


Rapidly activated by liver enzymes  
Trapped inside liver cells for maximum liver exposure and minimal systemic spread<sup>2,3,4</sup>



Cell death in tumor cells

Causes selective cell killing effect in tumor cells, sparing healthy liver cells as they very rarely divide<sup>2,3,4</sup>



No impact on healthy cells

<sup>1</sup>Bethell, R. et al P-035, ILCA 2016

<sup>2</sup>Kukhanova, M et al J Biol Chem 1995

<sup>3</sup>Albertella, M. et al EASL Summit P01-05, 2018

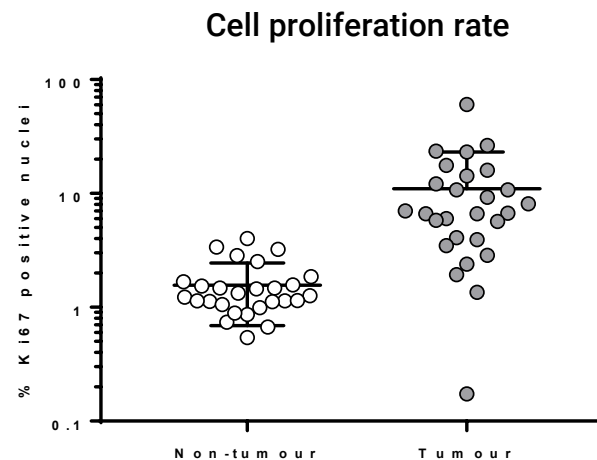
<sup>4</sup>Öberg F. et al, EASL PO-221, 2022

# 100-fold higher liver targeting vs IV administration & selective DNA damage in tumor cells enabling highly targeted mechanism

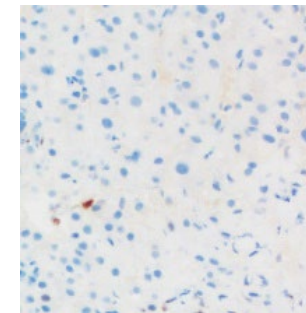
>100-fold higher liver targeting with fostrox than iv troxacitabine in rats

Compound	Route	Dose (µmol/kg)	AUC <sub>Liver</sub> (nmol*h/g)	AUC <sub>Plasma</sub> (µmol*h/L)	AUC ratio (Liver/Plasma)
Troxacitabine	iv	80	<1.2	80	<0.016
Fostrox	oral	80	10	5.4	1.9

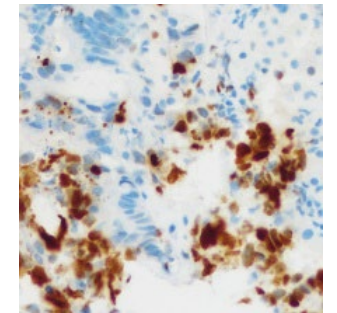
Liver tumor cells divide significantly more often than non-tumor cells<sup>1</sup>



Fostrox induces DNA damage in tumor cells, sparing normal liver tissue<sup>2</sup>



Normal liver tissue\*



Tumor tissue\*

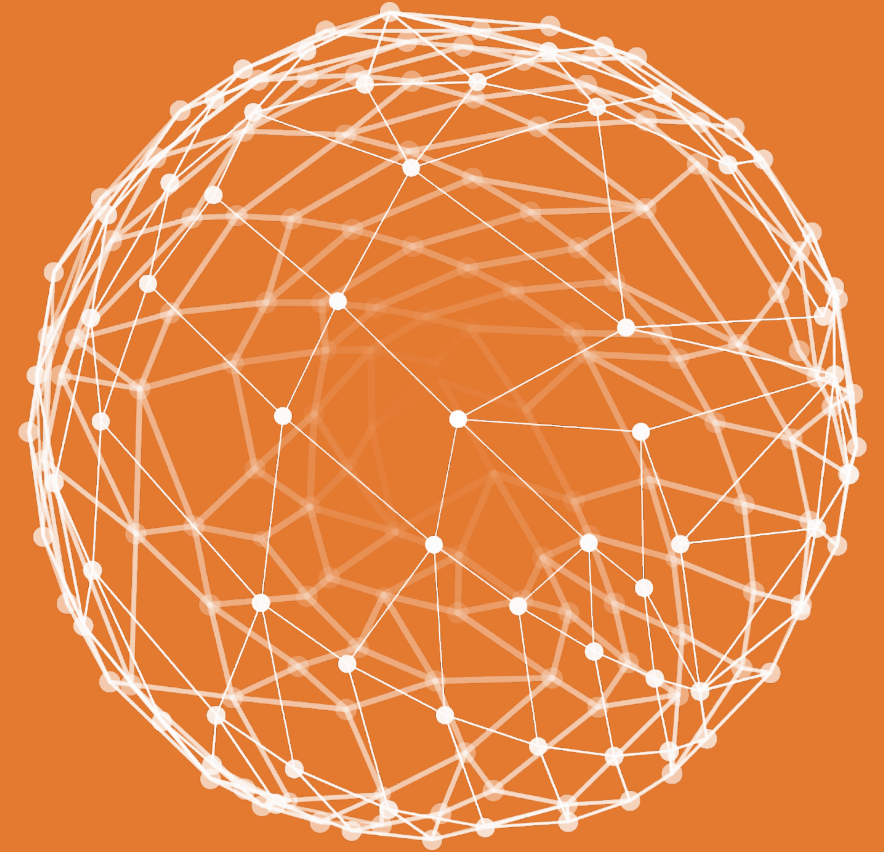
Fostrox-induced DNA-damage indicated by pH2AX immunohistochemistry (IHC) staining of liver biopsy from phase 1b monotherapy

