

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

**Jens Lindberg, CEO
Redeye Fight Cancer Day**

MEDIVIR

Important notice

You must read the following before continuing. The following applies to this document and the information provided in this presentation by Medivir AB (publ) (the “Company”) or any person on behalf of the Company and any other material distributed or statements made in connection with such presentation (the “Information”), and you are therefore advised to carefully read the statements below before reading, accessing or making any other use of the Information. In accessing the Information, you agree to be bound by the following terms and conditions.

The Information does not constitute or form part of, and should not be construed as, an offer of invitation to subscribe for, underwrite or otherwise acquire, any securities of the Company or a successor entity or any existing or future subsidiary or affiliate of the Company, nor should it or any part of it form the basis of, or be relied on in connection with, any contract to purchase or subscribe for any securities of the Company or any of such subsidiaries or affiliates nor shall it or any part of it form the basis of or be relied on in connection with any contract or commitment whatsoever. Specifically, this presentation does not constitute a “prospectus” within the meaning of the U.S. Securities Act of 1933, as amended.

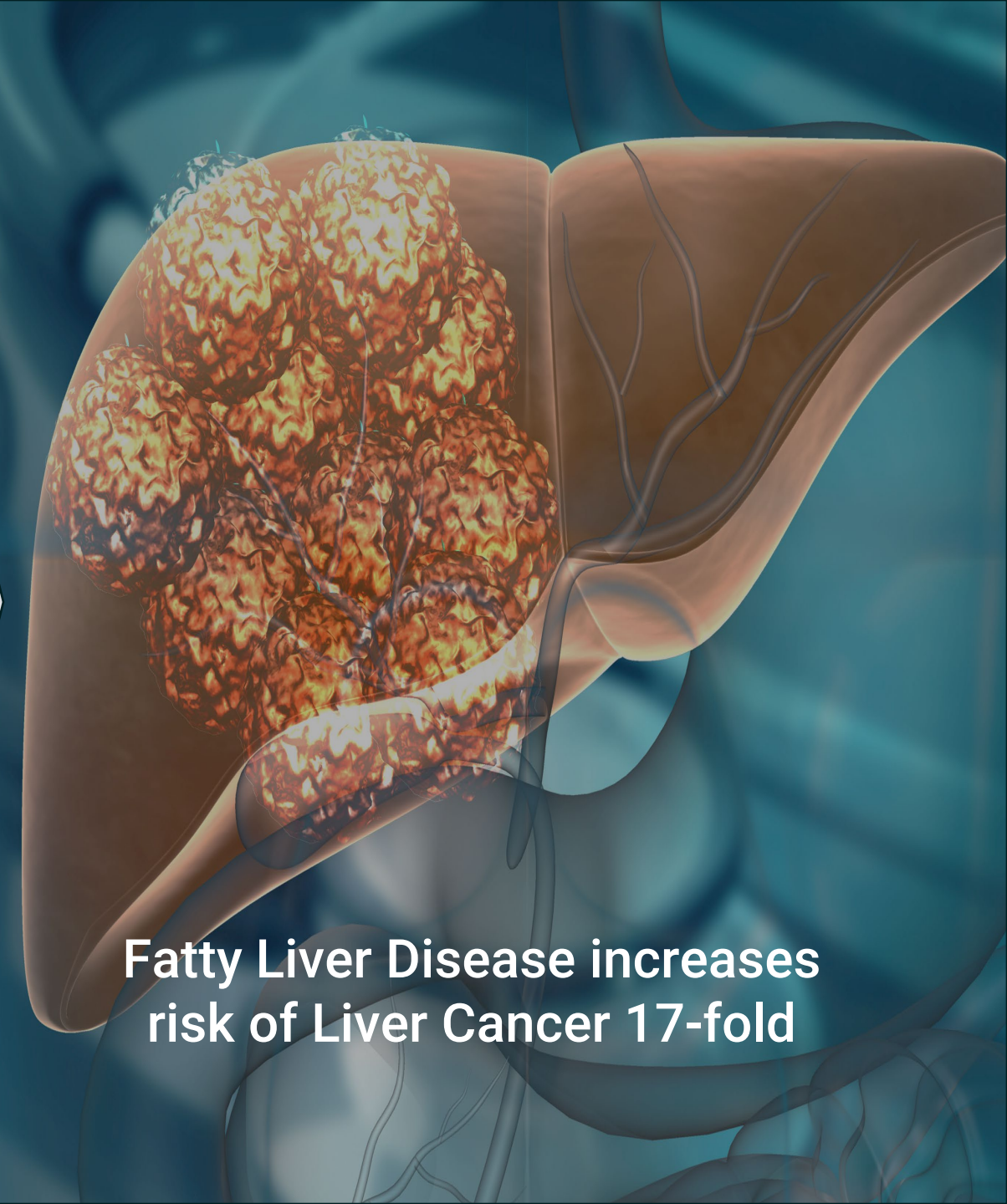
The Information may not be reproduced, redistributed, published or passed on to any other person, directly or indirectly, in whole or in part, for any purpose. The Information is not directed to, or intended for distribution to or use by, any person or entity that is a citizen or resident of, or located in, any locality, state, country or other jurisdiction where such distribution or use would be contrary to law or regulation or which would require any registration or licensing within such jurisdiction. The Information is not for publication, release or distribution in the United States, Australia, Canada or Japan, or any other jurisdiction in which the distribution or release would be unlawful.

