

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

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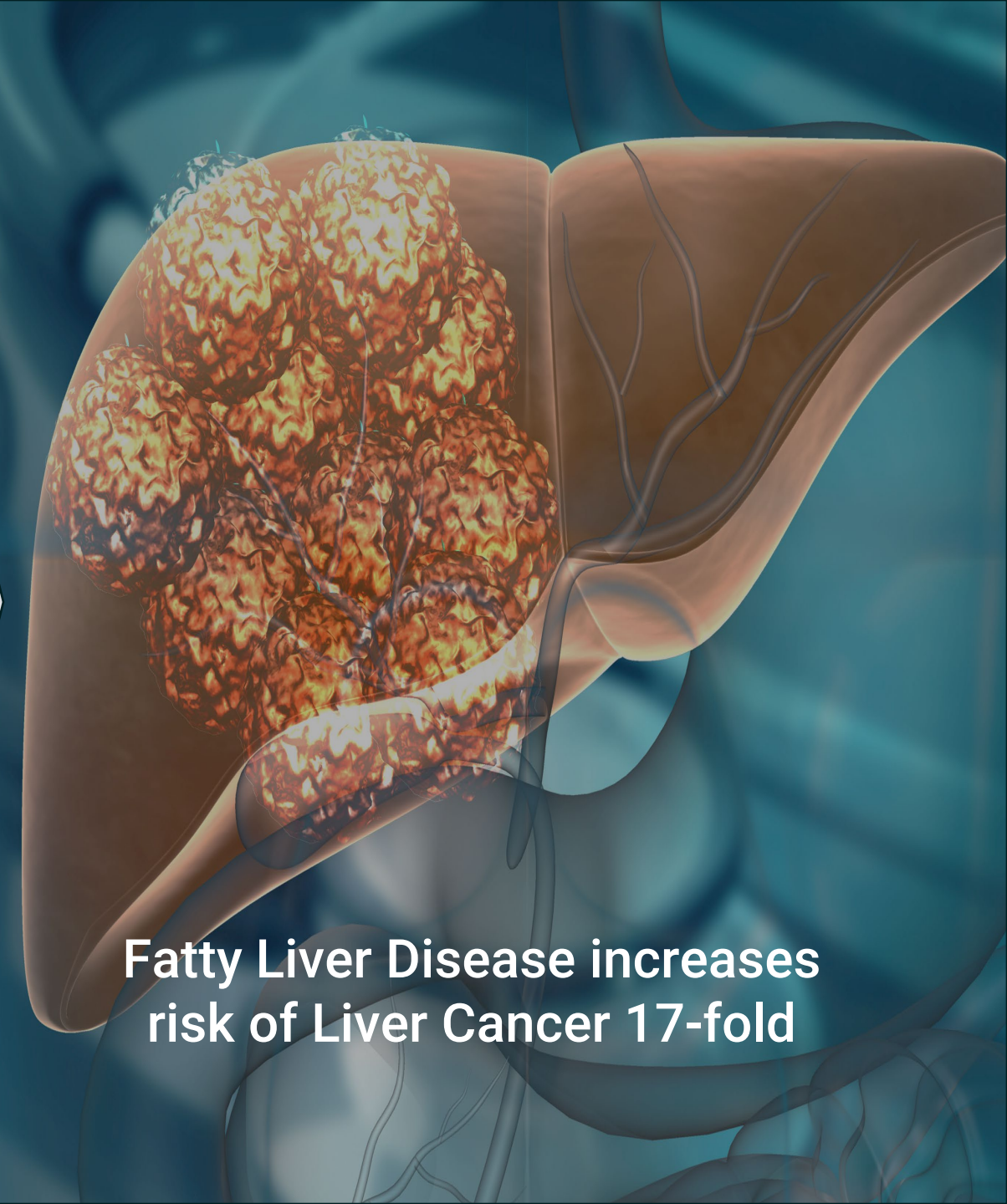
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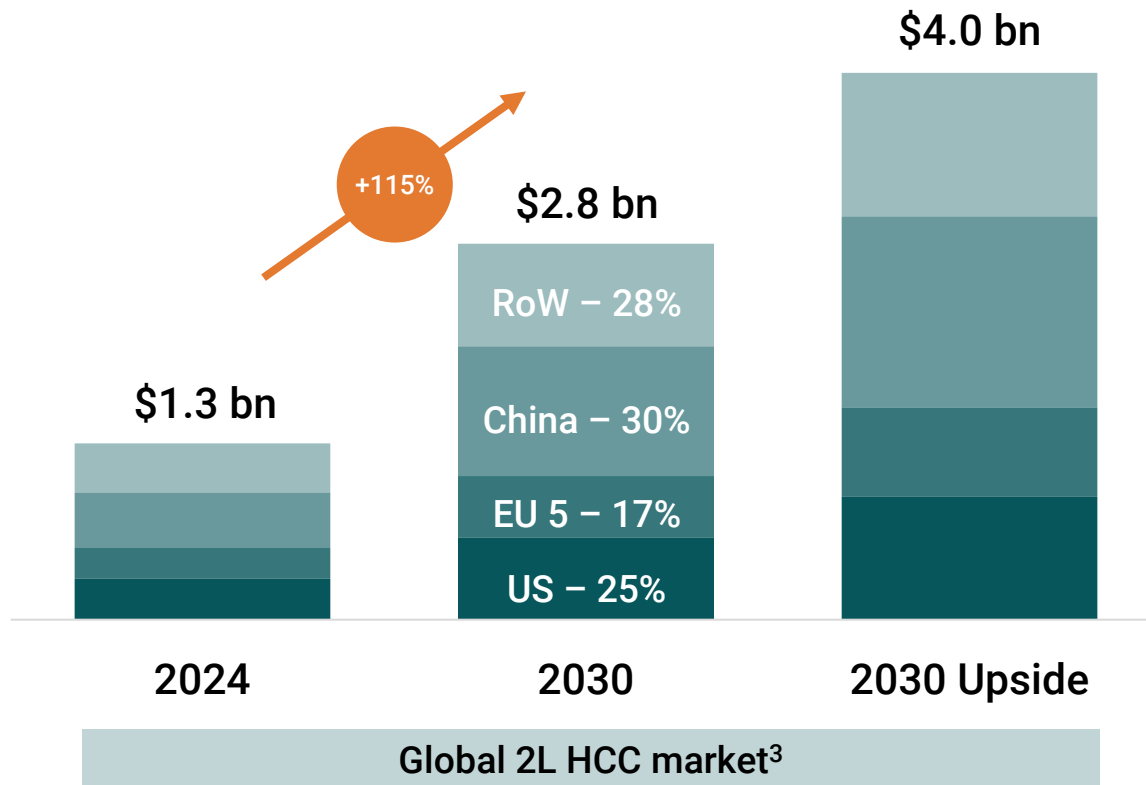