<sup>1</sup>Albertella, M. et al EASL Summit P01-05, 2017

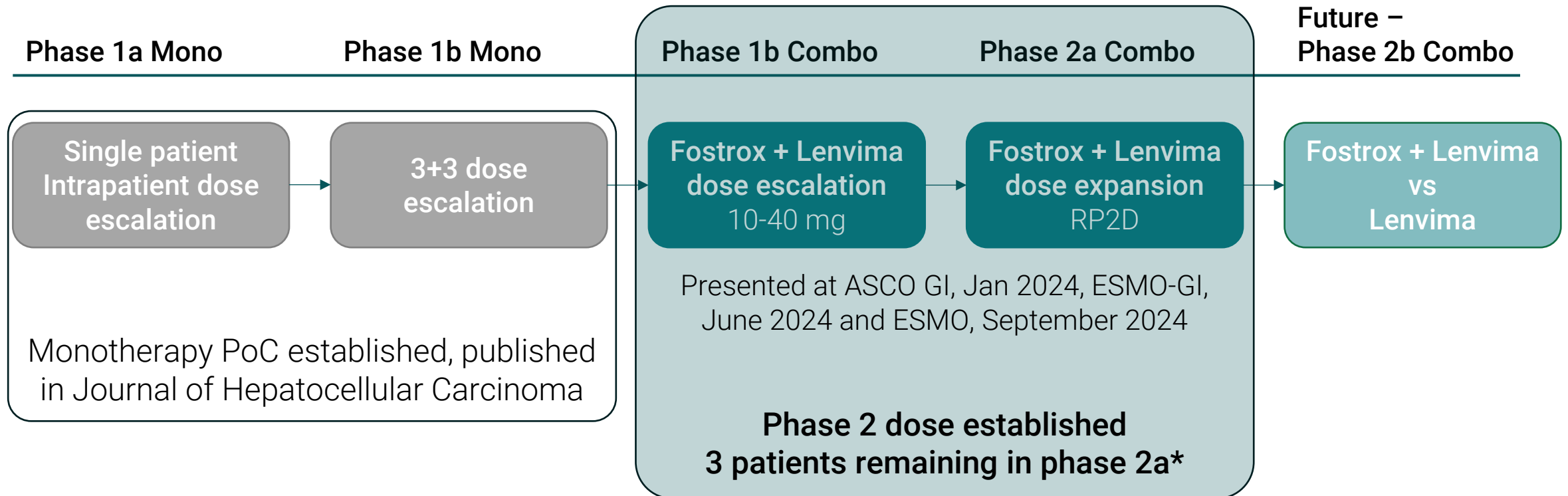
<sup>2</sup>Öberg F. et al, EASL PO-221, 2022

\*Induced DNA damage indicated by pH2AX IHC staining (brown color) in patient biopsies

**Fostrox + Lenvima shows  
promise of improved  
outcomes in 2L HCC**



# Fostrox Clinical Development Program; monotherapy PoC established, focus on combination approach in 2L HCC

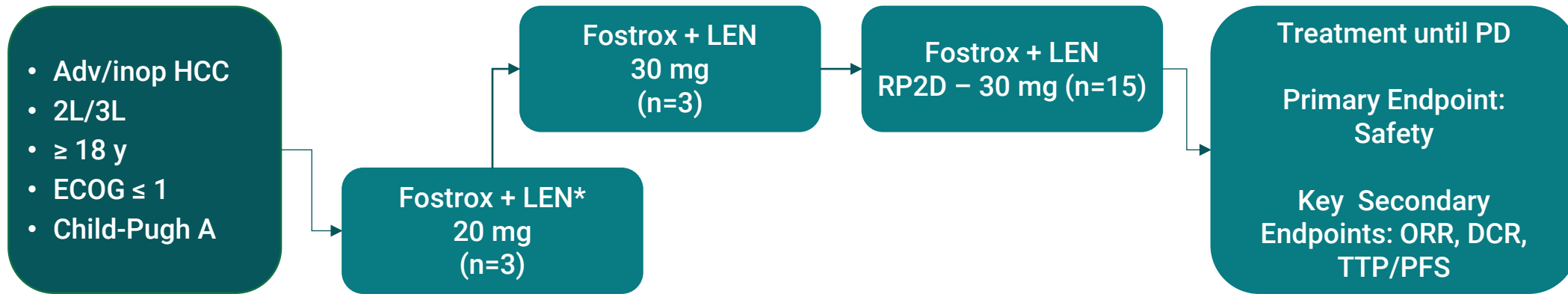


Monotherapy PoC established, published in Journal of Hepatocellular Carcinoma

Presented at ASCO GI, Jan 2024, ESMO-GI, June 2024 and ESMO, September 2024

**Phase 2 dose established**  
**3 patients remaining in phase 2a\***

# Fostrox + Lenvima phase 1b/2a study design



Patients were enrolled at 15 sites in the UK, Spain and South Korea. Imaging assessments (CT & MRI) every 6 weeks.