All of the Information herein has been prepared by the Company solely for use in this presentation. The Information contained in this presentation has not been independently verified. No representation, warranty or undertaking, express or implied, is made as to, and no reliance should be placed on, the fairness, accuracy, completeness or correctness of the Information or the opinions contained herein. The Information contained in this presentation should be considered in the context of the circumstances prevailing at that time and will not be updated to reflect material developments which may occur after the date of the presentation. The Company may alter, modify or otherwise change in any manner the content of this presentation, without obligation to notify any person of such revision or changes.

This presentation may contain certain forward-looking statements and forecasts which relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on the Company’s operations, financial position and earnings. The terms “anticipates”, “assumes”, “believes”, “can”, “could”, “estimates”, “expects”, “forecasts”, “intends”, “may”, “might”, “plans”, “should”, “projects”, “will”, “would” or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realized. Factors that could cause these differences include, but are not limited to, implementation of the Company’s strategy and its ability to further grow, risks associated with the development and/or approval of the Company’s products candidates, ongoing clinical trials and expected trial results, the ability to commercialize existing and any future products, technology changes and new products in the Company’s potential market and industry, the ability to develop new products, the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors. While the Company always intends to express its best judgment when making statements about what it believes will occur in the future, and although the Company bases these statements on assumptions that it believe to be reasonable when made, these forward-looking statements are not a guarantee of its performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks, uncertainties and other variable circumstances. Many of these risks are outside of the Company’s control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this presentation are made only as of the date hereof. The Company does not undertake, and specifically decline, any obligation to update any such statements or to publicly announce the results of any revisions to any of such statements to reflect future events or developments.

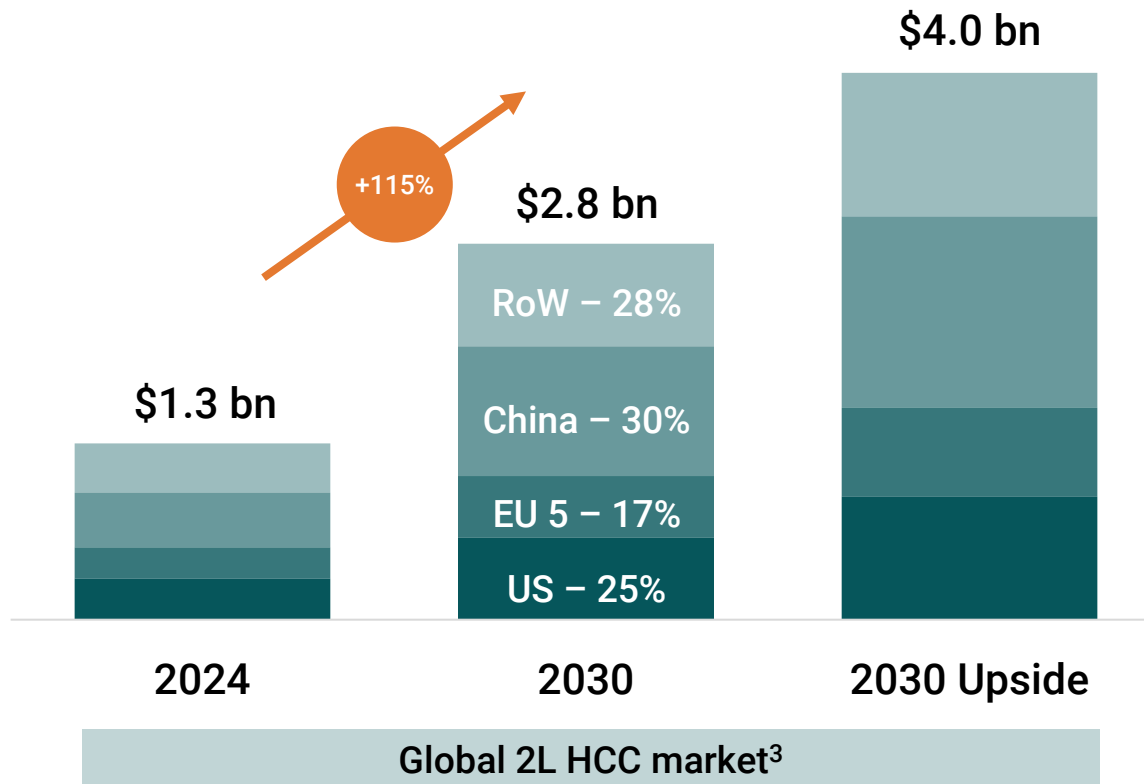


**45% of US adults are obese
More than 25% have Fatty Liver Disease**



**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

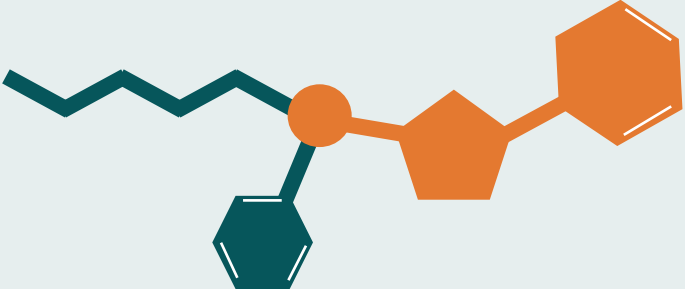
¹Rumguy et al. Journal of Hepatology 2022