**45% of US adults are obese
More than 25% have Fatty Liver Disease**



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

2nd line HCC – a large and growing commercial opportunity³



Growth driven by:

- HCC to increase **+122% in the US** and **+82% in China²** 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

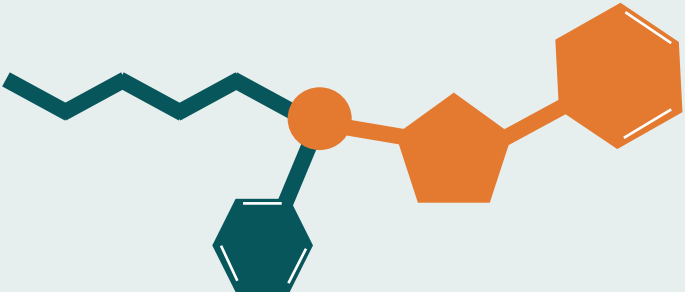
¹Rumguy et al. Journal of Hepatology 2022

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

³GlobalData 2021 and internal analysis

Fostrox – designed to selectively kill tumor cells in the liver

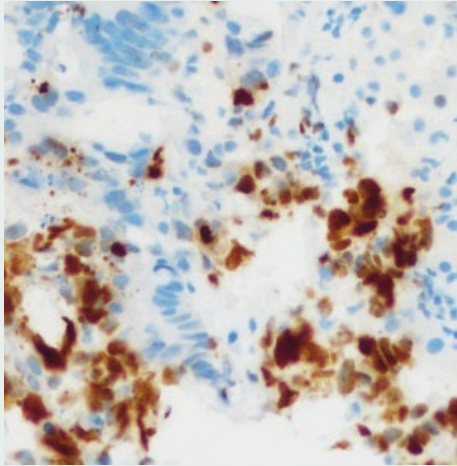
Prodrug transports inactive payload to the liver, where it is rapidly activated by liver enzymes¹



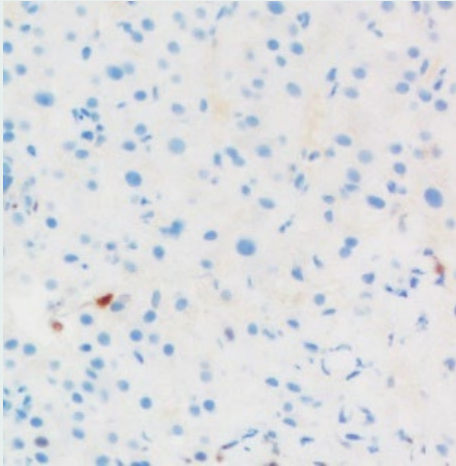
Liver-guided delivery – prodrug

Tumor-selective payload – troxacitabine

Kills tumor cells^{2,3,4}



Spares healthy cells^{2,3,4}



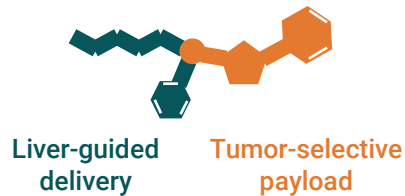
¹Bethell, R. et al P-035, ILCA 2016
²Kukhanova, M et al J Biol Chem 1995
³Albertella, M. et al EASL Summit P01-05, 2018
⁴Öberg F. et al, EASL PO-221, 2022

Fostrox (fostroxacitabine bralpamide)