**Fostrox:** Oral QD  
5 days in 21 days cycles

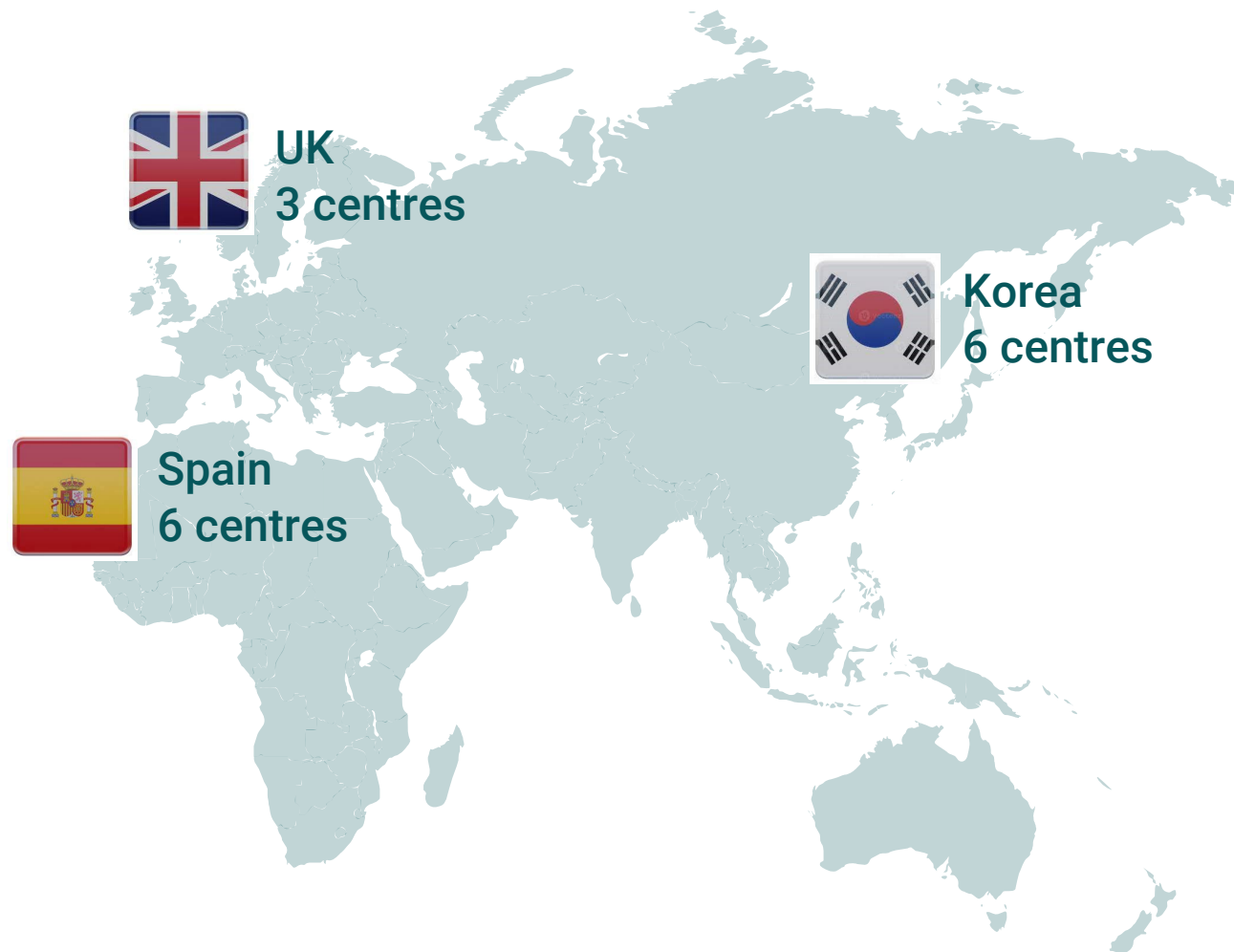


**LEN:** Oral QD continuous  
(8 or 12 mg)



One cycle 21 days

# Global phase 1b/2a study with fostrox + Lenvima (TKI)



## Key study features

- Fostrox + Lenvima in second and third line advanced HCC
- 15 sites in South Korea, Spain and UK
- Rapid recruitment speed, phase 2a dose expansion fully recruited in <5 months
- Median follow-up 10.5 months



# Patient characteristics reflecting generous inclusion criteria

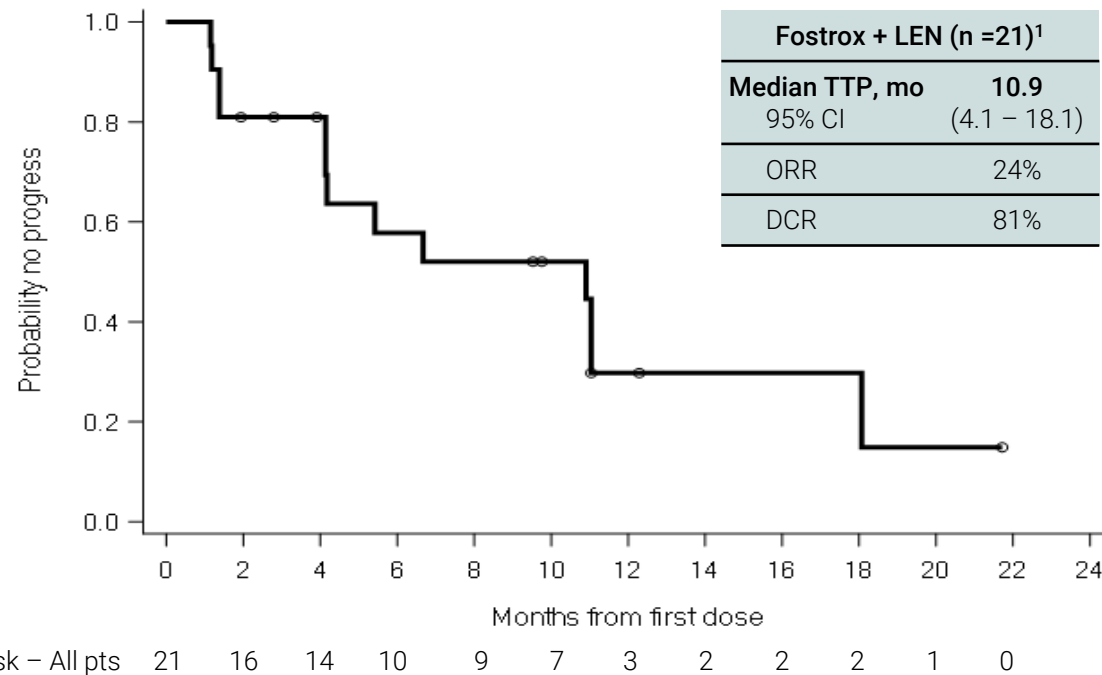
Patient characteristics <sup>1</sup>	N = 21
Mean age (range)	62 yrs (42 - 82)
Gender, Female / Male (%)	24 / 76
ECOG Performance status 0/1 (%)	71 / 29
Child-Pugh A (%)	100
Viral/Non-viral (%)	76* / 24
<b>Extra hepatic lesion(s) Y/N (%)</b>	67 / 33
<b>AFP ≥400 ng/mL at baseline Y/N (%)**</b>	45 / 55
Region, Asia / Europ (%)	67 / 33
<b>Prior treatment lines; 2nd line/3rd line (%)</b>	81 / 19
Prior atezolizumab/bevacizumab in 1L (%)	86
Prior local therapy (TACE, RFA etc)	70
PD on prior treatment (%)	100
<b>Primary refractory on prior therapy (%)***</b>	24
Starting dose fostrox, 20mg / 30mg (%)	14 / 86

\*HepB-81% and HepC-19%; \*\*AFP- NA for 1 pt; \*\*\*Active treatment ≤ 12 weeks. Data NA for 3 patients  
Slide 17

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# Median TTP 10.9 months, indicating substantially improved efficacy compared with Lenvima alone<sup>1</sup>

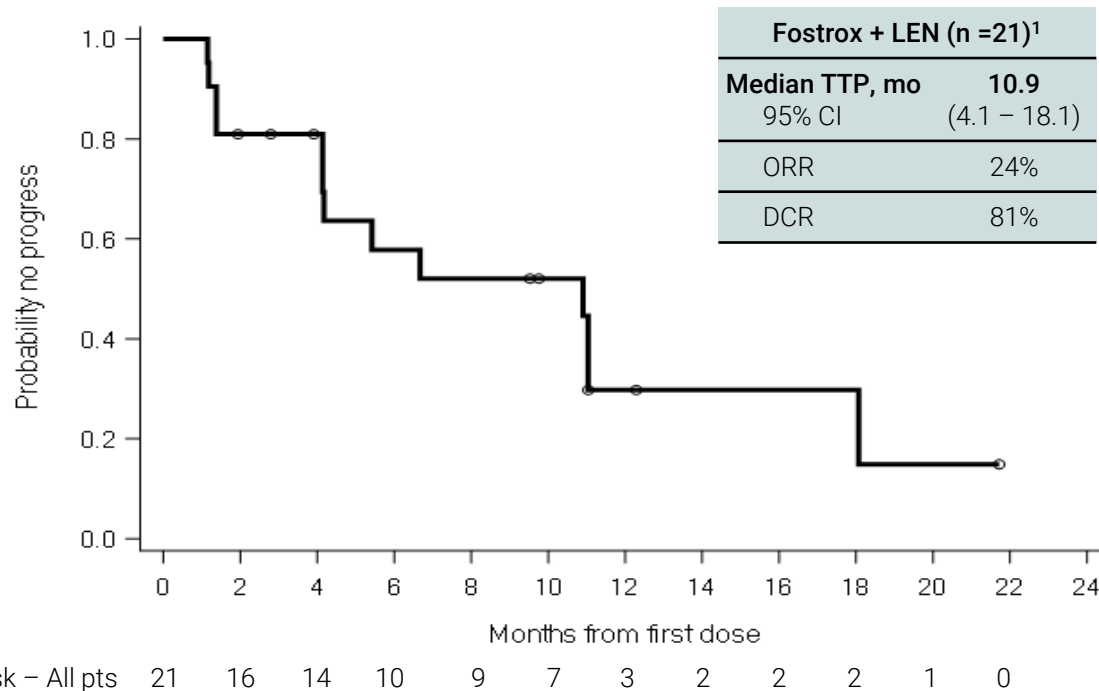
## Median time to progression (TTP) with fostrox + LEN – investigator review, RECISTv1.1



