

Medivir Q3 REPORT 2024

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

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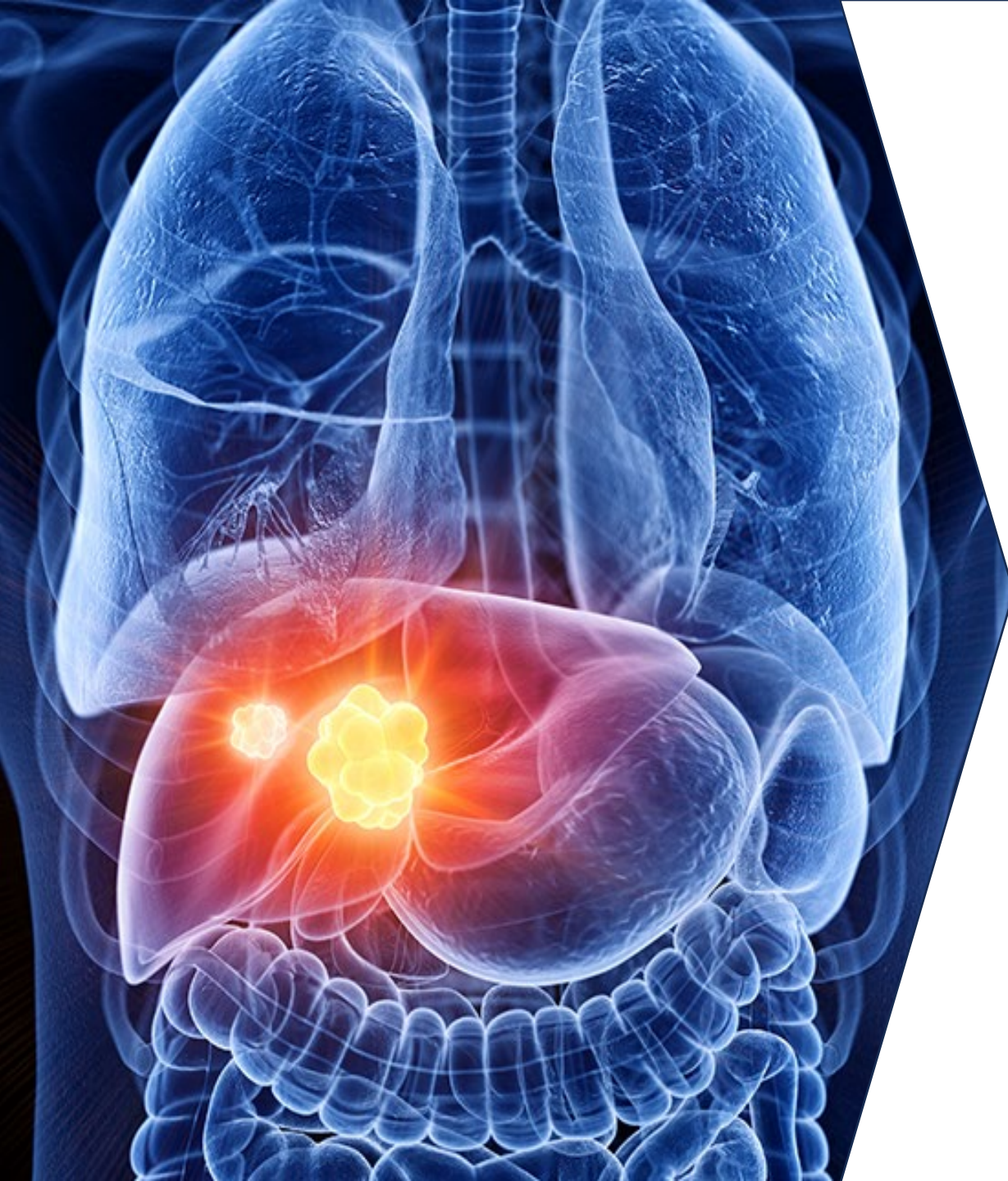
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Mature data at ESMO confirming promise of improved outcome with fostrox + Lenvima<sup>®</sup>



Eisai clinical trial collaboration further validates the potential of fostrox + Lenvima



Monotherapy proof-of-concept data published in Journal of Hepatocellular Carcinoma

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# Today's presenters



**CEO**  
**Jens Lindberg**



**CMO**  
**Pia Baumann**



**CFO**  
**Magnus Christensen**



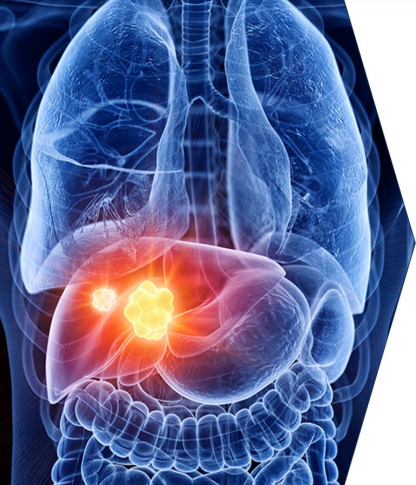
**CSO**  
**Fredrik Öberg**



**Mature data presented at ESMO confirm promise of improved clinical outcome with a median time to progression (TTP) of 10.9 months**

# Medivir activities at ESMO highlighting strength of fostrox + Lenvima data & unmet medical need in 2L HCC

BARCELONA 2024 **ESMO** congress  
BARCELONA SPAIN  
13-17 SEPTEMBER 2024



**Agenda**

Introduction – Fostrox and HCC  
*Dr Pia Baumann, Chief Medical Officer, Medivir AB*

Fostrox + Lenvatinib in second line HCC

- Results & experience from phase 1b/2a study
- Data in the context of current clinical practice in second line HCC

*Dr. Hong Jae Chon, CHA Bundang Hospital, Seoul, Korea*

Fostrox + Lenvatinib moving forward  
*Dr Pia Baumann, Chief Medical Officer, Medivir AB*

Q&A

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**Dr. Pia Baumann**  
CMO, Medivir