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

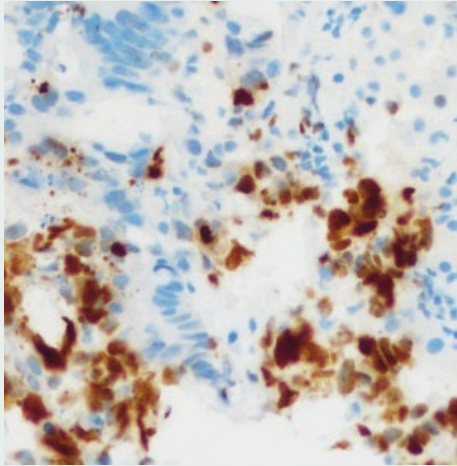
Prodrug transports inactive payload to the liver, where it is rapidly activated by liver enzymes¹



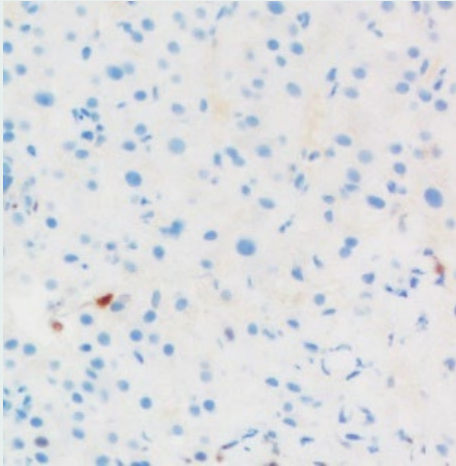
Liver-guided delivery – prodrug

Tumor-selective payload – troxacitabine

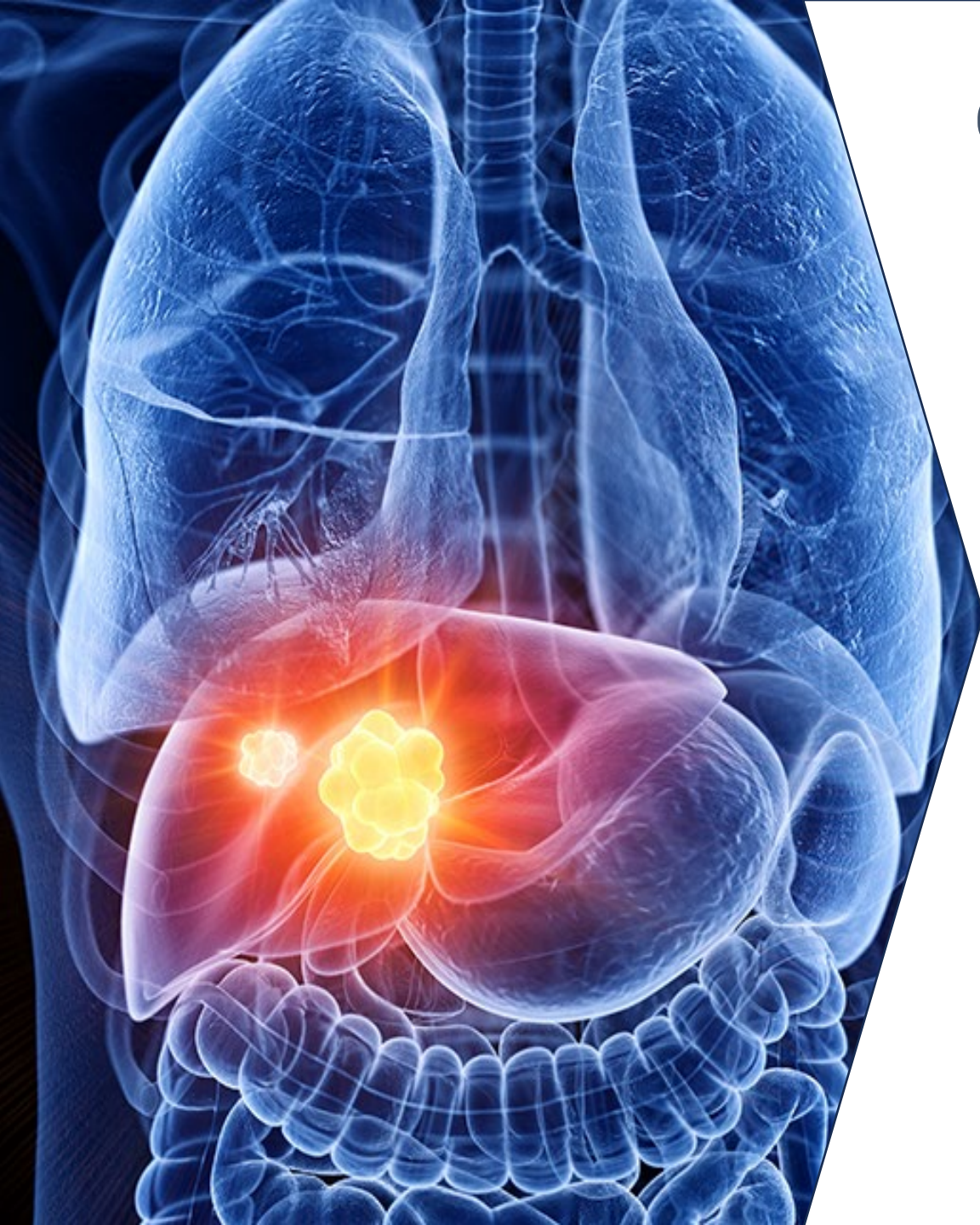
Kills tumor cells^{2,3,4}



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



Continued momentum in Q4



Phase 1b/2a study closed & end-of-treatment data to be presented at EASL LC Summit, Feb 20-22