- Median time to progression 10.9 months
- Median follow-up of 10.5 months
- Longest running patient still on treatment > 2 years
- 3 patients remaining on treatment at time of data cut (Aug 19, 2024)

# Median time to progression (TTP) 10.9 months, remarkably longer than Lenvima monotherapy and other 2L HCC treatments

## Median TTP (Kaplan-Meier) with fostrox + Lenvima



## Median TTP/PFS vs previous studies in 2L HCC

### Lenvima after IO combo:

- Kobayashi et al. 2023 (n=12)
- Chon et al. 2024 (n=40)
- Hiraoka et al. 2023 (n=101)
- Palmer et al. 2023 (n=53)
- Yoo et al. 2023 (n=19)
- Yano et al. 2023 (n=24)
- Persano et al. 2024 (n=86)

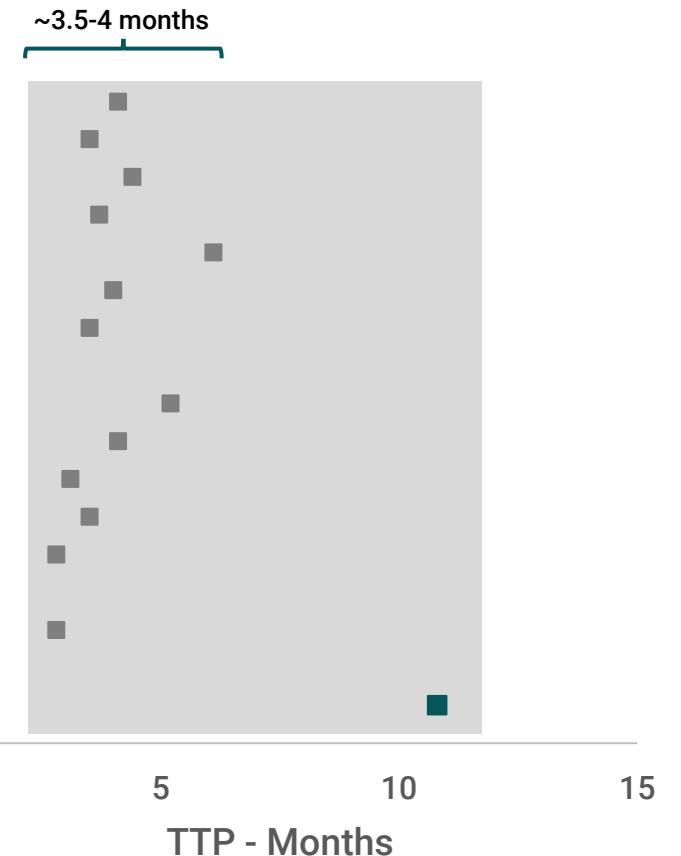
### Other TKIs in 2L:

- Abou-Alfa et al. 2018 (n=470)
- Chan et al. 2022 (n=48)
- Bruix et al. 2016 (n=379)
- Yoo et al. 2024 (n=40)
- Zhu et al. 2019 (n=292)

### Pembro + regorafenib in 2L:

- El-Khoueiry et al. 2024 (n=68)

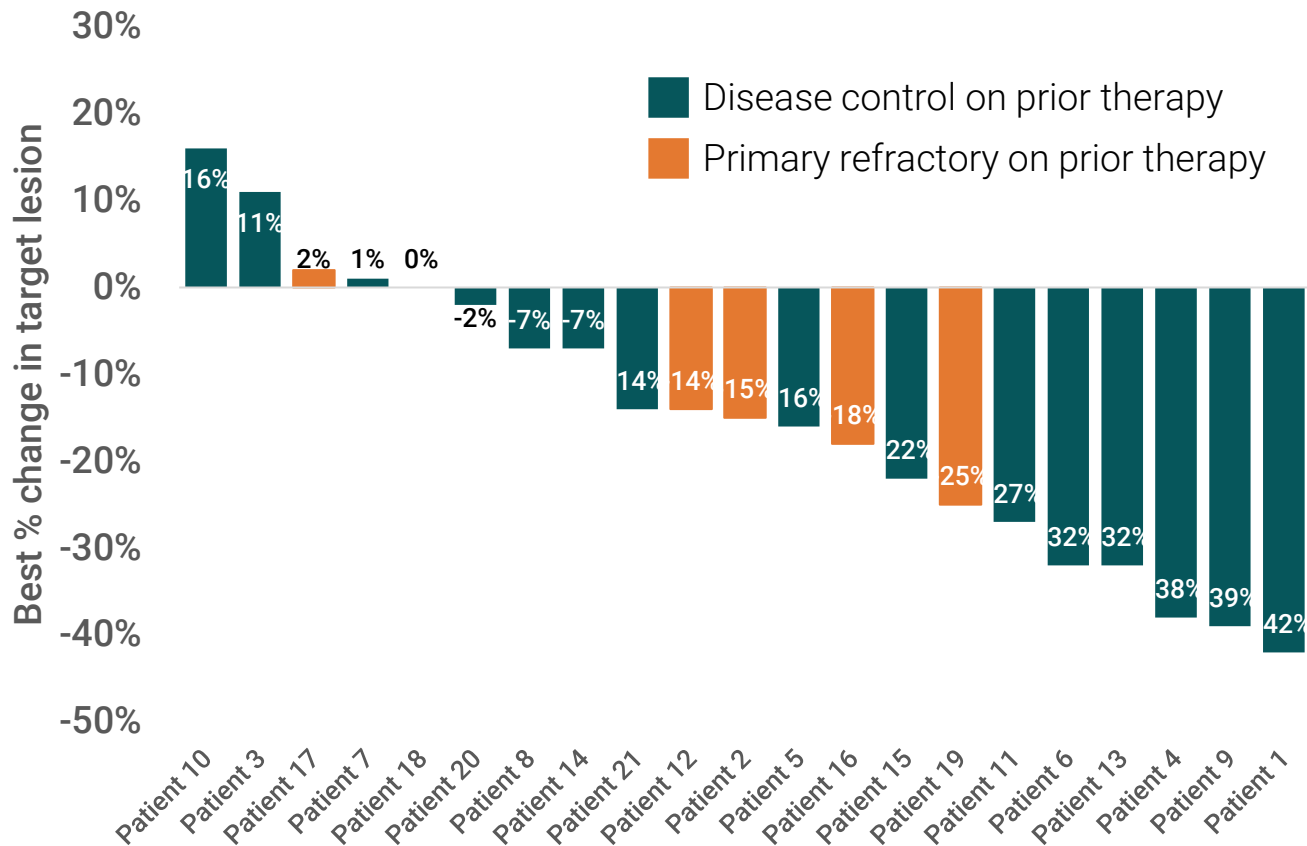
### Fostrox + Lenvima (n=21)