**Dr. Hong Jae Chon**  
CHA Bundang Hospital,  
Seoul, Korea

## Great timing as external focus shifts to 2L HCC

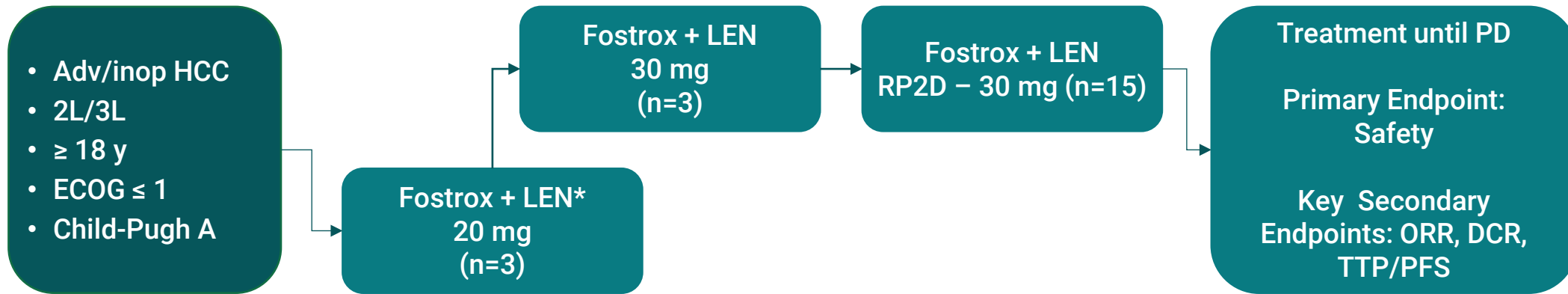
- Mature data confirming promise of improved clinical outcome with fostrox + Lenvima
- Dr Chon providing context highlighting additional benefit of combination beyond Lenvima alone
- Significantly increased level of interest by scientific community in fostrox current & future program

*“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

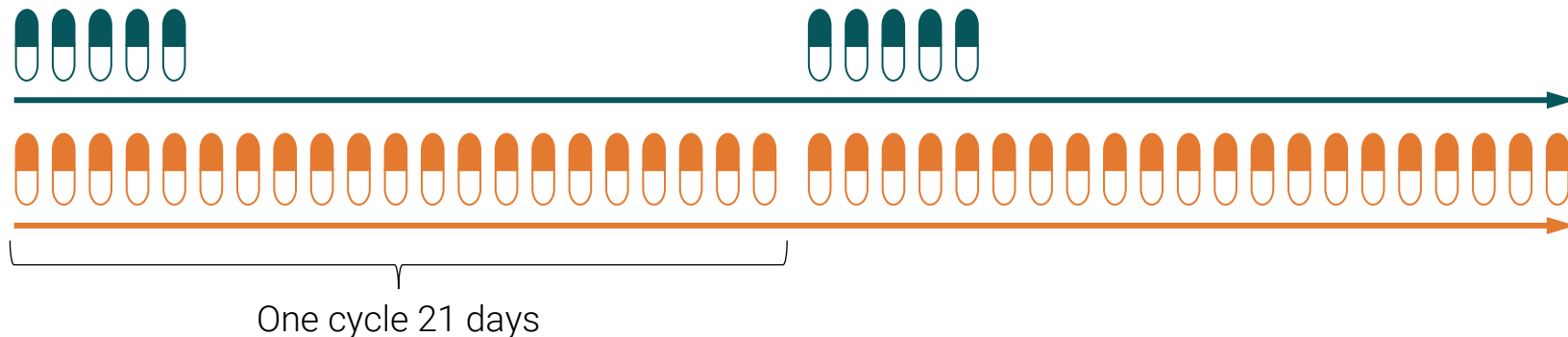
# Fostrox + Lenvima phase 1b/2a study design



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

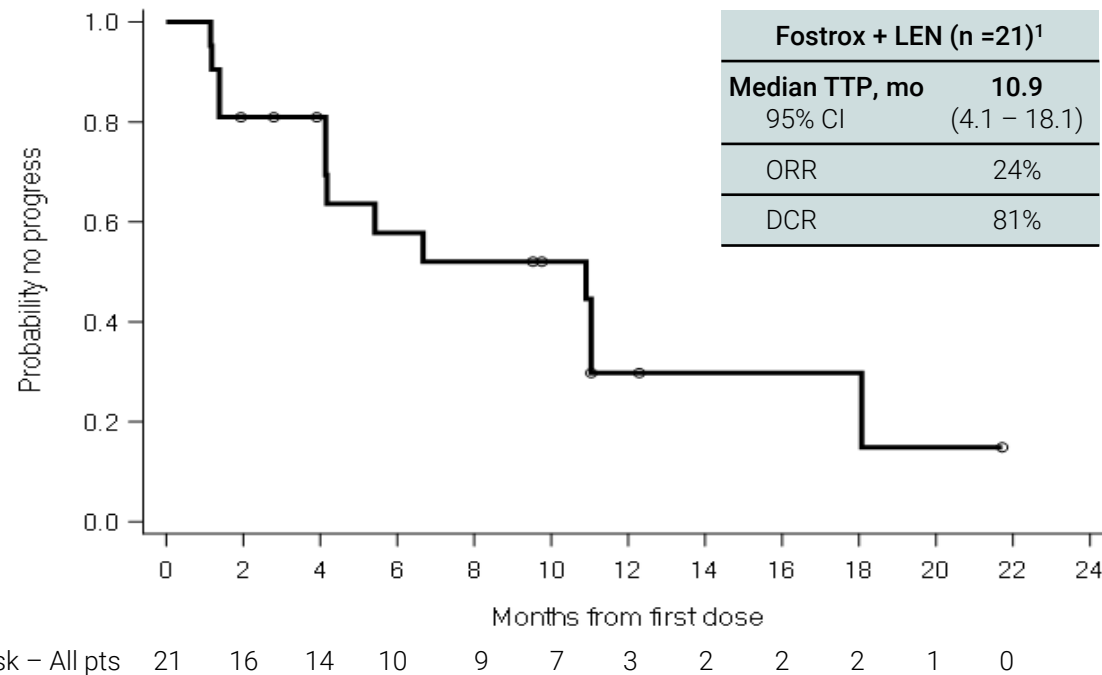
**Fostrox:** Oral QD  
5 days in 21 days cycles