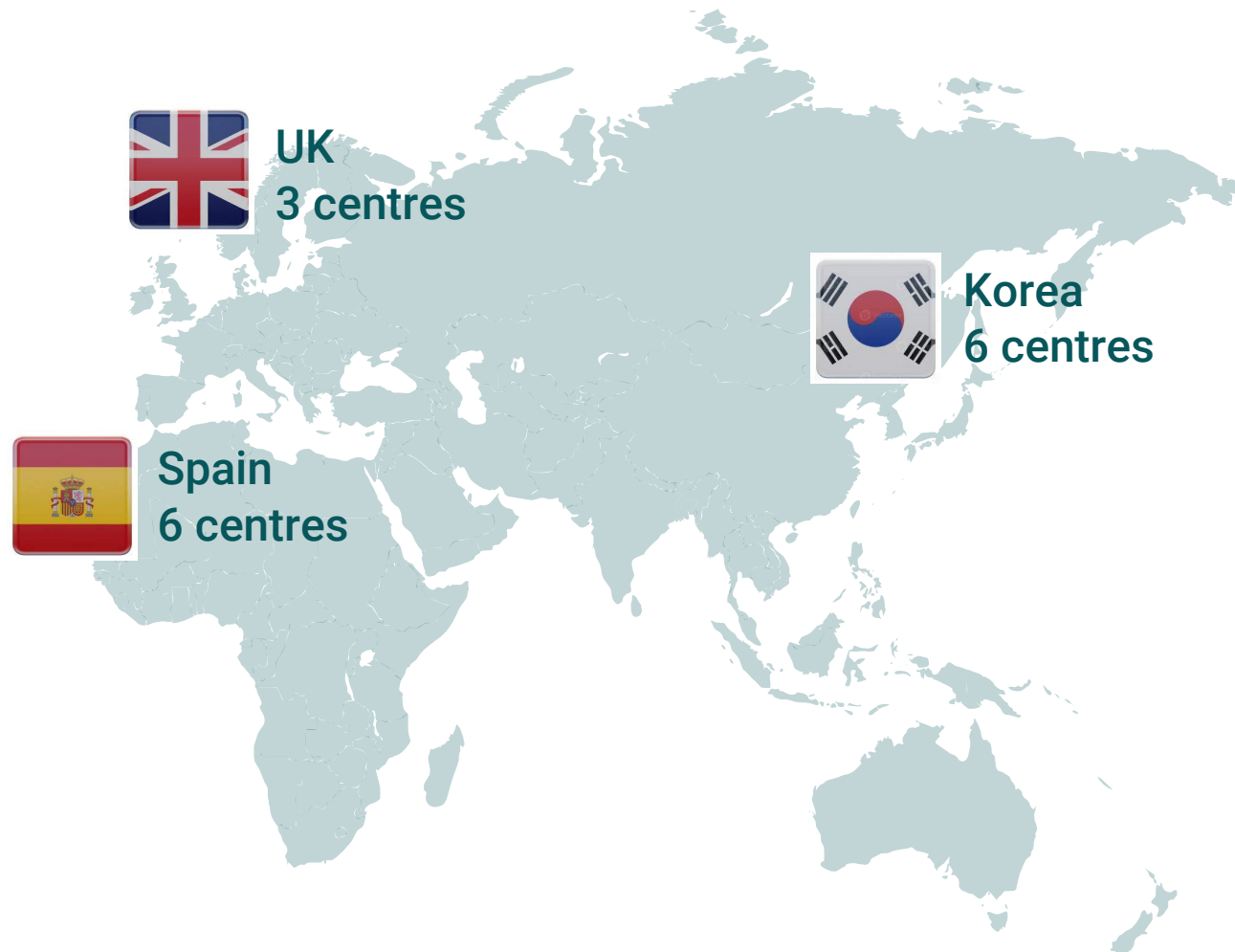


US IND approval for planned Phase 2b study



Eisai clinical trial collaboration validates the potential of fostrox + Lenvima

Global phase 1b/2a study with fostrox + Lenvima (TKI) now closed, data presentation at EASL, February 20-22

