

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

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DNB Nordic Healthcare Conference

**MEDIVIR**

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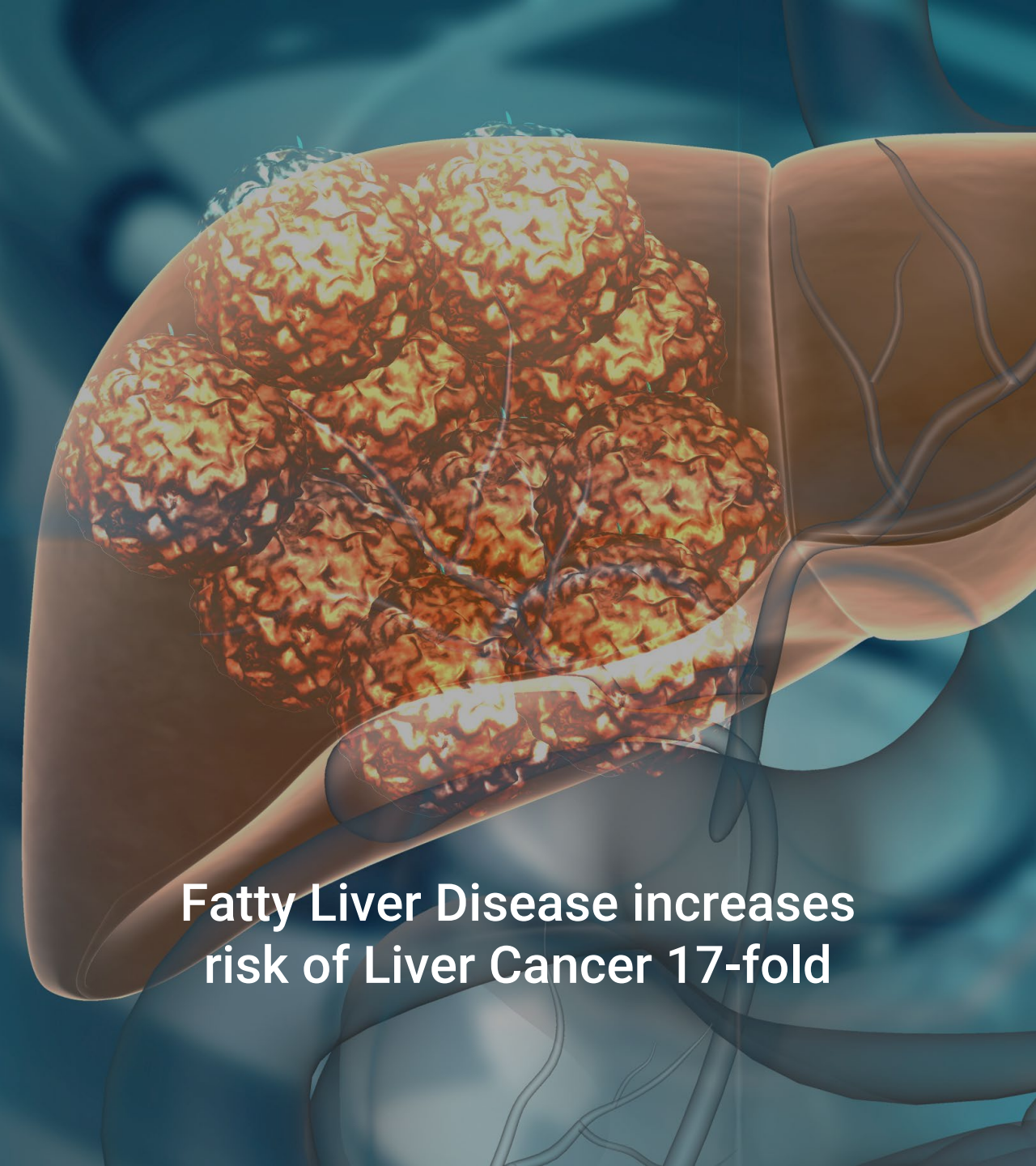
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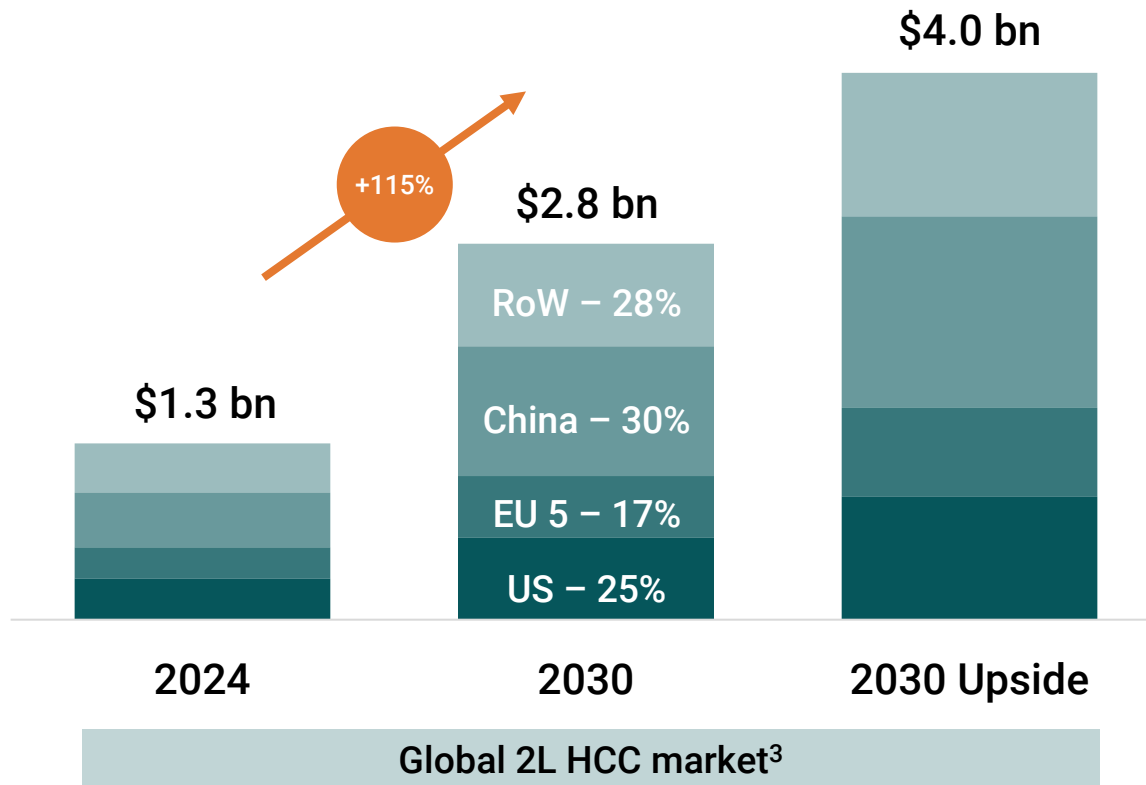