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



# 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



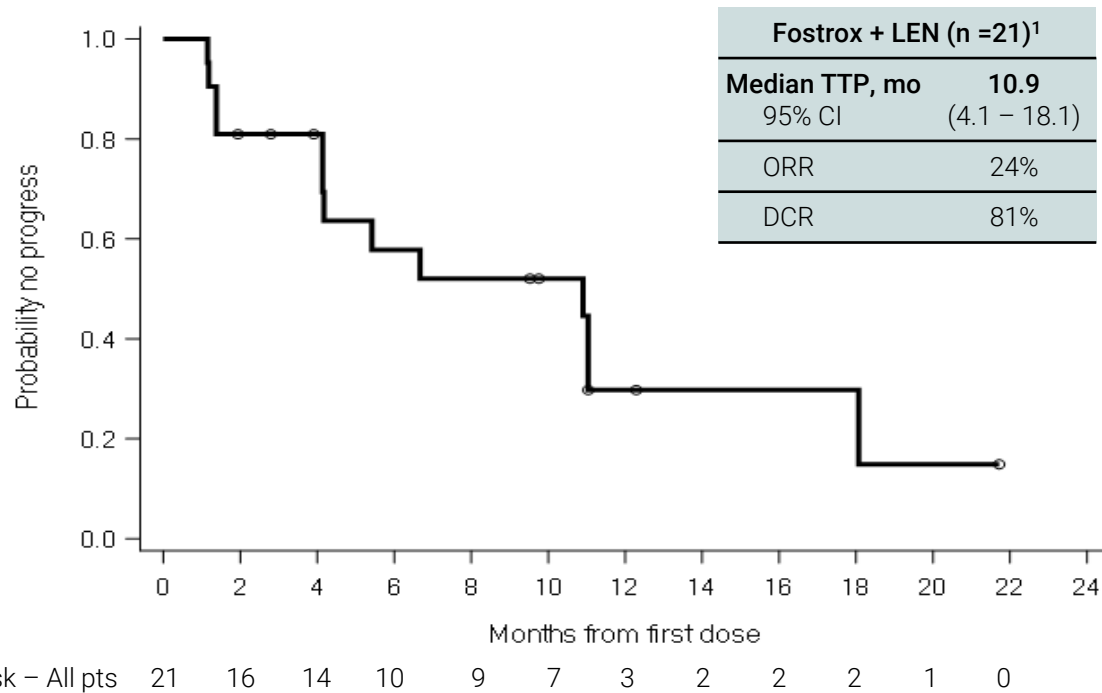
- Median time to progression 10.9 months
- Median follow-up of 10.5 months
- Longest running patient still on treatment > 2 years
- 3 patients remaining on treatment at time of data cut (Aug 19, 2024)

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



# Median time to progression (TTP) 10.9 months, substantially 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)

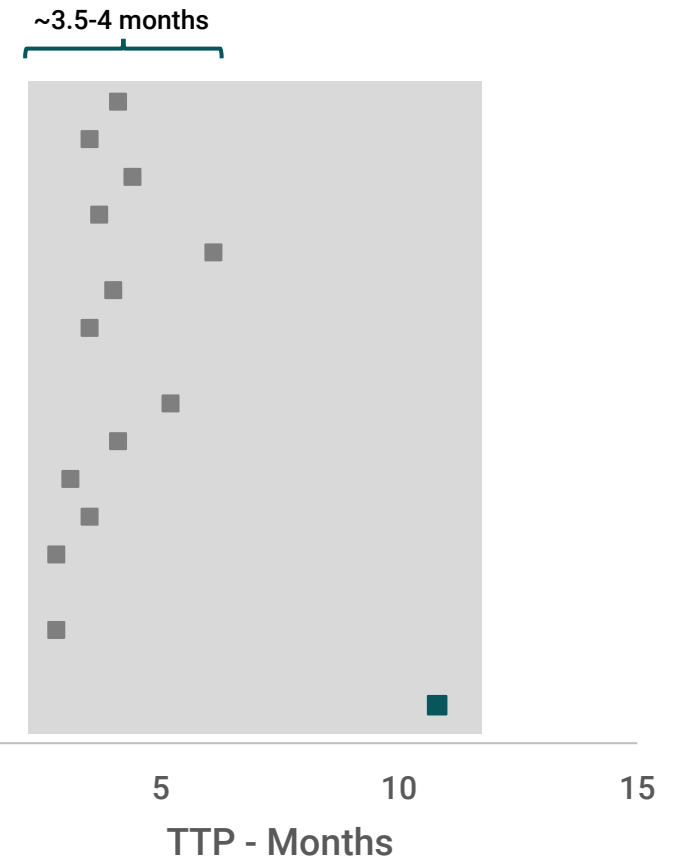
### Other TKIs in 2L:

- 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.

# Real-world study of Lenvima in 2nd line post Tecentriq/Avastin

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eISSN 2287-285X



**Original Article**

<https://doi.org/10.3350/cmh.2023.0553>  
Clinical and Molecular Hepatology 2024;30:345-359

## **Sorafenib vs. Lenvatinib in advanced hepatocellular carcinoma after atezolizumab/bevacizumab failure: A real-world study**

Young Eun Chon<sup>1,\*</sup>, Dong Yun Kim<sup>2,\*</sup>, Mi Na Kim<sup>2</sup>, Beom Kyung Kim<sup>2</sup>, Seung Up Kim<sup>2</sup>, Jun Yong Park<sup>2</sup>, Sang Hoon Ahn<sup>2</sup>, Yeonjung Ha<sup>1</sup>, Joo Ho Lee<sup>1</sup>, Kwan Sik Lee<sup>1</sup>, Beodeul Kang<sup>3</sup>, Jung Sun Kim<sup>3</sup>, Hong Jae Chon<sup>3</sup>, and Do Young Kim<sup>2</sup>

<sup>1</sup>Department of Gastroenterology, CHA Bundang Medical Center, CHA University, Seongnam; <sup>2</sup>Department of Internal Medicine, Yonsei University College of Medicine, Seoul; <sup>3</sup>Department of Medical Oncology, CHA Bundang Medical Center, CHA University, Seongnam, Korea

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

<sup>2</sup>Chon et al, ESMO 2024, Poster 986

# Fostrox + Lenvima data signals superiority compared with Lenvima monotherapy in 2nd line

	Lenvima in 2L HCC <sup>1</sup> – Korea	Fostrox + Lenvima <sup>4</sup>
Median PFS/TTP	3.5 mo	<b>10.9 mo</b>
Overall Response Rate	7.5%	<b>24%</b>
Disease Control Rate	67.5%	<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