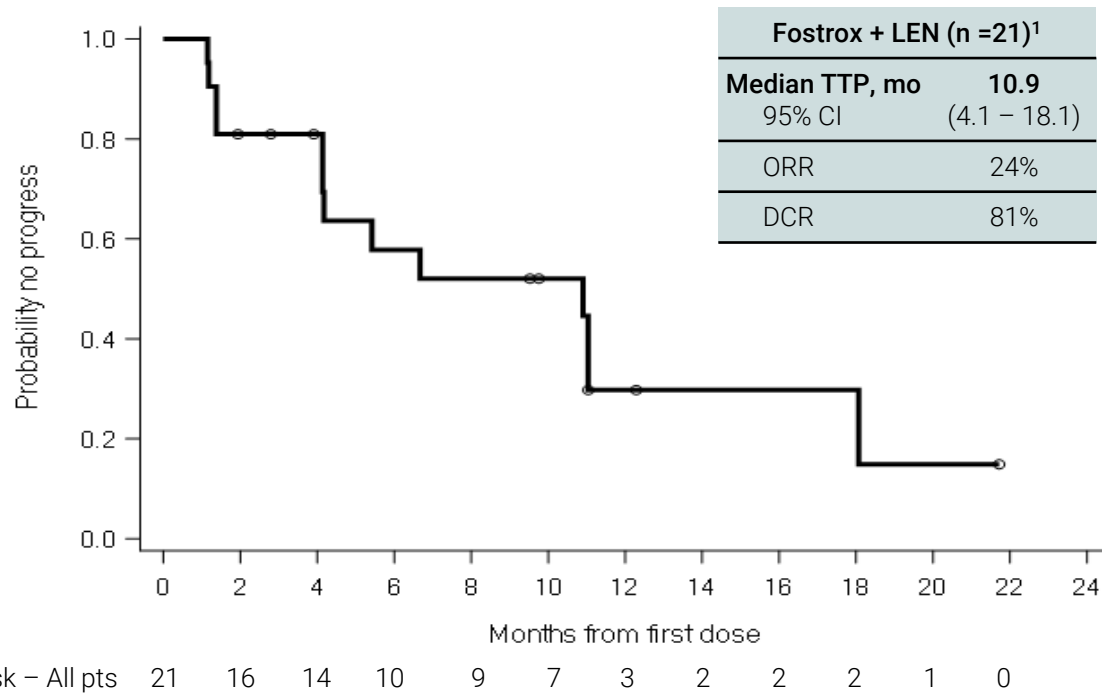


Key study features

- 2L & 3L advanced HCC patients
- 15 sites in Korea, Spain and UK
- Median follow-up 10.5 months

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

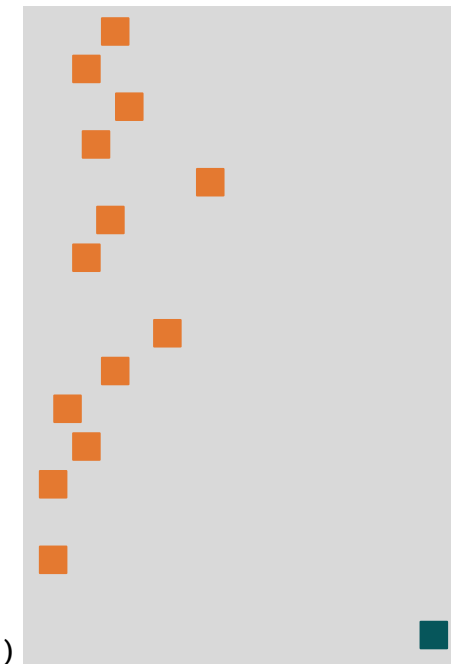
Median TTP (Kaplan-Meier) with fostrox + Lenvima



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

MEDIVIR

¹Chon et al., ESMO 2024, Poster 986.

ESMO Asia 24 – The first prospective 2nd line study evaluating Lenvima monotherapy post Tecentriq + Avastin in 1st line

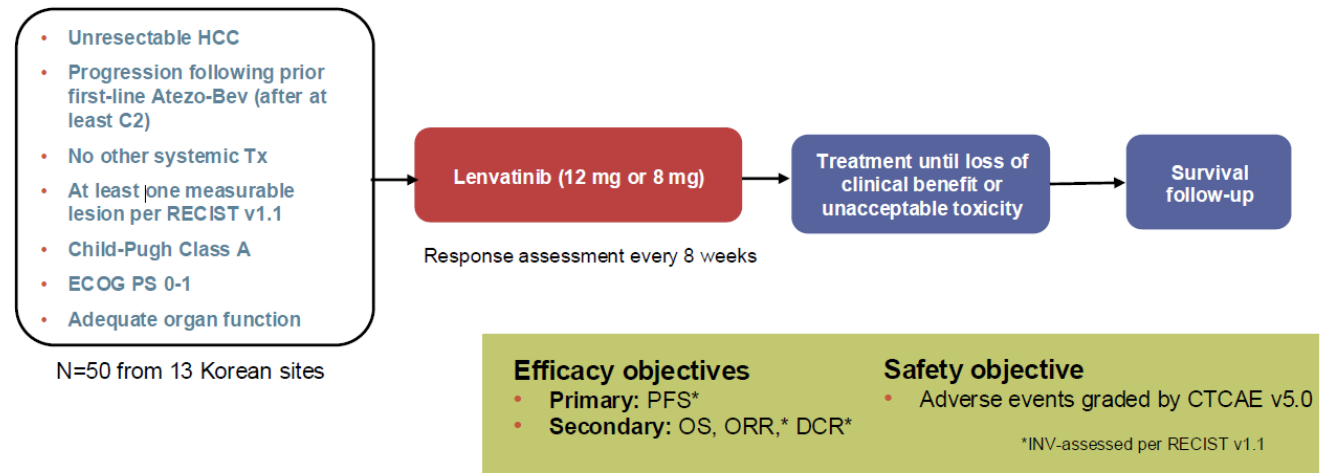


Multicenter phase 2 trial of lenvatinib in patients with advanced hepatocellular carcinoma after progression on first-line atezolizumab plus bevacizumab (KCSG HB23-04)