<sup>1</sup>Chon et al., ESMO 2024, Poster 986.

# More than 75% of patients experiencing tumor shrinkage<sup>1</sup>

## Best percentage change in target lesion size related to treatment response in first line



- Median duration of response 7.0 months
- Longest duration of response still ongoing at 19.5 months
- Patients benefitted from treatment independent of outcome in previous line of therapy

# Fostrox + Lenvima data signals superiority compared with Lenvima monotherapy or IO combo treatments in 2nd line HCC

	Lenvima in 2L HCC <sup>1</sup> – Korea	Lenvima in 2L HCC <sup>2</sup> – Japan	Keytruda + TKI in 2L HCC <sup>3</sup>	Fostrox + Lenvima <sup>4</sup>
Median PFS/TTP	3.5 mo	4.4 mo	2.8 mo	<b>10.9 mo</b>
Overall Response Rate	7.5%	15.4%	5.9%	<b>24%</b>
Disease Control Rate	67.5%	66.2%	54.4%	<b>81%</b>

“The response rate of 24% is higher than historical data of Lenvima alone in 2L, which is 10% or less. 10.9 months TTP is very impressive. In our local data and in clinical trials, we have seen that Lenvima after Tecentriq + Avastin shows 4 months time to progression and around 8 months overall survival.”

Dr. Hong Jae Chon, CHA Bundang Hospital, Seoul, Korea  
Investigator in Fostrox + Lenvatinib phase 1b/2a

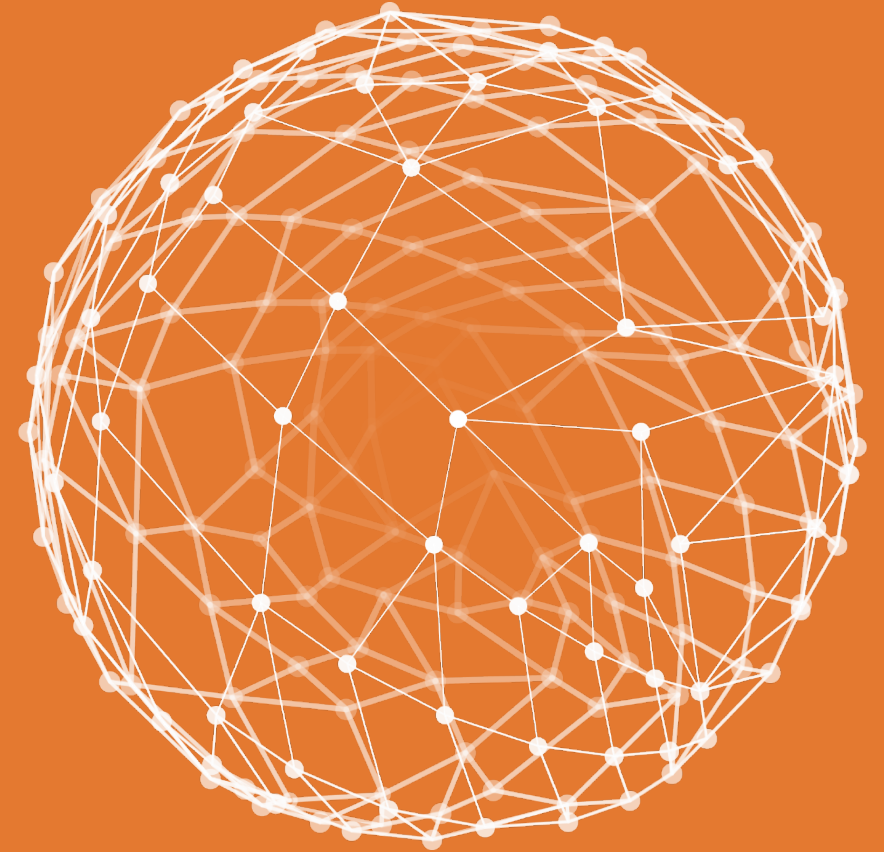
<sup>1</sup>Chon et al. Clinical and Molecular Hepatology 2024 Mar 12

<sup>2</sup>Hiraoka et al., Oncology 2023; 101:624-633

<sup>3</sup>El-Khoueiry et al. ASCO 2024, Abstract 4007

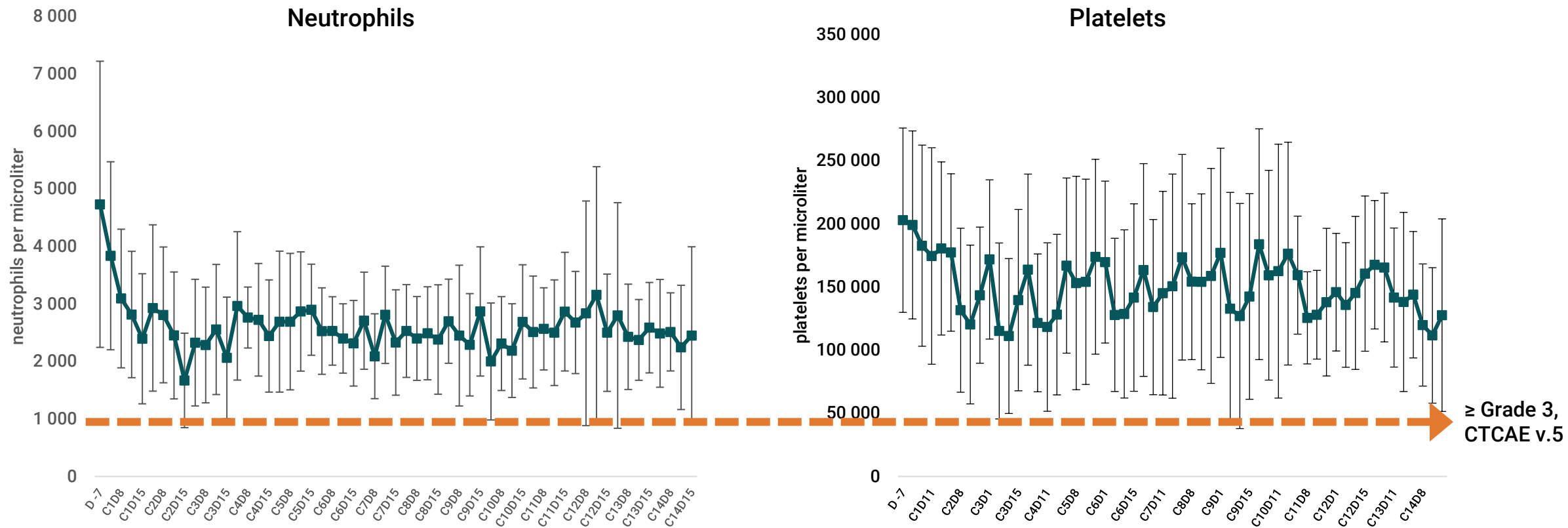
<sup>4</sup>Chon et al, ESMO 2024, Poster 986