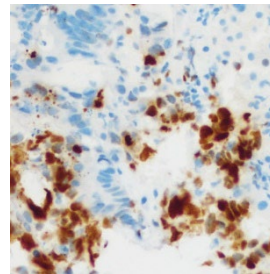
The first oral, liver-targeted treatment tailored for HCC

Selectively kills tumor cells, sparing healthy liver cells³

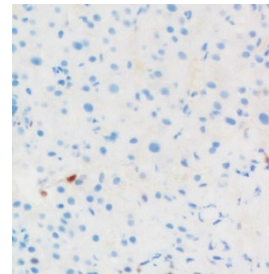
Unique, liver-targeted approach in HCC



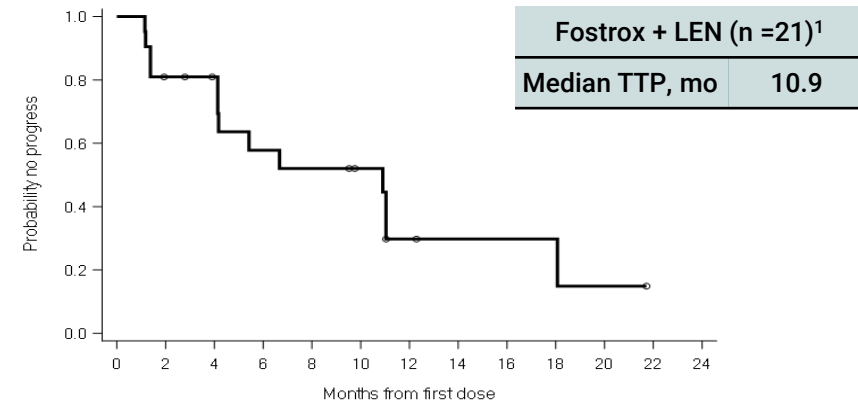
Kills tumor cells



Sparses healthy cells



Efficacy substantially better than current treatments^{1,2}



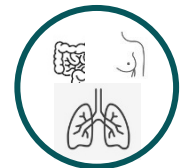
First-to-market opportunity for fostrox + Lenvima



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

In 2nd line HCC market valued >\$2.5bn

>\$2.5bn



2nd line HCC market by 2030, fastest growing cause of cancer death in US⁴

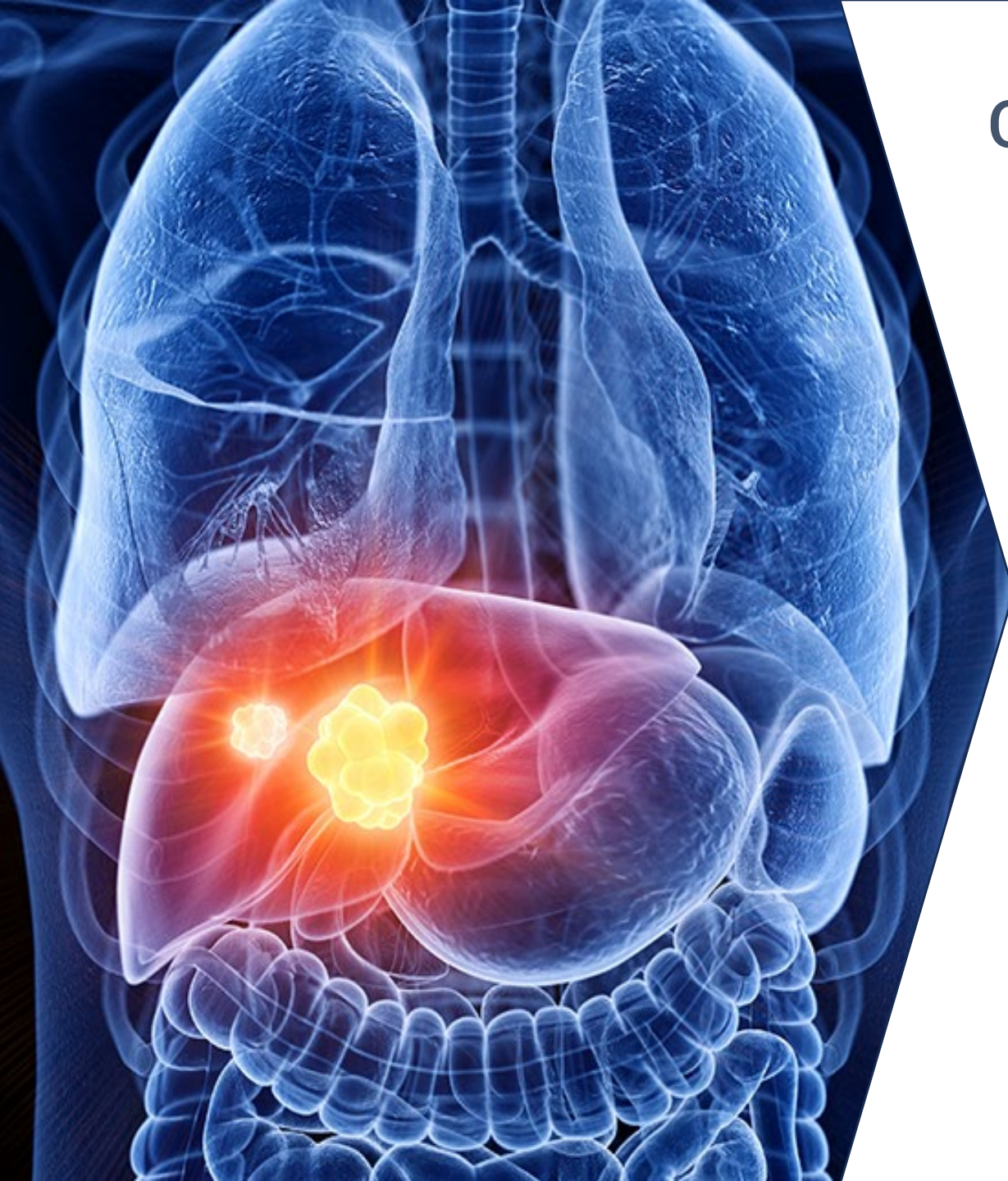
Significant upside in liver metastasis from other solid tumors