Changhoon Yoo, Hyung-Don Kim, Hong Jae Chon, Sun Jin Sym, Moonho Kim, Jung Hun Kang, Baek-Yeol Ryoo, Choong-kun Lee, Joohyun Hong, Hyewon Ryu, Woo Kyun Bae, Hyeyeong Kim, Hyunho Kim, Jin Won Kim, Tae-Yong Kim

KCSG HB23-04 Study design

Investigator-initiated multicenter single-arm phase 2 trial (NCT06138769)

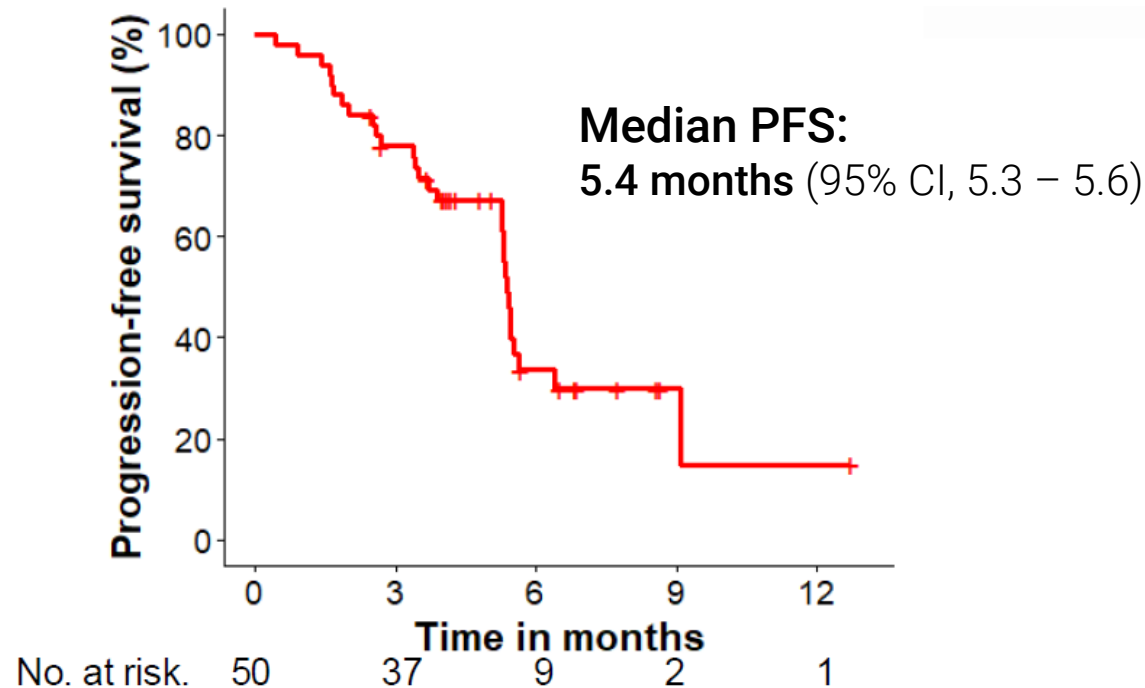


Changhoon Yoo, MD, PhD

Content of this presentation is copyright and responsibility of the author. Permission is required for re-use.

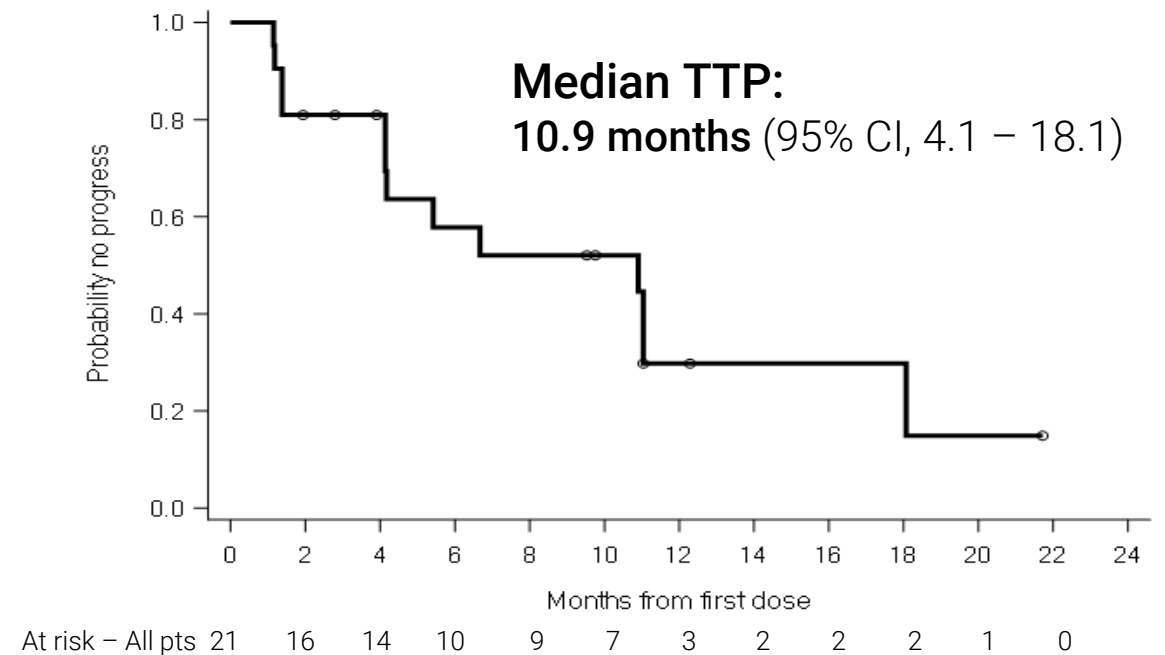
Fostrox + lenvatinib shows substantially longer PFS/TTP