**Fostrox + Lenvima shows encouraging tolerability enabling patients to remain on treatment long-term**



# Absolute neutrophil and platelet counts were stable over the course of treatment, enabling long-term use<sup>1</sup>

Longitudinal neutrophil & platelet counts, at all time points measured over first 10 months of treatment



<sup>1</sup>Chon et al., ESMO 2024, Poster 986.

# Liver targeting properties supports encouraging tolerability profile, enabling patients to remain on treatment long-term

Adverse Events*	Treatment emergent AEs any grade No of pts (%)	Treatment emergent AEs Grade ≥ 3 No of pts (%)	Fostrox Treatment-related Grade ≥ 3 No of pts (%)	LEN Treatment-related Grade ≥ 3 No of pts (%)
<b>Any AE</b>	<b>21 (100)</b>	<b>17 (81)</b>	<b>11 (52)</b>	<b>14 (67)</b>
<b>Hematologic AE</b>				
Thrombocytopenia	13 (62)	6 (29)	5 (24)	6 (29)
Neutropenia (no febrile)	10 (48)	8 (38)	8 (38)	6 (29)
Anaemia	7 (33)	3 (14)	3 (14)	3 (14)
Leukocyte decrease	5 (24)	1 (5)	1 (5)	1 (5)
<b>Other AE</b>				
Hypothyroidism	12 (57)			
Diarrhoea	10 (48)	1 (5)		1 (5)
Hand-foot syndrome	10 (48)	1 (5)		1 (5)
Fatigue	9 (43)			
Asthenia	8 (38)	3 (14)	1 (5)	2 (10)
Decreased appetite	8 (38)			
Proteinuria	7 (33)	1 (5)		1 (5)
Hypertension	6 (29)	2 (10)		2 (10)
Cough	5 (24)			
Pruritus	5 (24)			

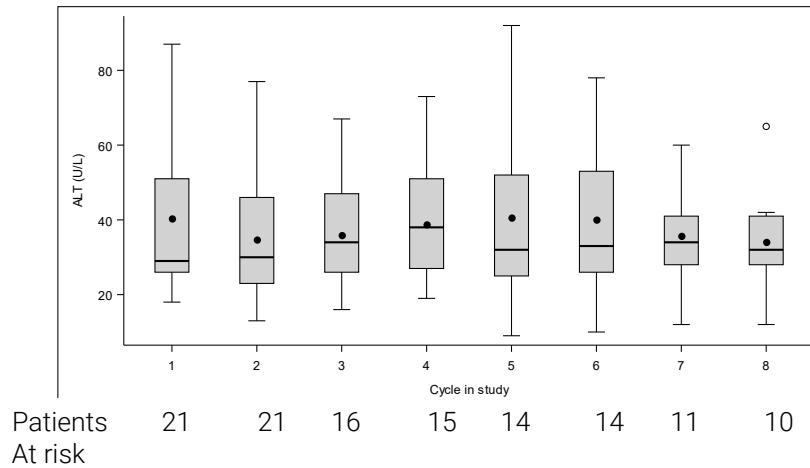
- No unexpected adverse events
- Hematological AEs were transient and manageable in nature
- Grade ≥ 3 events in 11 patients (52%) with only 7 events resulting in dose delay or discontinuation
- No patients with febrile neutropenia or low platelet count with bleeding
- No fostrox related deaths or SAEs



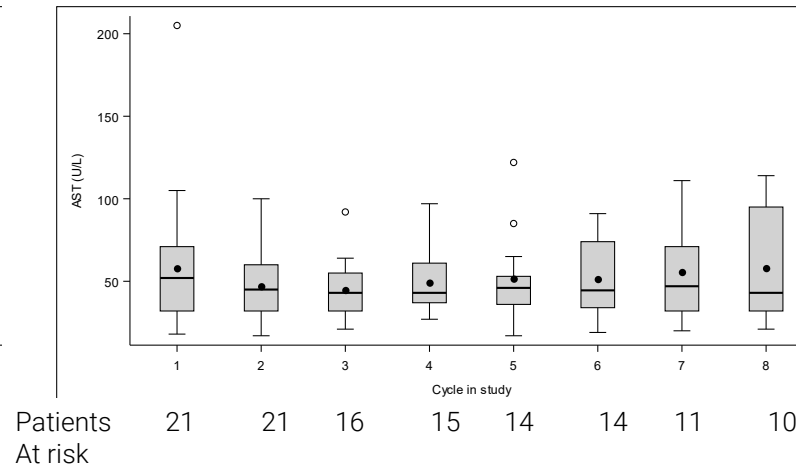
# Stable liver function during treatment with fostrox + Lenvima