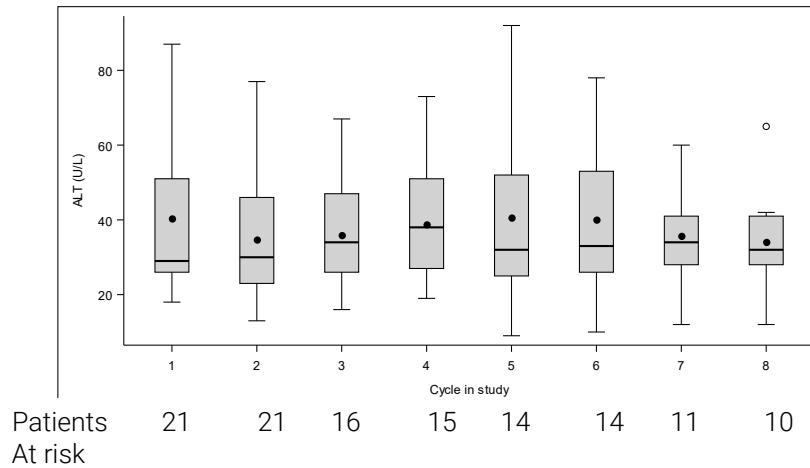
<sup>1</sup>Chon et al. Clinical and Molecular Hepatology 2024 Mar 12

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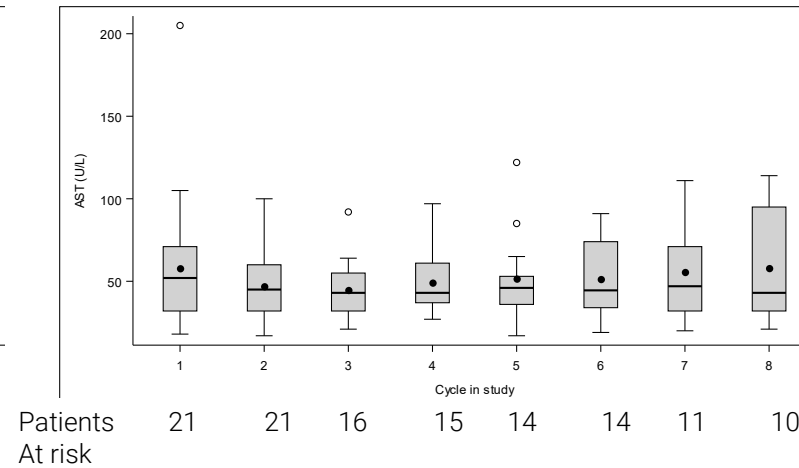