Median PFS – Lenvatinib monotherapy²



Scans performed with 8 weeks interval

Median TTP – Fostrox + Lenvatinib¹



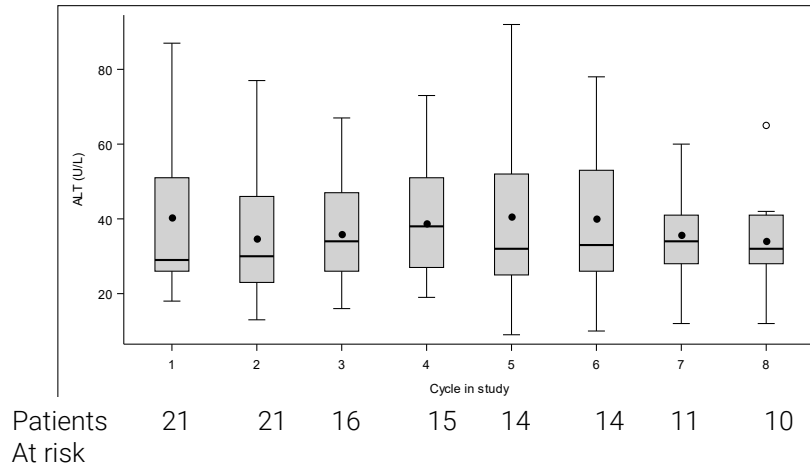
Scans performed with 6 weeks interval

¹Chon et al., ESMO 2024, Poster 986

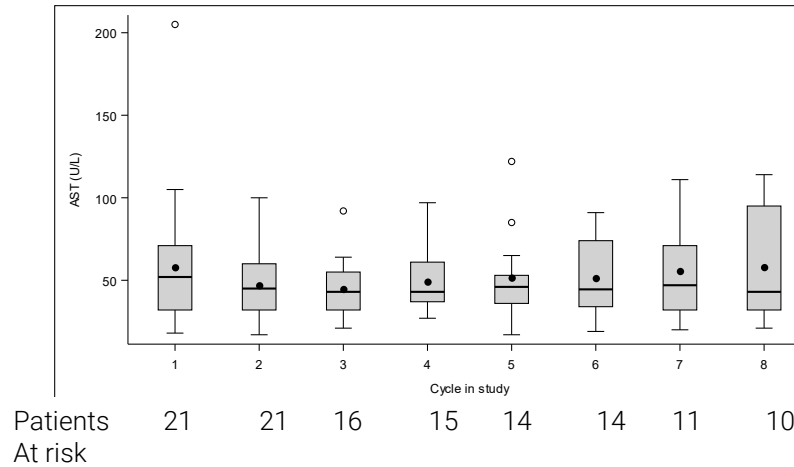
²Yoo et al., ESMO Asia 2024

Stable liver function during treatment with fostrox + Lenvima

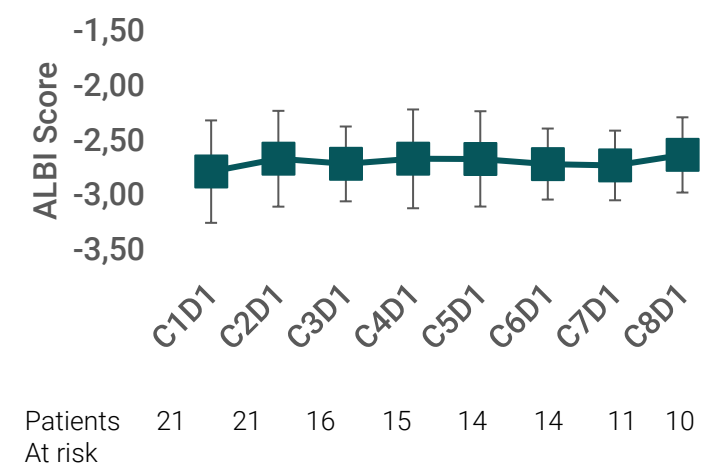
ALT change over duration of treatment



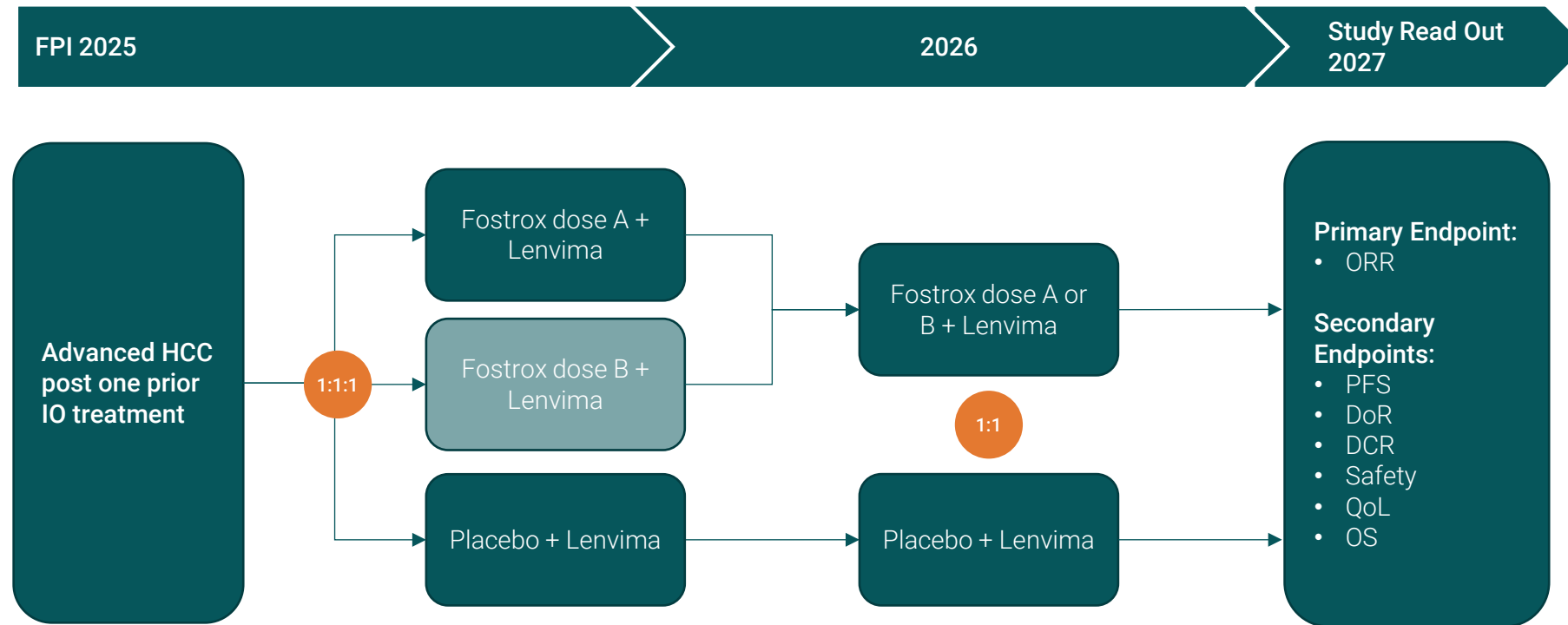
AST change over duration of treatment



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

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 but not approved
- Target population for Fostrox + lenvatinib

90%

Tecentriq + Avastin or