## – no deterioration in liver enzymes or change in ALBI score

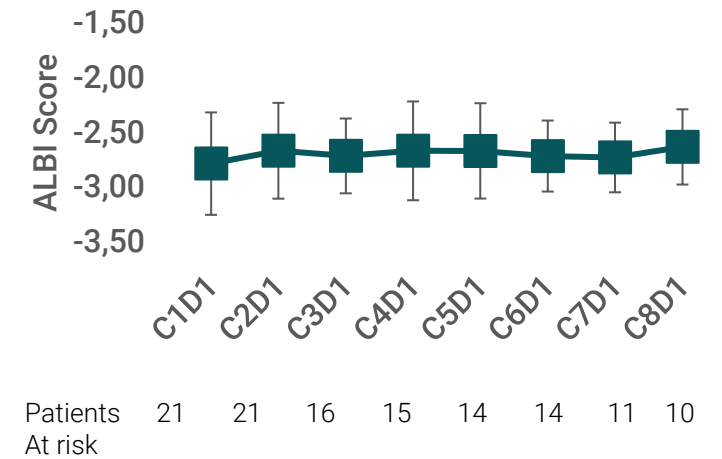
ALT change over duration of treatment



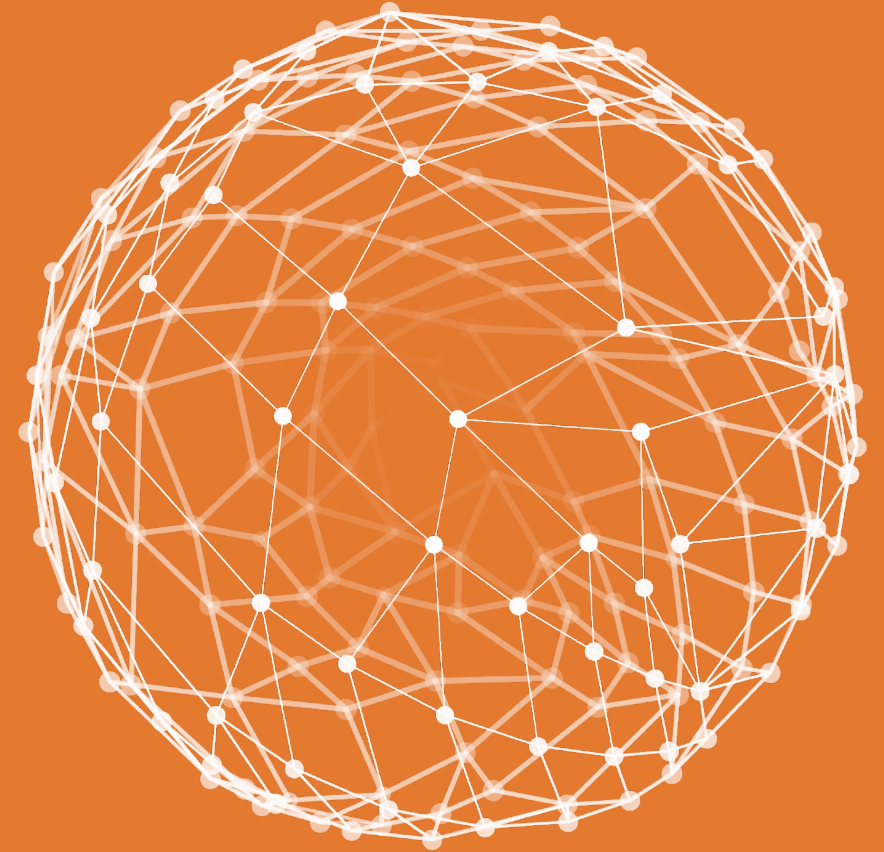
AST change over duration of treatment



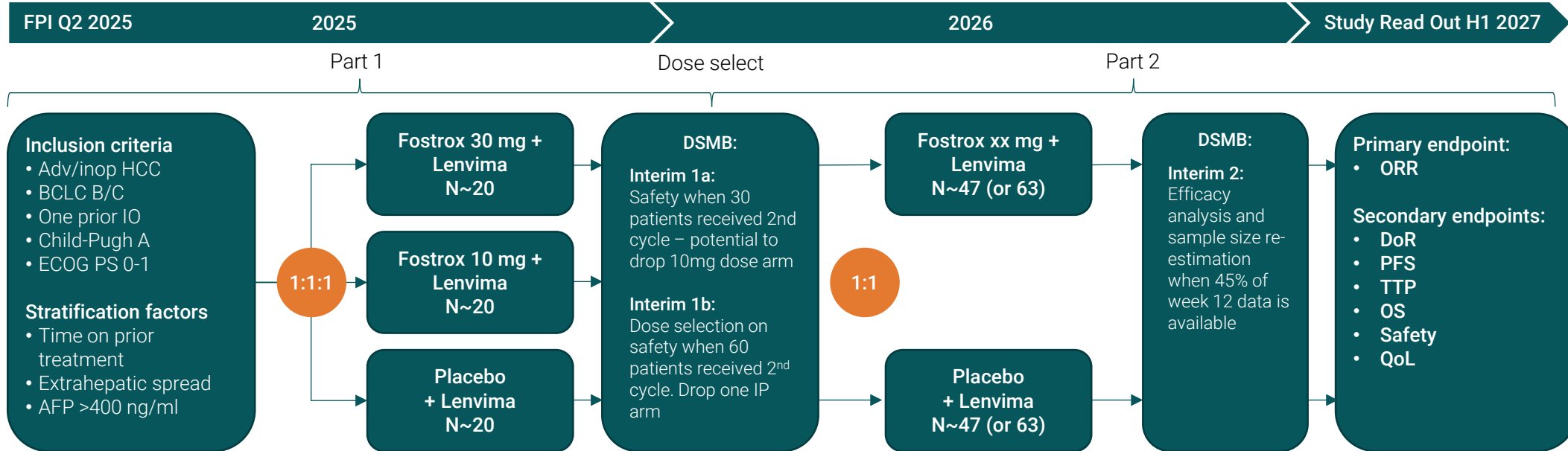
ALBI score change over duration of treatment



**Randomized phase 2b to  
enable breakthrough  
designation & accelerated  
approval**



# Phase 2b; dose optimization run in & adaptive design to enable breakthrough therapy designation & accelerated approval filing



## Statistics

- **Total sample size = 154**
- Interim 1a/1b (safety): dose selection based on safety (descriptive)
- Interim 2 (efficacy) with possible adaptations, when 45% of pts been treated for >12-week
  - Stop and claim efficacy using O'Brian Fleming boundary
  - Continue as planned (final analysis on 154 subjects (20 + 67 + 67))
  - Increase sample size with 25% to gain power if promising results in IA (promising zone:  $0.3 < CP < 0.8$ ) (Final analysis on 186 subjects (20 + 83 + 83))
  - Non-binding stop for futility if conditional power (CP)  $< 2.5\%$
- Power  $> 80\%$  to detect difference in ORR 10% in control group and 25% in IP group using a one-sided test at significance level 10%. 10% dropouts are assumed

## Time estimate and sites:

- Enrolment: 16 months (may be extended to ~62 weeks if decision to increase sample size in interim 2)
- Primary endpoint FU: 6 months
- Active study duration: ~22 months
- Total survival FU: 24 months
- 40 sites in 8 countries in the US, Europe and Asia

# Coordinating PI and US PI for fostrox + Lenvima phase 2b study among the most well renowned global HCC thought leaders



**Dr. Maria Reig – Coordinating PI**

- Head of the BCLC (Barcelona Clinic for Liver Cancer), who authors the globally renowned BCLC treatment guidelines for liver cancer
- Head of 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.