# Fostrox tumor selectivity and tolerability in combination with Lenvima, provides opportunity for durable efficacy

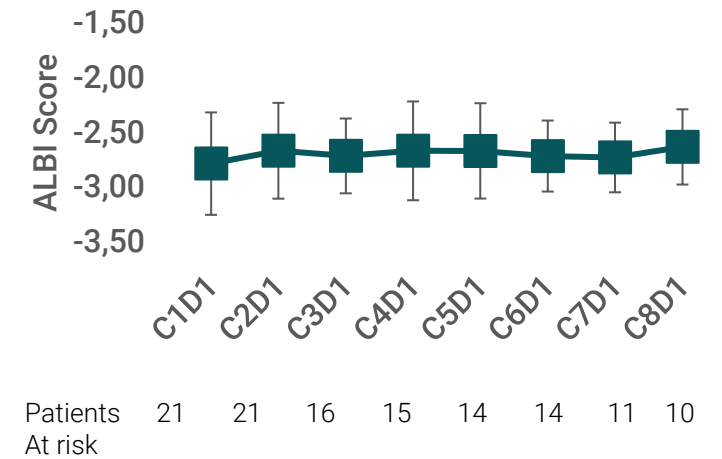
ALT change over duration of treatment



AST change over duration of treatment

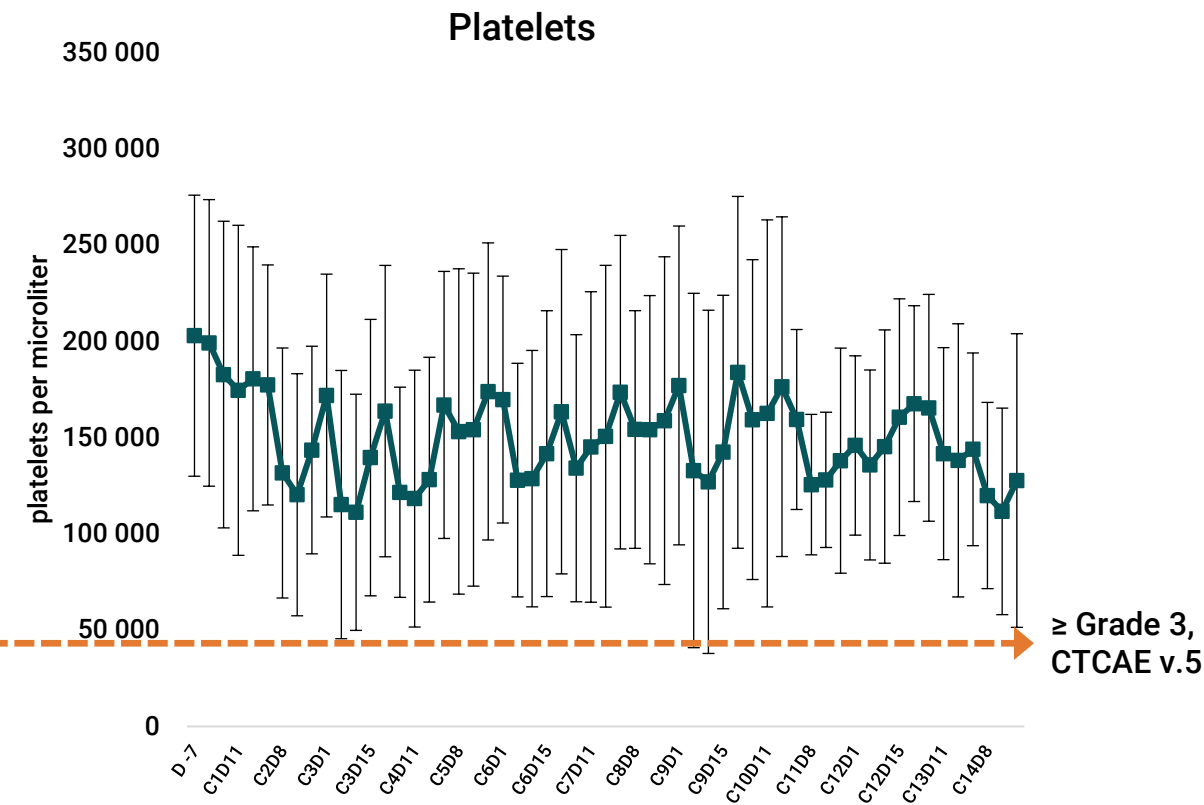
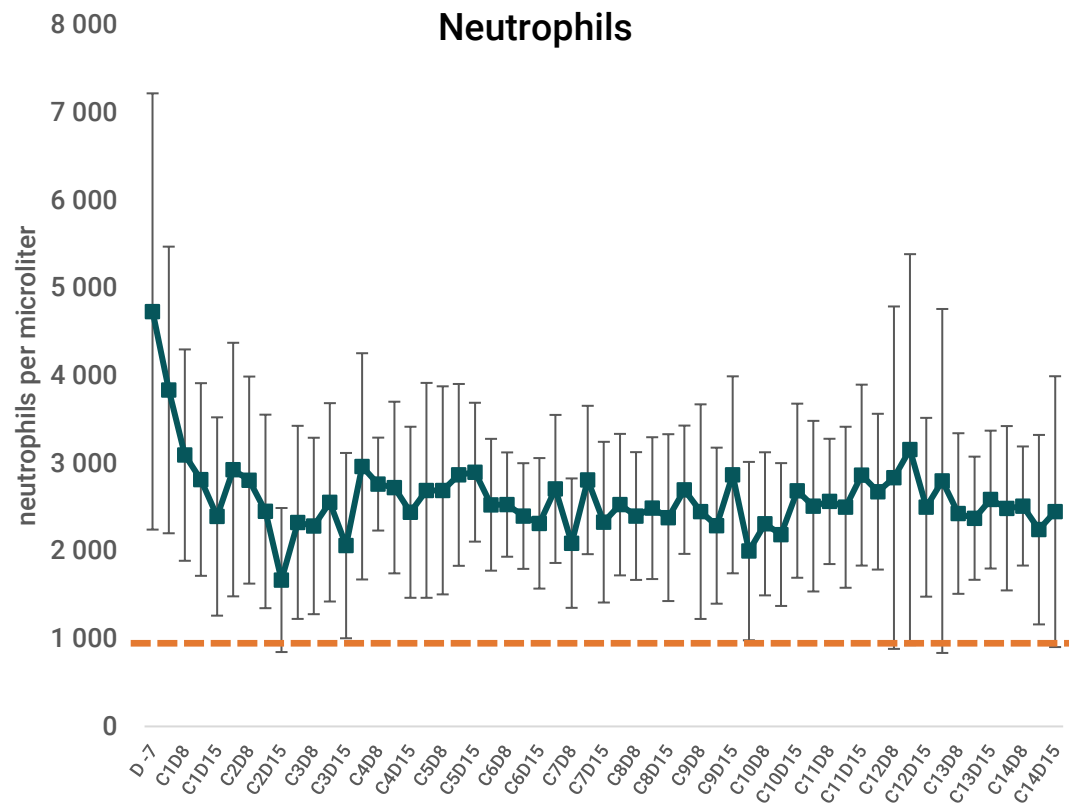


ALBI score change over duration of treatment



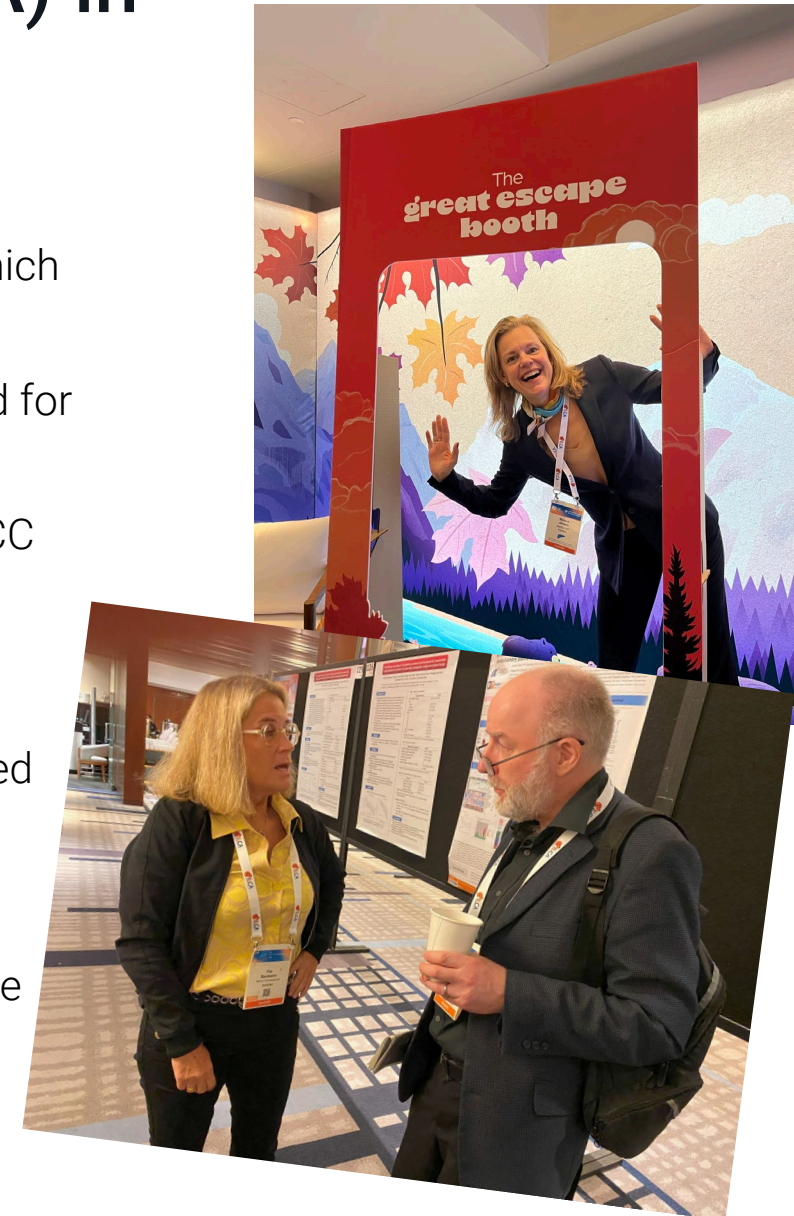
# Long-term treatment made possible with neutrophils and platelets remaining stable over time