**45% of US adults are obese  
More than 25% have Fatty Liver Disease**



**Fatty Liver Disease increases  
risk of Liver Cancer 17-fold**

# 2<sup>nd</sup> line HCC – a large and growing commercial opportunity<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

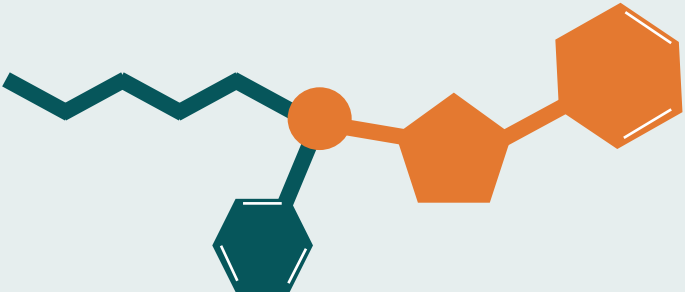
<sup>1</sup>Rumguy et al. Journal of Hepatology 2022

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

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

# Fostrox – designed to selectively kill tumor cells in the liver

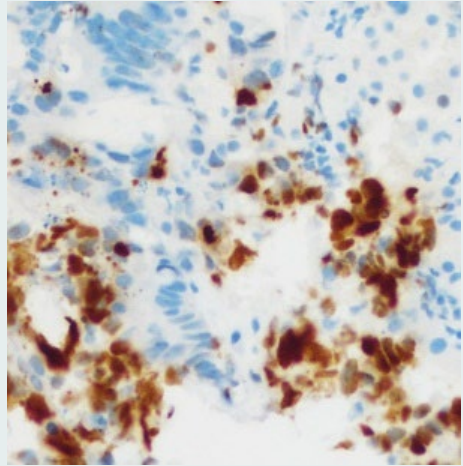
Prodrug transports inactive payload to the liver, where it is rapidly activated by liver enzymes<sup>1</sup>



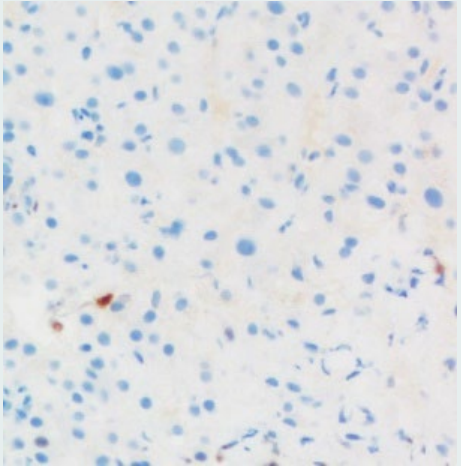
Liver-guided delivery – prodrug

Tumor-selective payload – troxacitabine

Kills tumor cells<sup>2,3,4</sup>



Spares healthy cells<sup>2,3,4</sup>



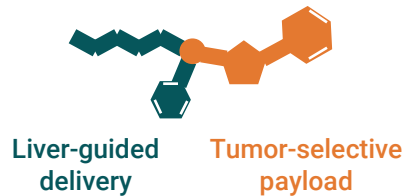
<sup>1</sup>Bethell, R. et al P-035, ILCA 2016  
<sup>2</sup>Kukhanova, M et al J Biol Chem 1995  
<sup>3</sup>Albertella, M. et al EASL Summit P01-05, 2018  
<sup>4</sup>Öberg F. et al, EASL PO-221, 2022