¹Chon et al., ESMO, 2024, Poster 986

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

³Evans et al ASCO GI, 2021

⁴Ma et al., Cancer, June 15, 2019; 2089-2098



Continued momentum during Q3



Mature data at ESMO confirming improved outcome with fostrox + Lenvima[®]

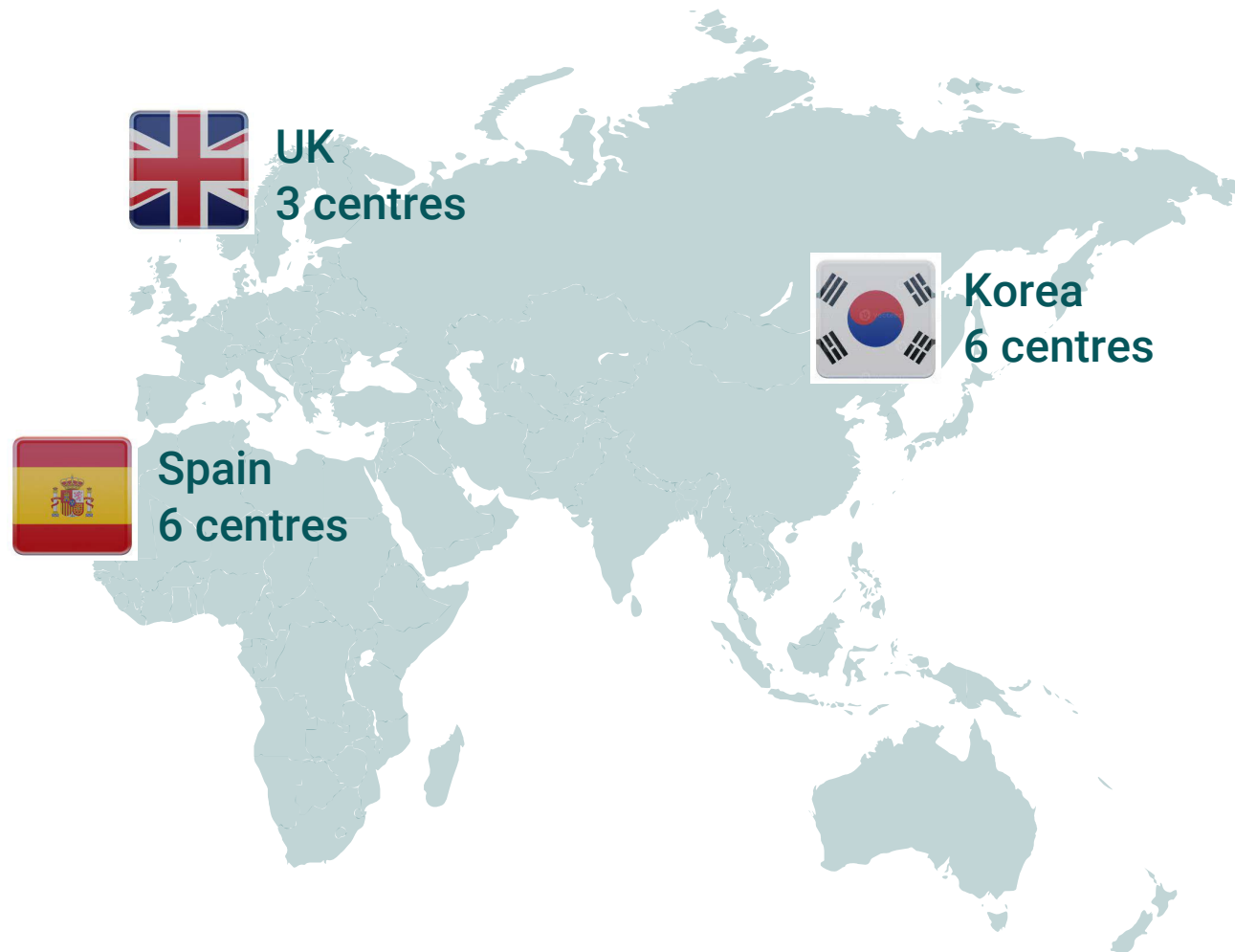


Eisai clinical trial collaboration validates the potential of fostrox + Lenvima



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

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

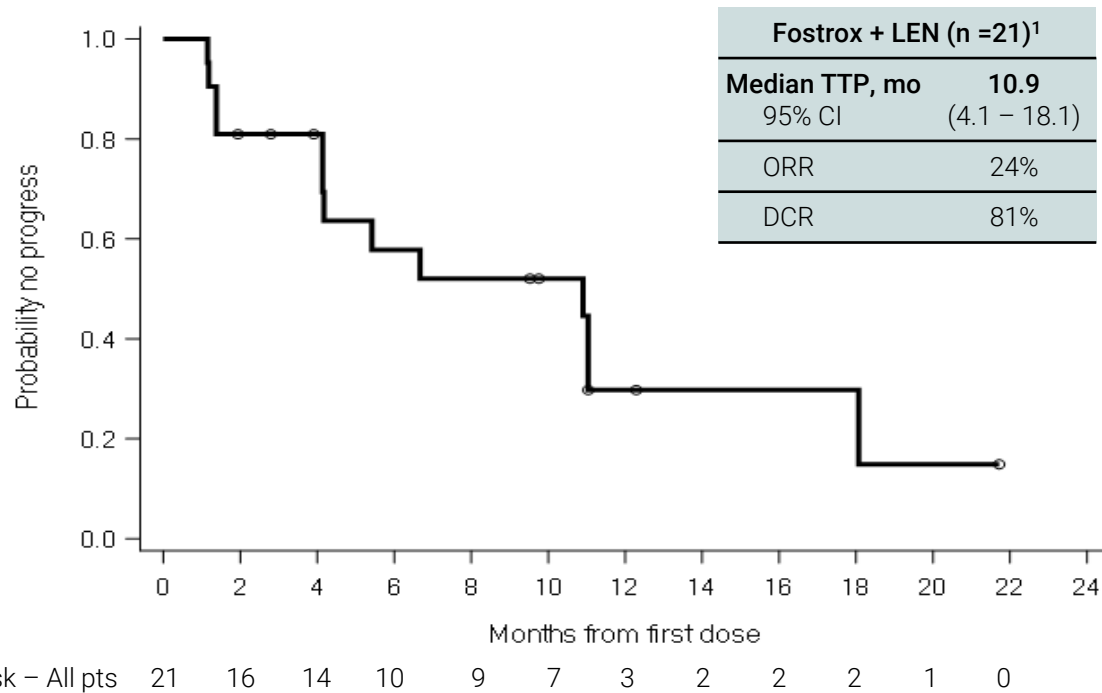


Key study features

- 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