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



# International Liver Cancer Association (ILCA) in Toronto, October 17-19

- Extensive engagement with scientific community for planned phase 2b study, which generated very positive feedback overall
- No new data presented in second line advanced HCC, further cementing the need for additional treatment options
- Data focus at ILCA on the potential for systemic treatment in earlier stages of HCC
  - Early stage: Neo-Adjuvant, awaiting read-out from several ongoing studies
  - Early stage: Adjuvant, downplayed due to negative data presented at ESMO
  - Intermediate: Positive trend but without OS data not ready to be implemented
- **Overall takeaway**
  - Significant unmet need remains in 2L advanced HCC
  - Fostrox + Lenvima at the forefront of development as an effective alternative





# Phase 1a/1b monotherapy study providing clinical proof-of-concept published in Journal of Hepatocellular Carcinoma

Journal of Hepatocellular Carcinoma Dovepress

Open Access Full Text Article CLINICAL TRIAL REPORT

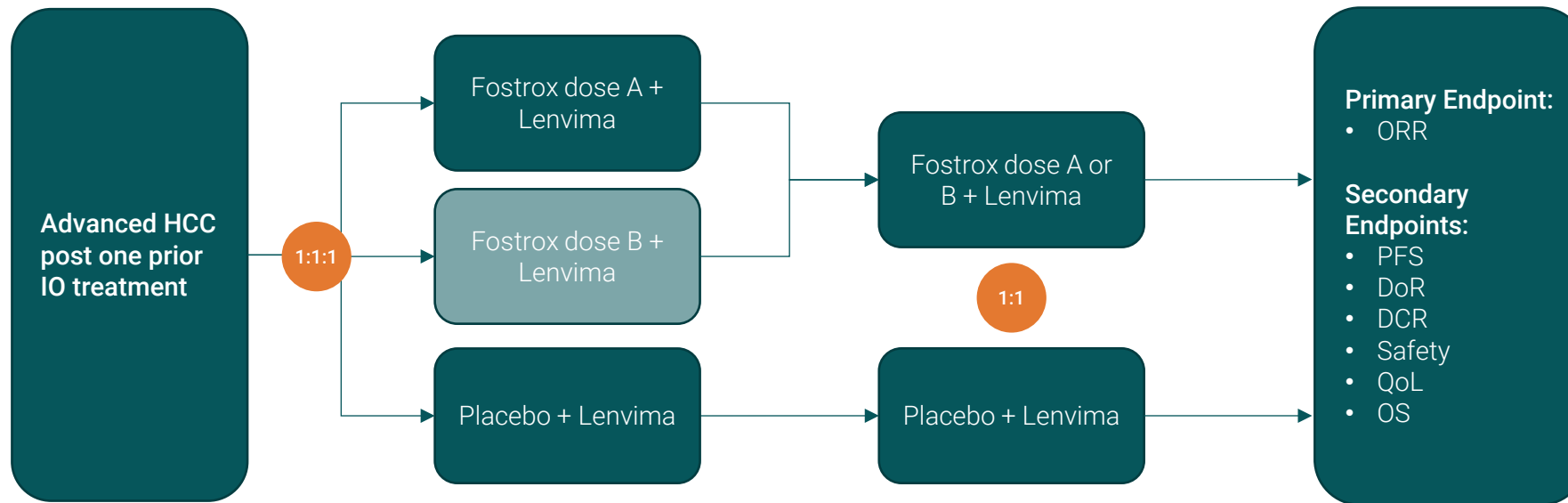
## A Phase Ia/Ib Study of Fostroxacitabine Bralpamide (Fostrox) Monotherapy in Hepatocellular Carcinoma and Solid Tumor Liver Metastases

Ruth Plummer<sup>1</sup>, Alastair Greystoke<sup>1</sup>, Gregory Naylor<sup>2</sup>, Debashis Sarker<sup>3,4</sup>, ANM Kaiser Anam<sup>4</sup>, Hans Prenen<sup>5</sup>, Laure-Anne Teuwen<sup>5</sup>, Eric Van Cutsem<sup>6</sup>, Jeroen Dekervel<sup>6</sup>, Beate Haugk<sup>1</sup>, Thomas Ness<sup>1</sup>, Sujata Bhoi<sup>7</sup>, Malene Jensen<sup>7</sup>, Tom Morris<sup>7</sup>, Pia Baumann<sup>7</sup>, Niclas Sjögren<sup>8</sup>, Karin Tunblad<sup>7</sup>, Hans Wallberg<sup>7</sup>, Fredrik Öberg<sup>7</sup>, Thomas R. Jeffry Evans<sup>2</sup>

<sup>1</sup>Newcastle University and Newcastle Hospitals NHS Foundation Trust, Newcastle Upon Tyne, UK; <sup>2</sup>Beatson West of Scotland Cancer Centre, University of Glasgow, Glasgow, UK; <sup>3</sup>School of Cancer and Pharmaceutical Sciences, King's College London, London, UK; <sup>4</sup>Department of Medical Oncology, Guy's Hospital, London, UK; <sup>5</sup>Department of Oncology, Antwerp University Hospital, Edegem, Belgium; <sup>6</sup>Department of Oncology, University Hospitals Gasthuisberg Leuven and KU Leuven, Leuven, Belgium; <sup>7</sup>Medivir AB, Huddinge, Sweden; <sup>8</sup>SDS Life Science, Stockholm, Sweden

- Established clinical proof-of-concept for fostrox monotherapy in patients with cancer in the liver.
- The results show that fostrox is safe and tolerable with preliminary anti-tumor activity.
- Confirmation of fostrox' liver-targeted mechanism inducing DNA damage selectively in tumor cells.

# Next step: randomized phase 2b with dose optimization run-in



# Important clinical trial collaboration with Eisai further validates the potential of fostrox + Lenvima

Medivir announces new clinical trial collaboration and supply agreement with Eisai to evaluate fostrox in combination with lenvatinib in advanced liver cancer

2024-11-04

- Agreement to support expansion of fostroxacitabine bralpamide (fostrox) program with a randomised phase 2b study evaluating fostrox in combination with lenvatinib vs lenvatinib alone in second-line advanced liver cancer (HCC).
- Phase 1b/2a data has demonstrated that the combination of fostrox + lenvatinib has shown to have a manageable safety profile and encouraging anti-tumor activity in second-line population, including a median time to progression (TTP) of 10.9 months [1].
- Medivir's fostrox is the first oral, liver-targeted treatment in development for advanced liver cancer. Its unique mechanism delivers the cell-killing compound to tumor cells locally in the liver while minimizing harm to healthy cells.