other IO combination

Lenvima or other TKI
monotherapy

10%

Lenvima (or Sorafenib)

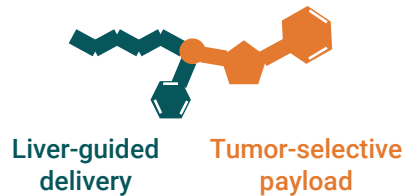
IO combination

Fostrox (fostroxacitabine bralpamide)

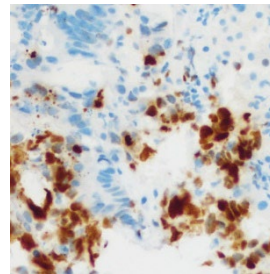
The first oral, liver-targeted treatment tailored for HCC

Selectively kills tumor cells, sparing healthy liver cells³

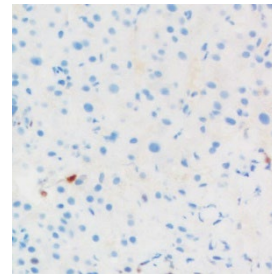
Unique, liver-targeted approach in HCC



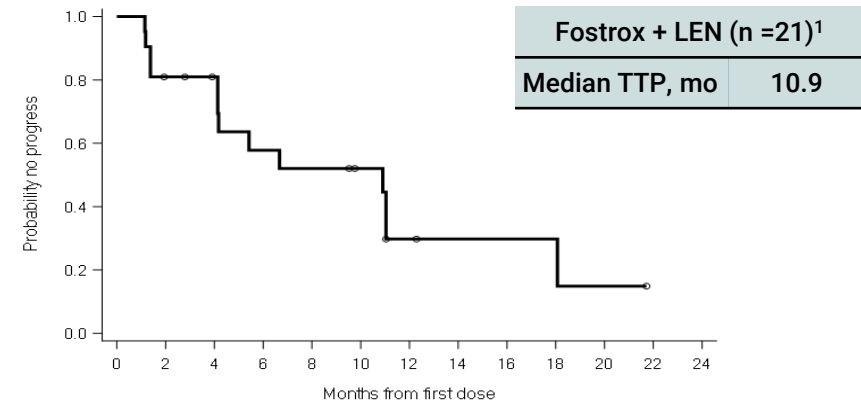
Kills tumor cells



Sparses healthy cells



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



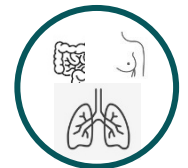
First-to-market opportunity for fostrox + Lenvima



- 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

Thank You!