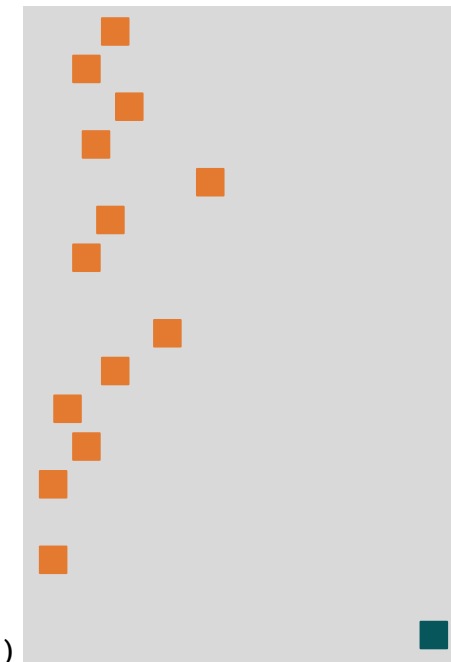
Median TTP (Kaplan-Meier) with fostrox + Lenvima



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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¹Chon 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 ¹ – Korea	Lenvima in 2L HCC ² – Japan	Keytruda + TKI in 2L HCC ³	Fostrox + Lenvima⁴
Median PFS/TTP	3.5 mo	4.4 mo	2.8 mo	10.9 mo
Overall Response Rate	7.5%	15.4%	5.9%	24%
Disease Control Rate	67.5%	66.2%	54.4%	81%

¹Chon et al. Clinical and Molecular Hepatology 2024 Mar 12

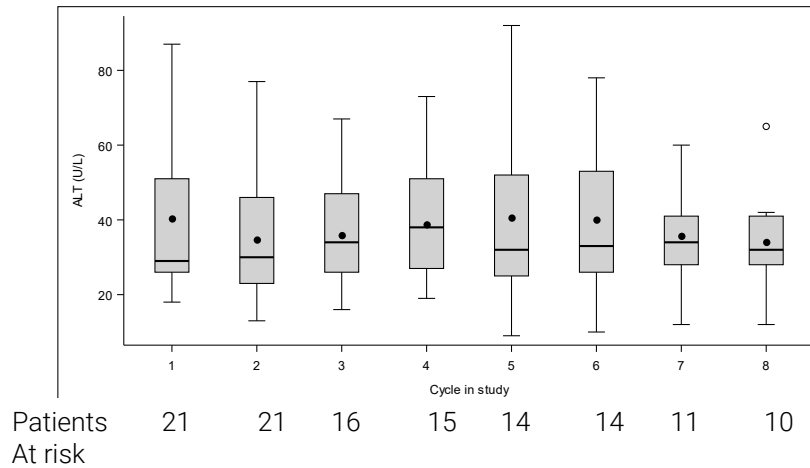
²Hiraoka et al., Oncology 2023; 101:624-633