# Fostrox (fostroxacitabine bralpamide)

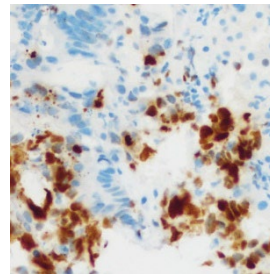
## The first oral, liver-targeted treatment tailored for HCC

Selectively kills tumor cells, sparing healthy liver cells<sup>3</sup>

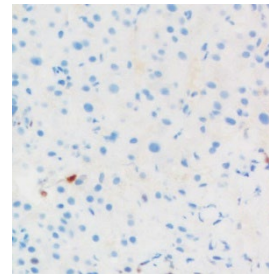
Unique, liver-targeted approach in HCC



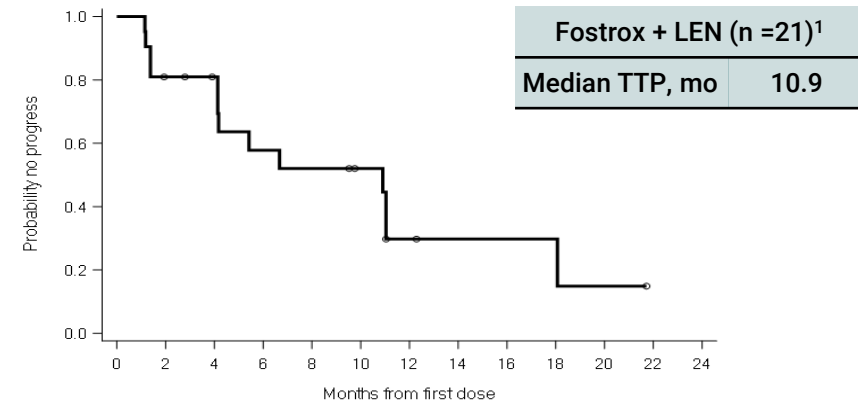
Kills tumor cells



Sparses healthy cells



Efficacy substantially better than current treatments<sup>1,2</sup>



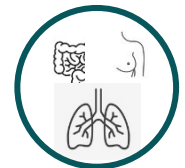
### First-to-market opportunity for fostrox + Lenvima



- No 2<sup>nd</sup> line treatments approved in HCC
- Global phase 2b, designed to enable breakthrough designation & accelerated approval process