Eisai to provide drug supply for full, randomized phase 2b study while Medivir retains full rights



Establishment of a Joint Development Committee with Eisai for planning and execution of the study.

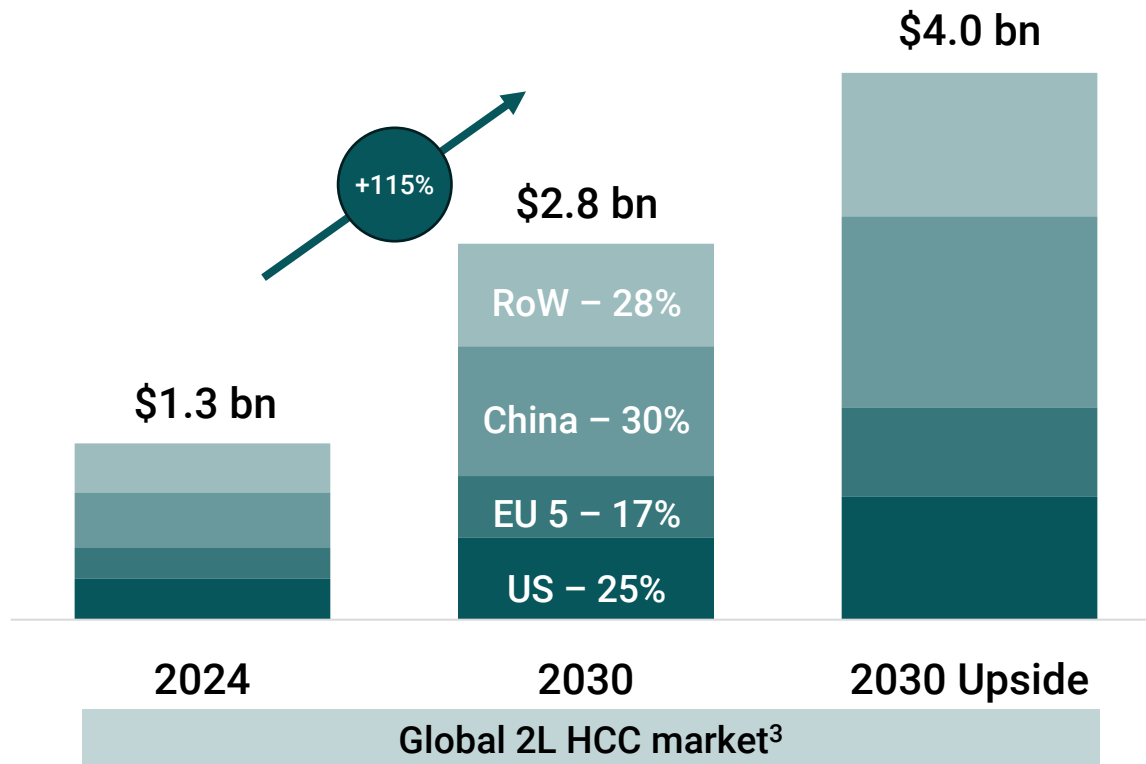


Eisai clinical trial collaboration further validates the potential of fostrox + Lenvima

Preparations for randomized phase 2b are proceeding according to plan with intent to open IND in the US in Q4



# Second 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 study

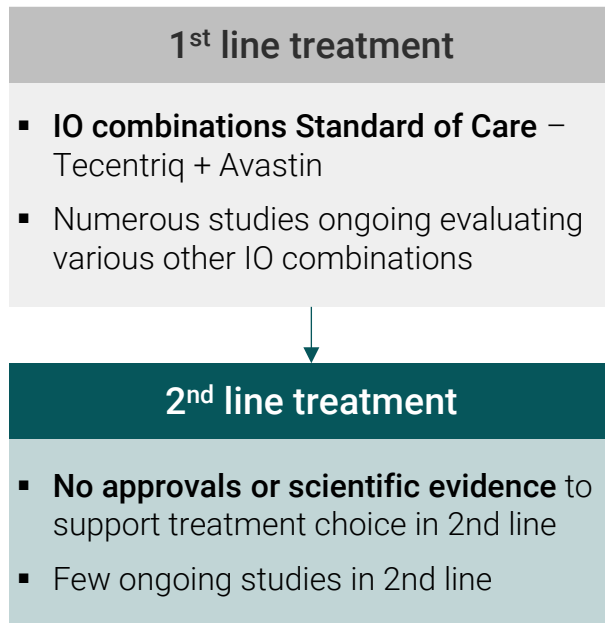
<sup>1</sup>Rumguy et al. Journal of Hepatology 2022

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

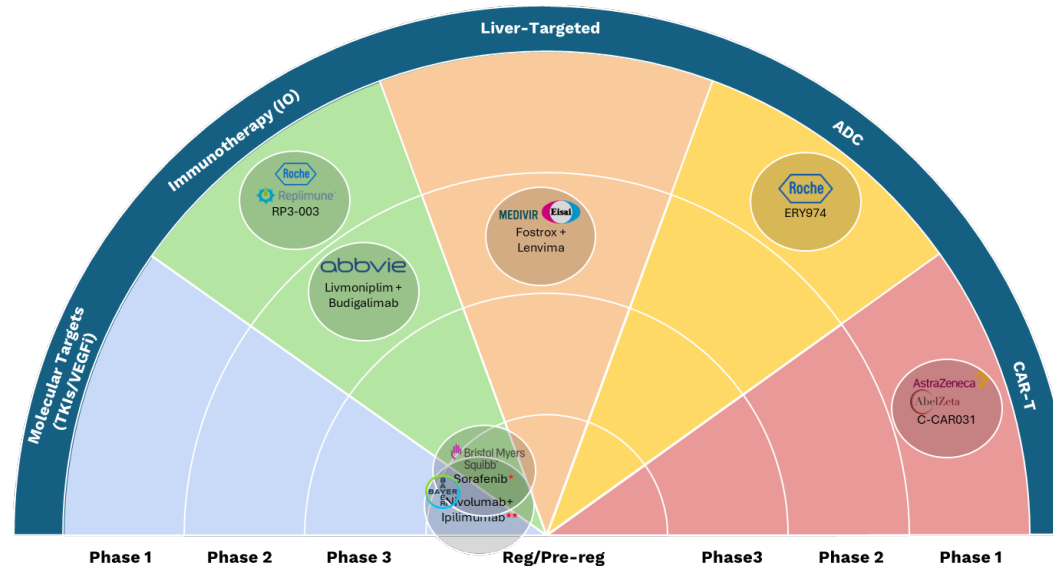
<sup>3</sup>GlobalData 2021 and internal analysis

# 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”

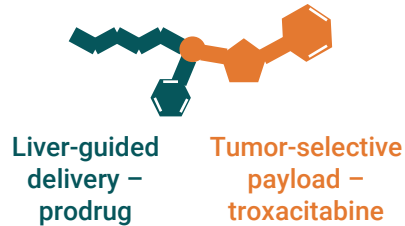
Rachna T Schroff, University of Arizona Cancer Center  
Late Breaking Abstract session at ESMO, September 2024

\*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](#))).