³El-Khoueiry et al. ASCO 2024, Abstract 4007

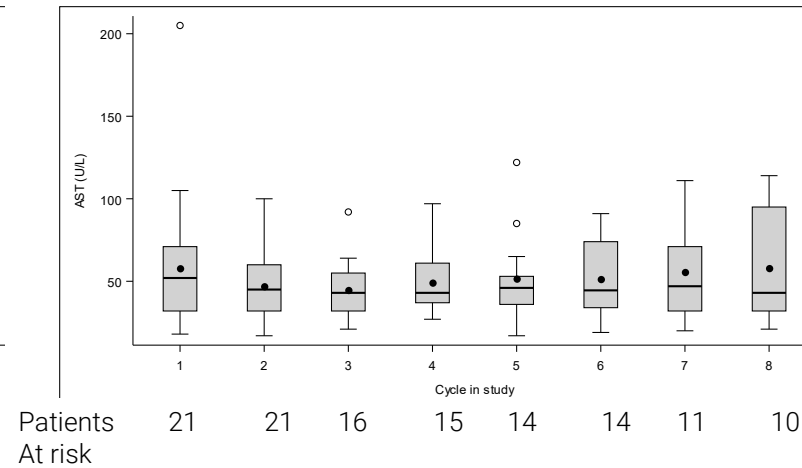
⁴Chon et al, ESMO 2024, Poster 986

Stable liver function during treatment with fostrox + Lenvima

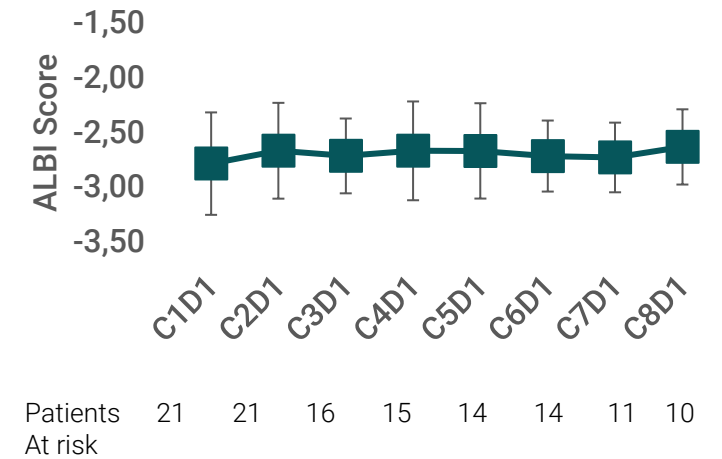
ALT change over duration of treatment



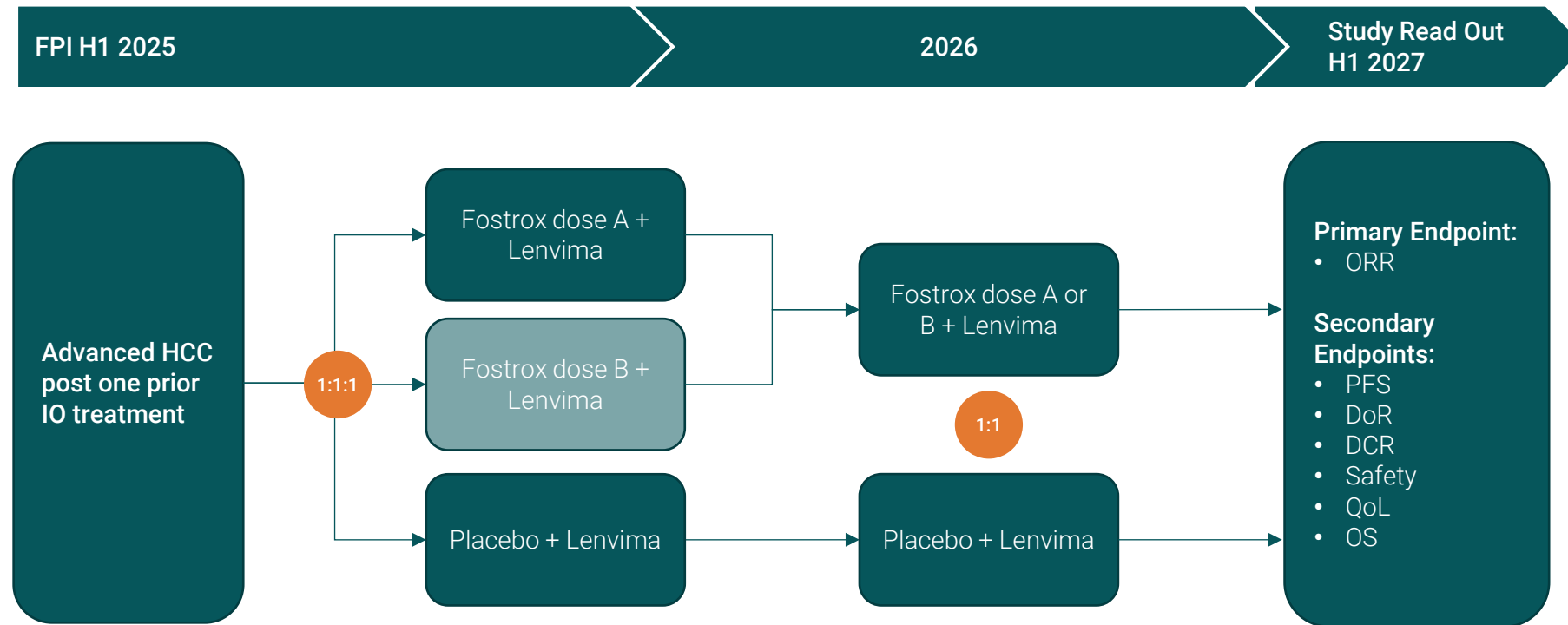
AST change over duration of treatment



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