### In 2<sup>nd</sup> line HCC market valued >\$2.5bn

>\$2.5bn



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

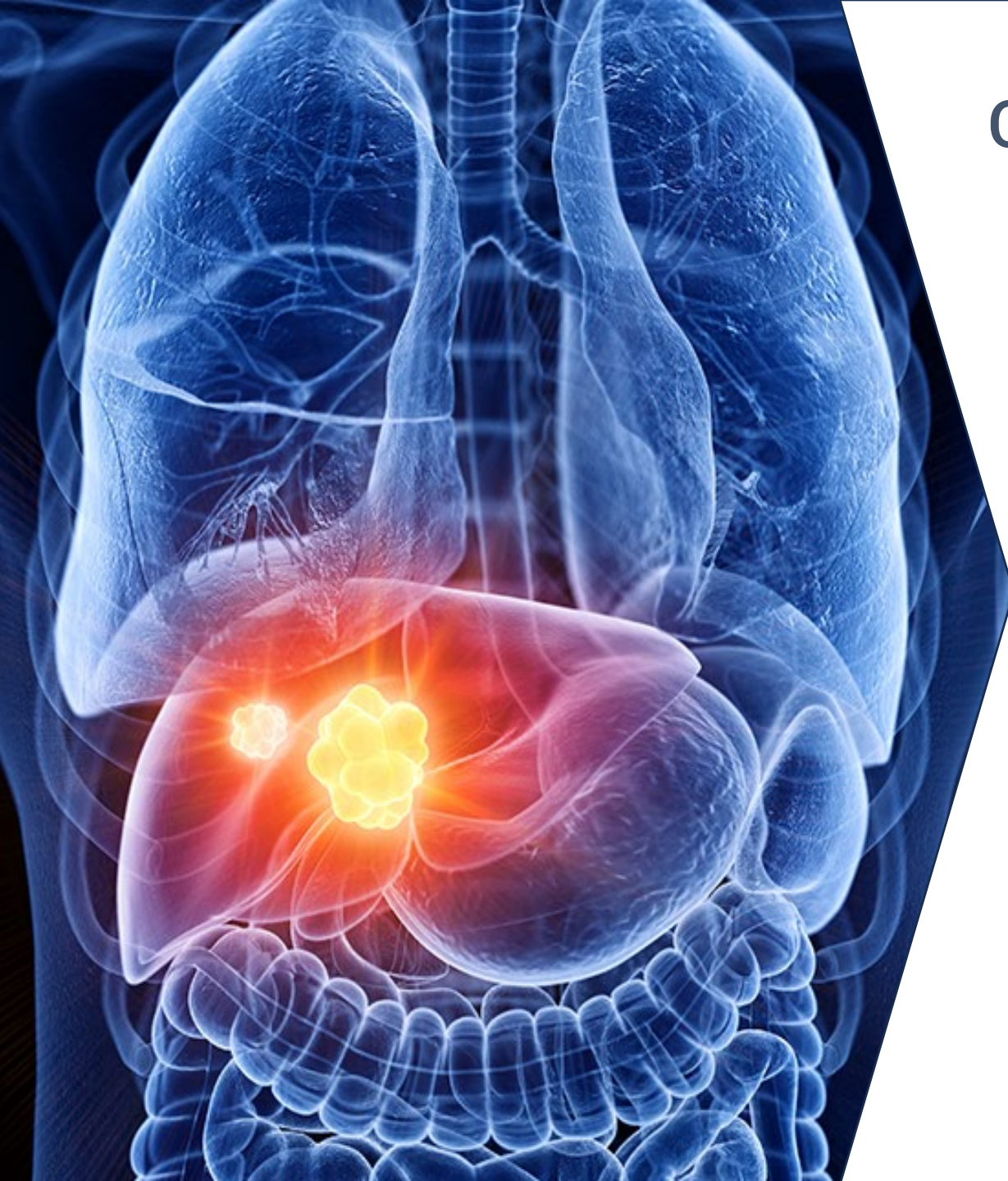
Significant upside in liver metastasis from other solid tumors