**Dr. Anthony B. El-Khoueiry, MD – US PI**

- Associate Director for Clinical Research at USC Norris and Associate Professor of Clinical Medicine at the Keck School of Medicine of USC.
- He has led several multicenter trials in HCC, including checkmate 040 with nivolumab (PD-1) in patients with HCC which resulted in accelerated approval by the FDA.
- He also served on the steering committee of international studies such as the randomized phase 3 study of cabozantinib, which culminated in the approval of cabozantinib in HCC.

# Highly distinguished steering committee

## Phase 2b fostrox + Lenvima vs Lenvima



### **Dr. Maria Reig – Coordinating PI**

- 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.



### **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.



### **Dr. Arndt Vogel**

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



### **Dr. Anthony B. El-Khoueiry, MD – US PI**

- Associate Director for Clinical Research at USC Norris and Associate Professor of Clinical Medicine at the Keck School of Medicine of USC.
- Member of the National Cancer Institute Hepatobiliary Cancers Task Force and chair of the Southwest Oncology Group hepatobiliary cancers subcommittee.



### **Dr. Hong Jae Chon**

- Professor, Medical Oncology, CHA Bundang Medical Center, CHA University, Korea
- Professor Chon has held a number of academic positions, university & hospital appointments and has extensive experience from phase I-IV clinical trials in HCC.



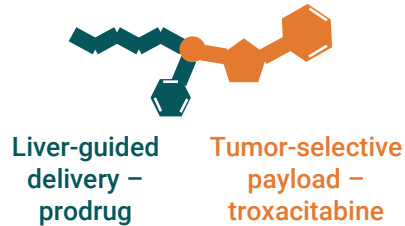
### **Dr. Lorenza Rimassa**

- Associate Professor of Medical Oncology, Humanitas Research Hospital, Milan, Italy & Head of HepatoPancreatoBiliary at IRCCS Humanitas Research Hospital
- Treasurer, member of the Executive Committee and Governing Board of the International Liver Cancer Association (ILCA)

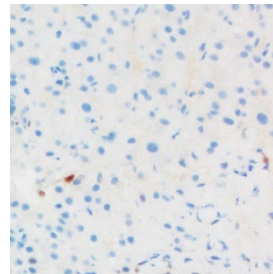
# Fostrox – The first oral, liver-targeted treatment tailored for HCC

Oral, liver-activated small molecule inducing DNA damage in tumor cells, sparing healthy liver cells<sup>3</sup>

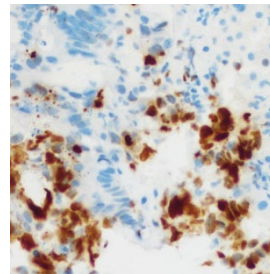
Unique, liver-targeted approach in HCC



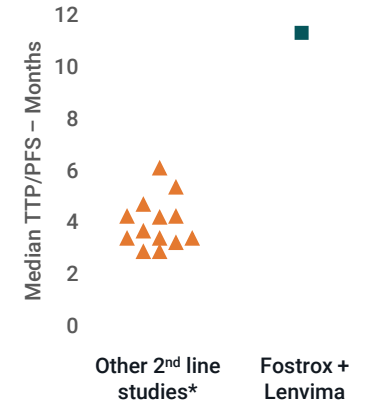
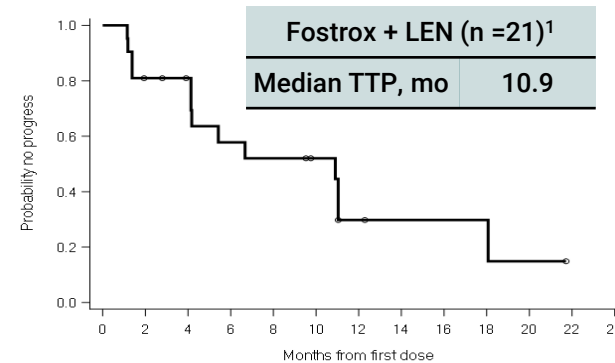
No DNA damage in healthy liver tissue



DNA damage in tumor tissue



10.9 months time to progression, substantially better than SoC<sup>1,2</sup>



\*see slide 20 for details regarding individual study data

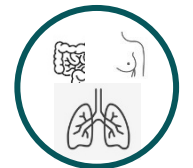
Absence of effective treatment options in 2<sup>nd</sup> line enables first-to-market opportunity for fostrox + Lenvima



- No 2<sup>nd</sup> line treatments approved in advanced HCC
- Global phase 2b start H1 '25
- Designed to enable breakthrough designation and support accelerated approval process

Market opportunity in 2<sup>nd</sup> line HCC >\$2.5bn, with significant upside potential

>\$2.5bn



2<sup>nd</sup> line HCC market by 2030, fastest growing cause of cancer death in US<sup>4</sup>

Significant upside in liver metastasis from other solid tumors

<sup>1</sup>Chon et al., ESMO, 2024, Poster 986

<sup>2</sup>Based on data from previous 2L phase 3 HCC studies with Stivarga, Cyramza & Cabometyx and investigator initiated prospective & retrospective 2L studies with Lenvatinib

<sup>3</sup>Evans et al ASCO GI, 2021

<sup>4</sup>Ma et al., Cancer, June 15, 2019; 2089-2098

# Board with extensive early & late stage drug development experience



- **Chairman of the Board – Dr. Uli Hacksell**
- Member since 2018, Chairman since 2021
- Over 30 years pharma & biotech experience, including 10 years' experience as CEO of publicly owned companies



- **Dr. Lennart Hansson, Ph D Genetics**
- Member since 2018
- Extensive experience of pharmaceutical & commercial development in biotech & pharma companies.



- **Dr. Bengt Westermark, Prof Tumor Biology**
- Member since 2017
- Published >300 papers in scientific journals, primarily on the mechanisms of uncontrolled growth of cancer cells.



- **Dr. Yilmaz Mashid, Ph D Medical Sciences**
- CFO at Egetis Therapeutics AB with prior experience at at Industrifonden and Pareto Securities.
- Previous experience from Biolipox and Orexo.



- **Dr. Anna Törner, Ph D Statistics, MScs Pharmacy**
- Broad experience from drug development, especially regulatory affairs
- Founder consulting company SDS Life Science within drug development and statistics.



- **Dr. Angelica Loskog, Ph D, Clin. Immunology**
- CEO Lokon Pharma & scientific advisor at venture cap Nexttobe
- More than 25 year's academic drug development experience within immune oncology

# Thank You!