Fostrox + Lenvima targets 2L population where few treatments are approved today

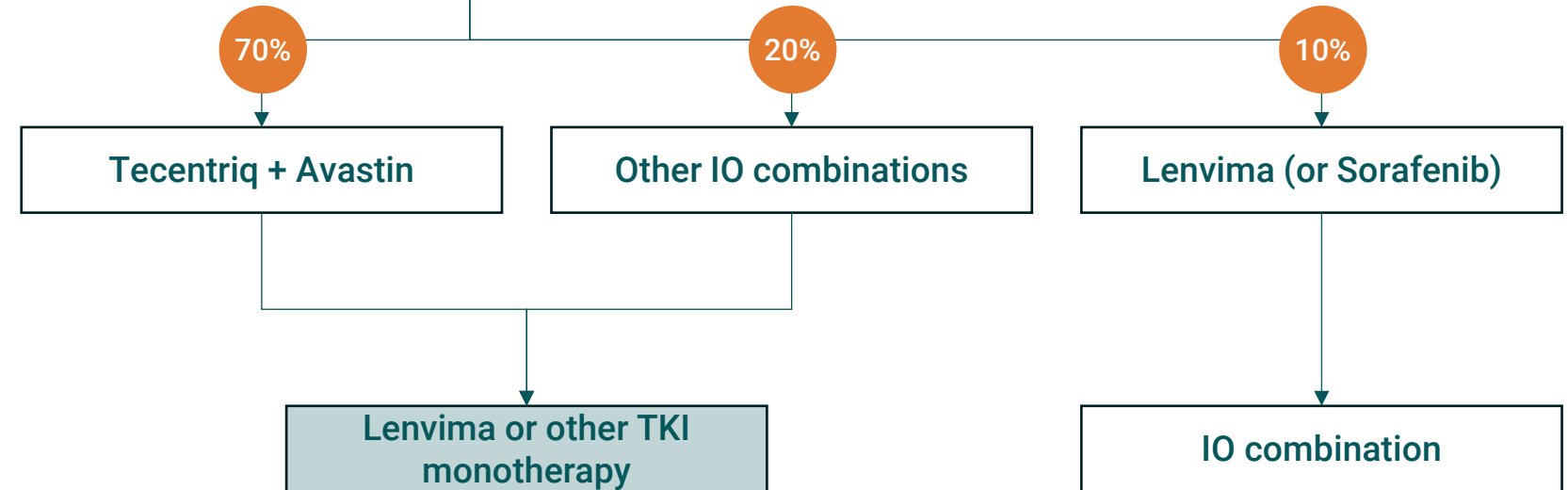
Advanced HCC – Current Treatment Algorithm

1L

- Majority treated with IO combo
- Tecentriq + Avastin preferred

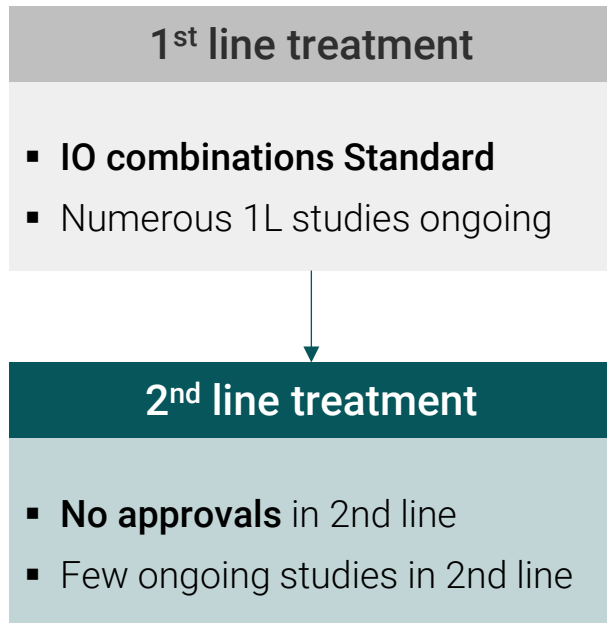
2L

- No approved options in 2L after IO combo
- Lenvima preferred alternative
- Fostrox + lenvatinib target population