<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



## Continued momentum during Q3



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

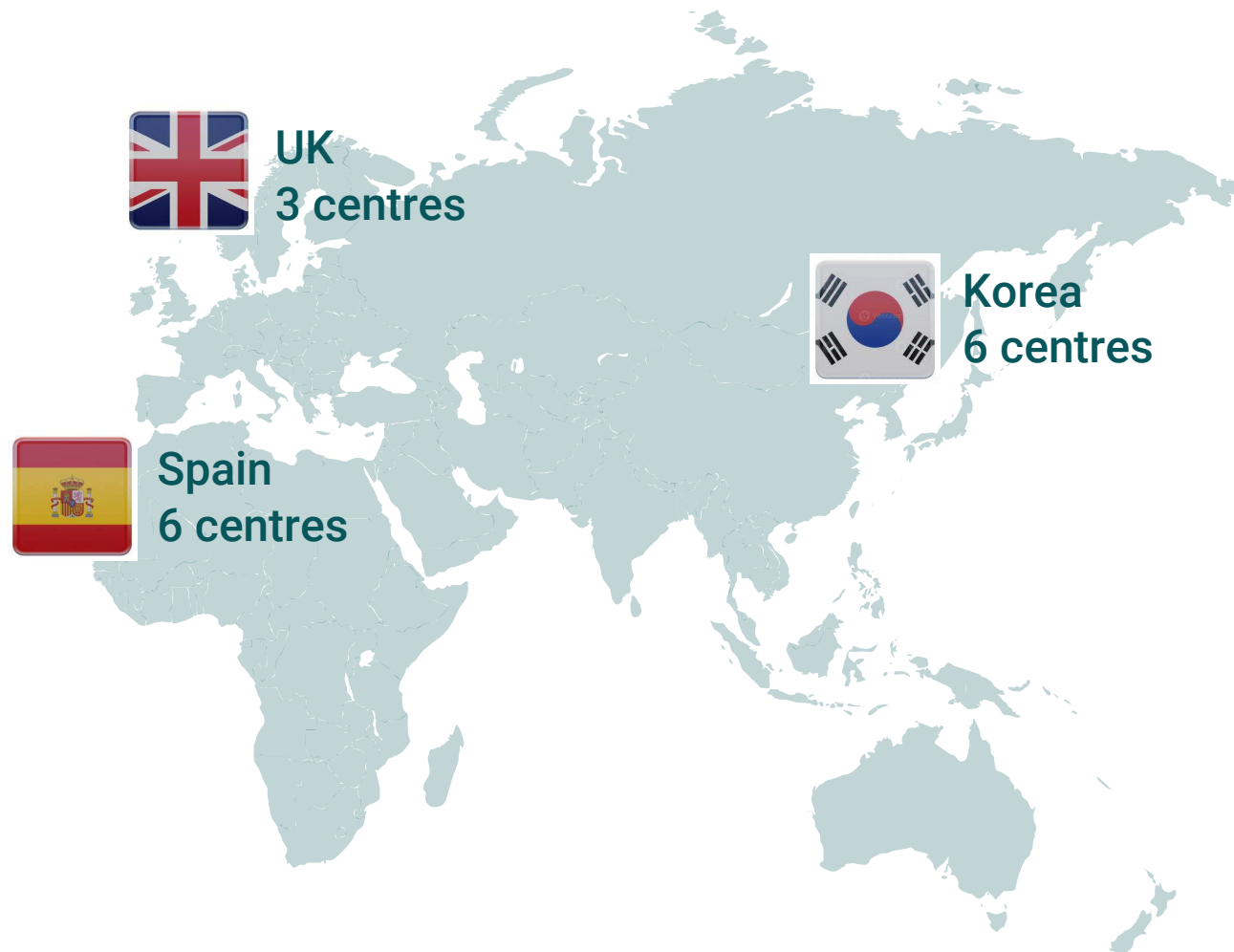


Eisai clinical trial collaboration validates the potential of fostrox + Lenvima



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

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



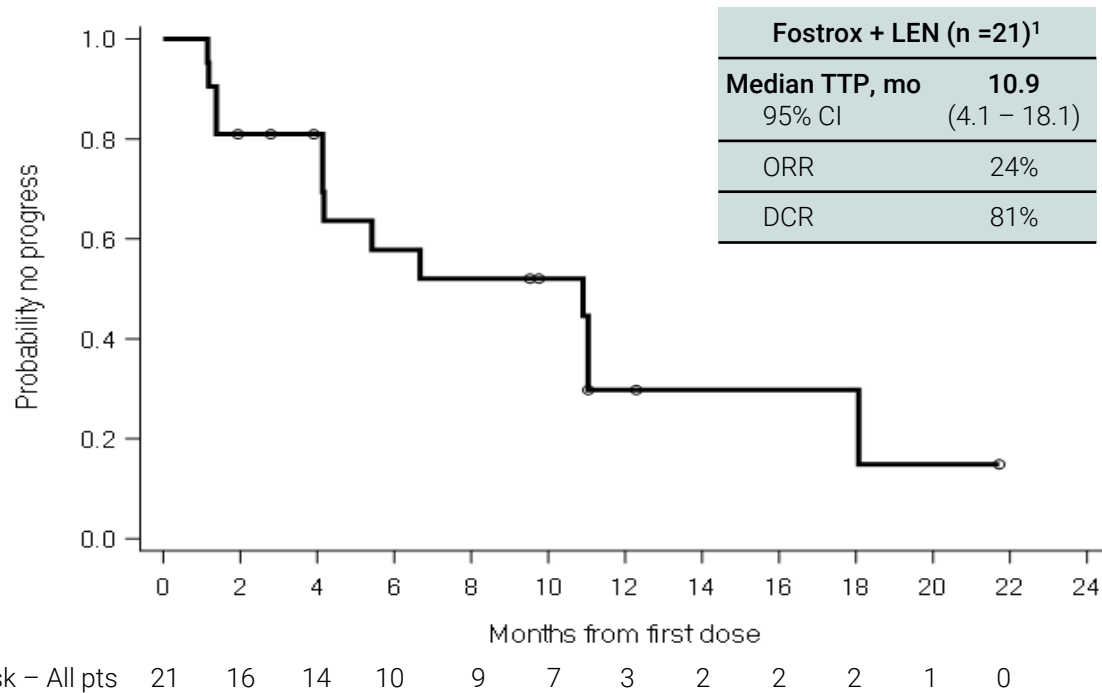
## Key study features

- Fostrox + Lenvima in 2L/3L advanced HCC
- 15 sites in South Korea, Spain and UK
- Very rapid recruitment speed
- Median follow-up 10.5 months



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

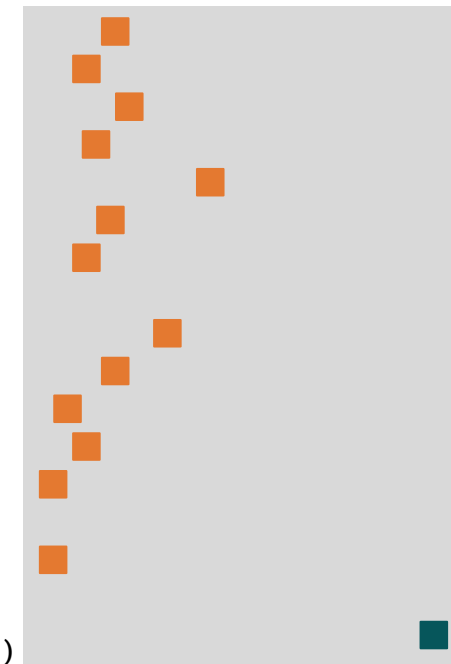
## Median TTP (Kaplan-Meier) with fostrox + Lenvima