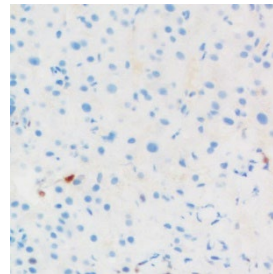
# Fostrox – The first oral, liver-targeted treatment tailored for HCC

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

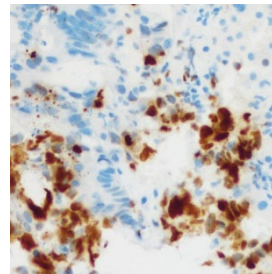
Unique, liver-targeted approach in HCC



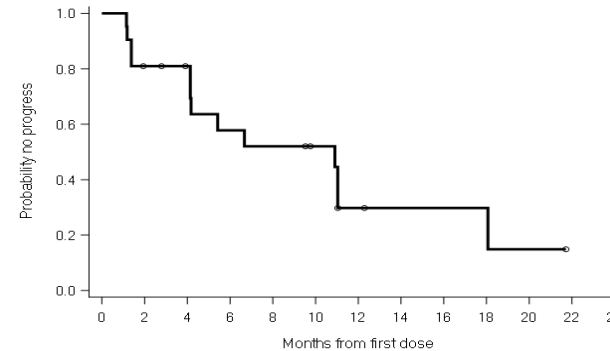
No DNA damage in healthy liver tissue



DNA damage in tumor tissue



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



Fostrox + LEN (n =21) <sup>1</sup>	
Median TTP, mo	10.9
95% CI	(4.1 – 18.1)
ORR	24%
DCR	81%

\*see slide 20 for details regarding individual study data

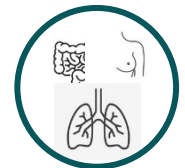
Absence of effective treatment options in 2<sup>nd</sup> line enables first-to-market opportunity for fostrox + Lenvima



- 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

# Financial highlights Q3

# Financial summary Q3, 2024

## Consolidated Income Statement, summary

(SEK m)

	Q3		Q1 - Q3		Full year
	2024	2023	2024	2023	2023
Net turnover	0.9	0.8	2.5	3.2	7.6
Other operating income	0.3	0.2	0.5	1.1	1.4
<b>Total income</b>	<b>1.2</b>	<b>1.0</b>	<b>3.1</b>	<b>4.3</b>	<b>9.0</b>
Other external expenses	-29.6	-18.1	-80.6	-52.4	-68.9
Personnel costs	-6.3	-5.8	-20.4	-19.5	-27.4
Depreciations and write-downs	-0.7	-0.7	-2.0	-2.1	-2.7
Other operating expenses	-0.3	-0.4	-0.4	-1.0	-1.4
<b>Operating profit/loss</b>	<b>-35.7</b>	<b>-24.1</b>	<b>-100.4</b>	<b>-70.6</b>	<b>-91.4</b>
Net financial items	1.1	0.5	3.8	1.6	2.1
<b>Profit/loss after financial items</b>	<b>-34.6</b>	<b>-23.6</b>	<b>-96.7</b>	<b>-69.1</b>	<b>-89.3</b>
Tax	-	-	-	-	-
<b>Net profit/loss for the period</b>	<b>-34.6</b>	<b>-23.6</b>	<b>-96.7</b>	<b>-69.1</b>	<b>-89.3</b>
<b>Net profit/loss for the period attributable to:</b>					
Parent Company shareholders	-34.6	-23.6	-96.7	-69.1	-89.3

- Net turnover for Q3 was SEK 0.9 million
- Operating loss for Q3 was SEK -35.7 million
- Cash flow from operating activities for Q3 was SEK -33.4 million
- Cash balance end of Q3 was SEK 92.6 million
- Loan facility from Linc AB MSEK 30

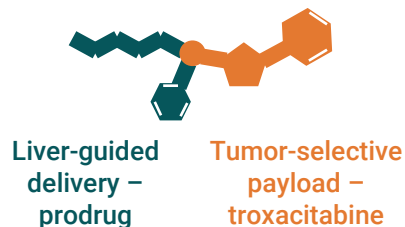


Q/A

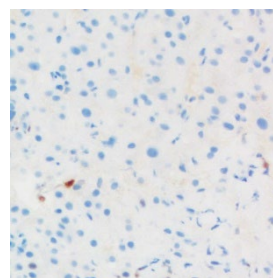
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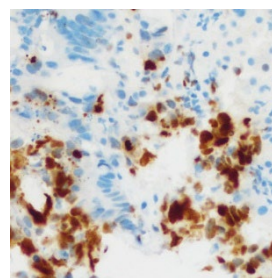
Unique, liver-targeted approach in HCC



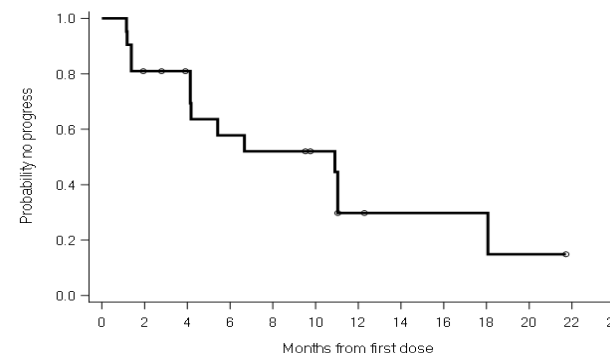
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<sup>1</sup>Chon et al., ESMO, 2024, Poster 986

<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



**Thank You!**