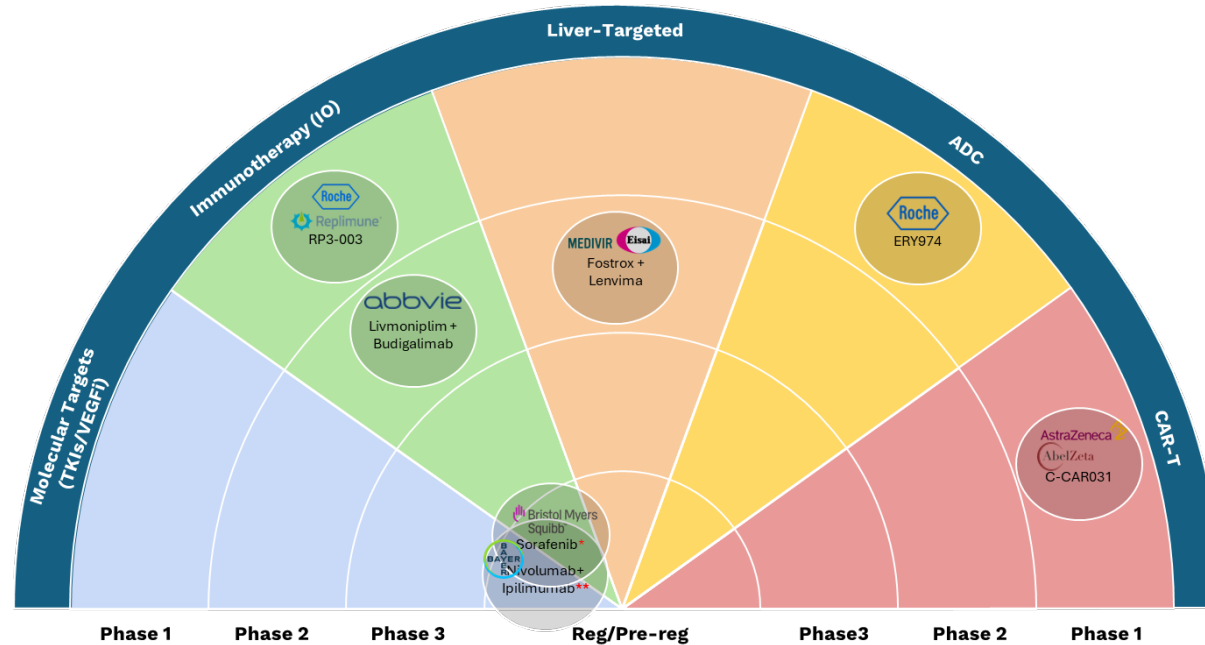


Absence of effective treatment options in 2nd line HCC

Treatment algorithm – no 2nd line treatments approved



Weak competitive landscape in 2nd line HCC – fostrox + Lenvima at the forefront



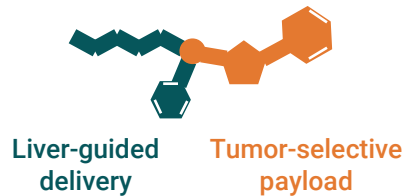
*Sorafenib was the first approved 1st-line treatment for HCC. Although approved for 2nd-line use, guidelines recommend against it due to a lack of evidence showing efficacy after immunotherapy combinations.
 **Nivolumab + Ipilimumab were approved for patients post-sorafenib but are now moving into 1st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

Fostrox (fostroxacitabine bralpamide)

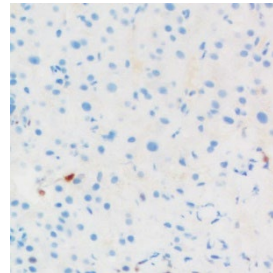
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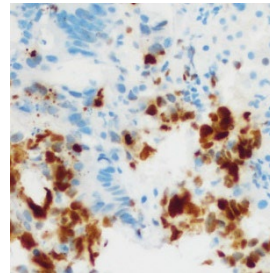
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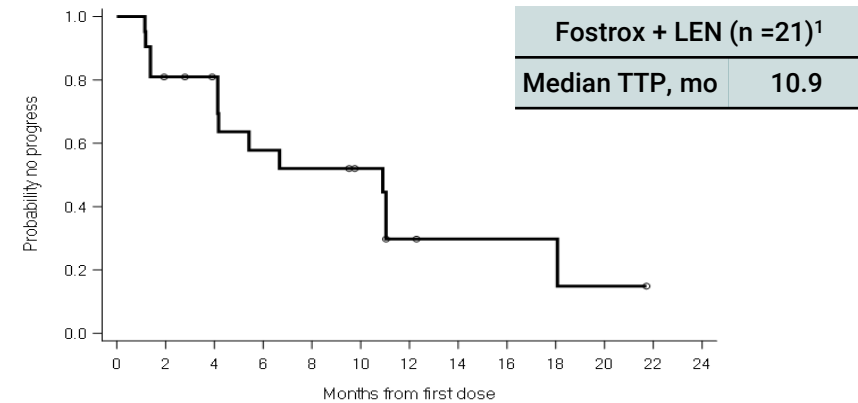
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Kills tumor cells



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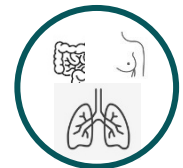
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Thank You!