## 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)

~3.5-4 months



**Fostrox + Lenvima (n=21)**

0 5 10 15  
TTP - Months

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

# 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>	<b>Fostrox + Lenvima<sup>4</sup></b>
<b>Median PFS/TTP</b>	3.5 mo	4.4 mo	2.8 mo	<b>10.9 mo</b>
<b>Overall Response Rate</b>	7.5%	15.4%	5.9%	<b>24%</b>
<b>Disease Control Rate</b>	67.5%	66.2%	54.4%	<b>81%</b>

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

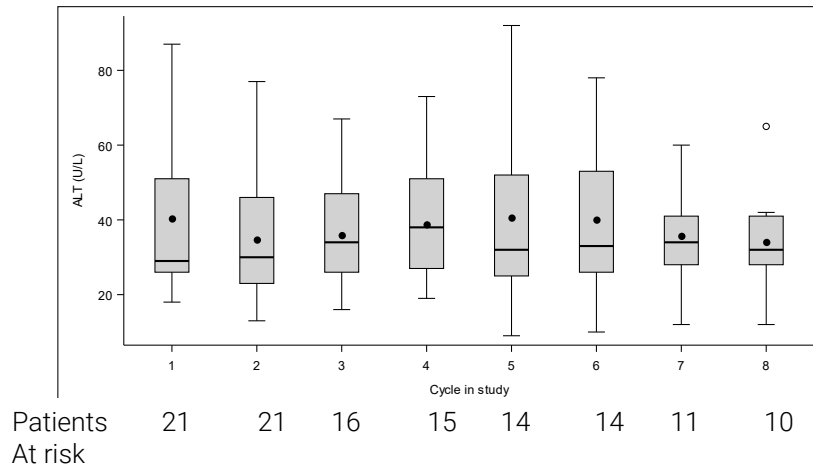
<sup>2</sup>Hiraoka et al., Oncology 2023; 101:624-633

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

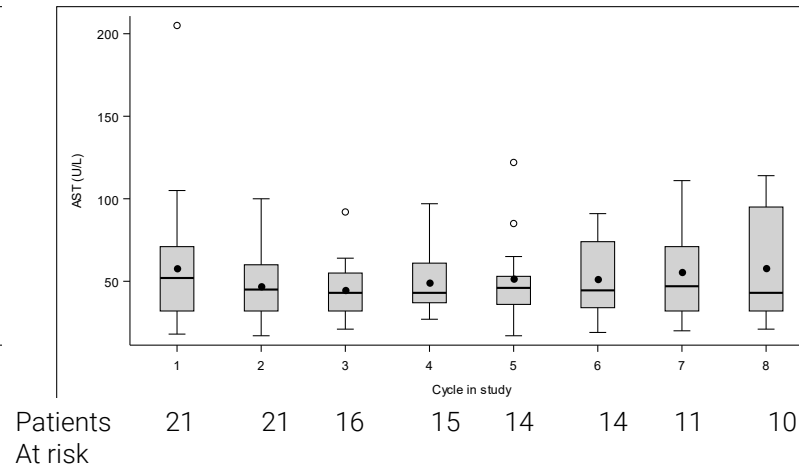
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# Stable liver function during treatment with fostrox + Lenvima

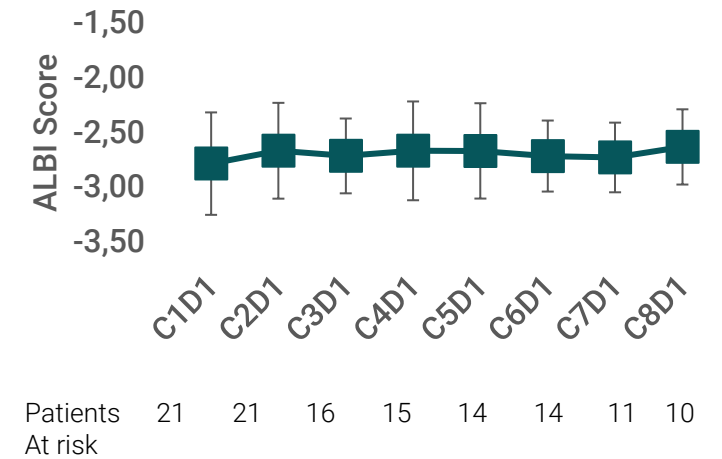
ALT change over duration of treatment



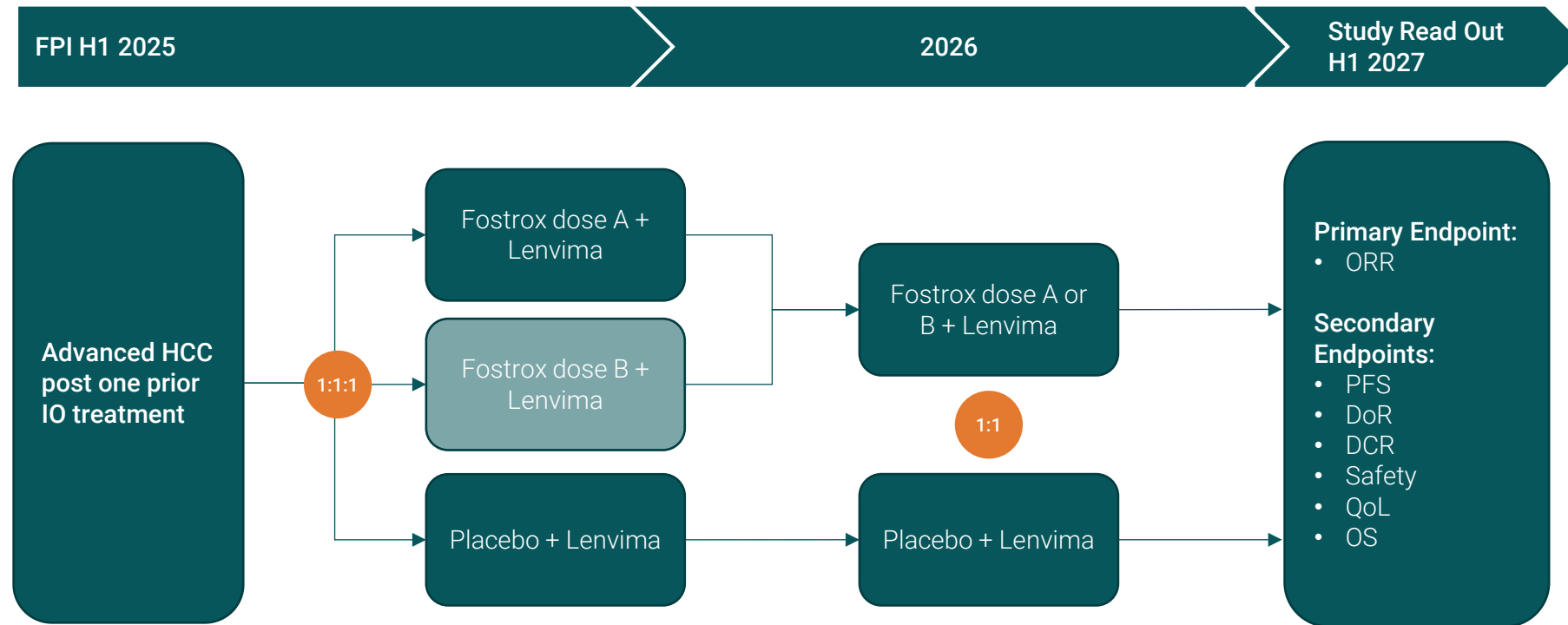
AST change over duration of treatment



ALBI score change over duration of treatment



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



# Important clinical trial collaboration with Eisai/Lenvima 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 Lenvima drug supply for randomized phase 2b study while Medivir retains full rights to fostrox



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

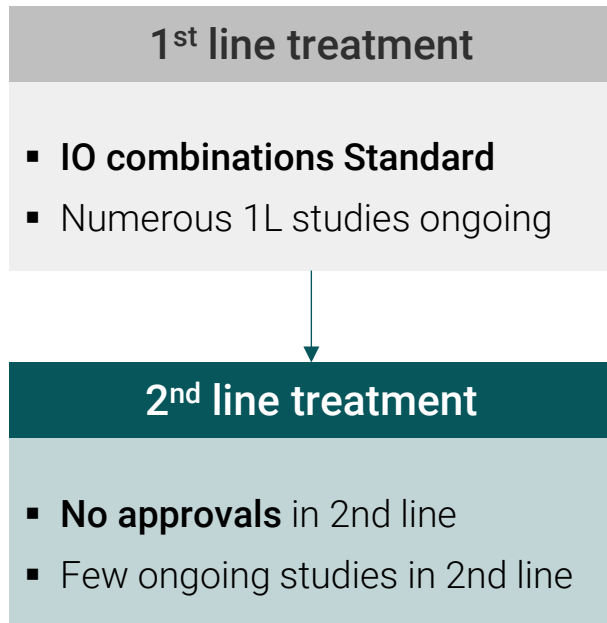


Eisai clinical trial collaboration further validates the potential of fostrox + Lenvima

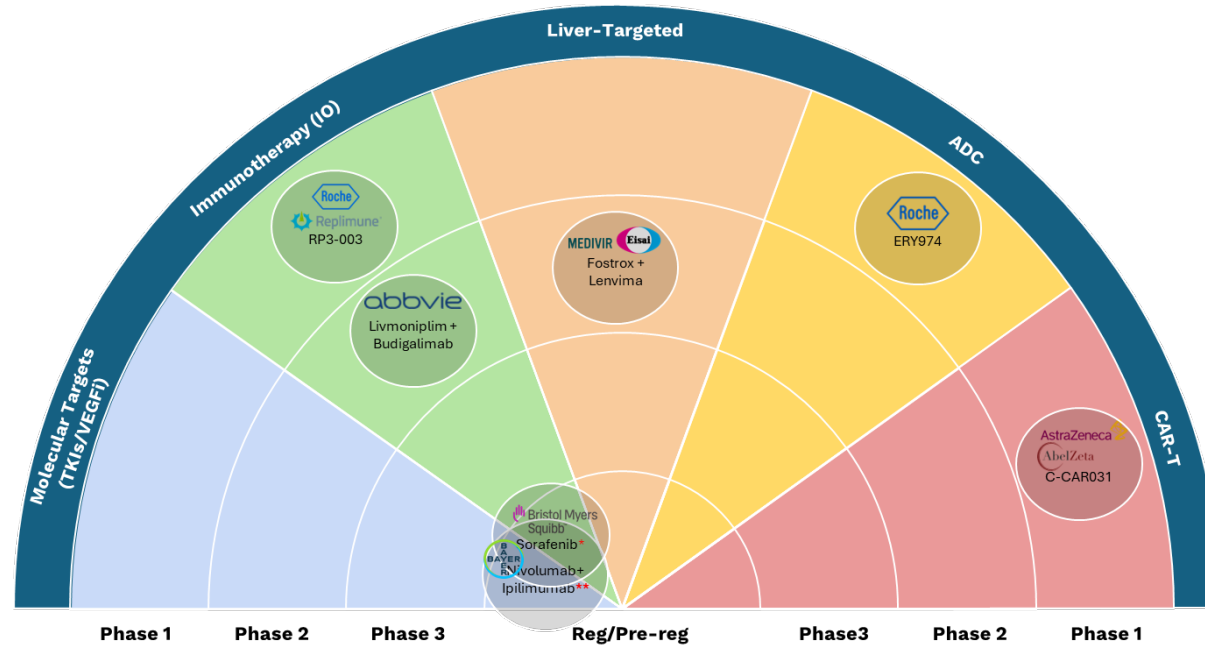
Preparations for randomized phase 2b are proceeding according to plan with intent to open IND in the US in Q4

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

Treatment algorithm – no 2<sup>nd</sup> line treatments approved



Weak competitive landscape in 2<sup>nd</sup> line HCC – fostrox + Lenvima at the forefront



\*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.

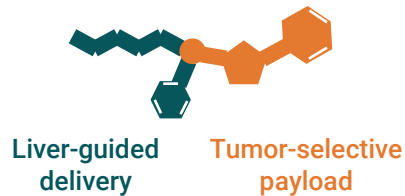
\*\*Nivolumab + Ipilimumab were approved for patients post-sorafenib but are now moving into 1st line HCC treatment (positive phase III, awaiting approval ([source](#))).

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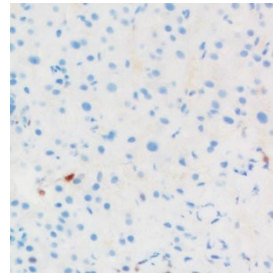
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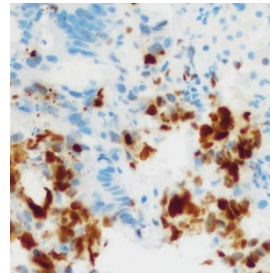
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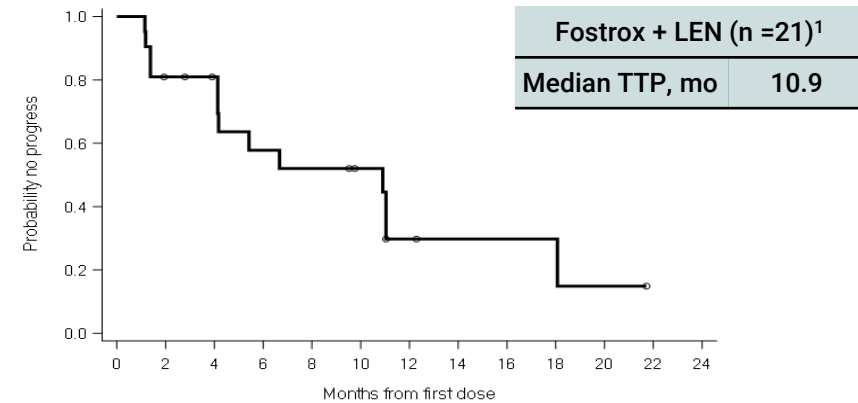
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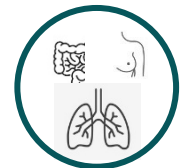
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# Thank You!

