

The background of the slide features a complex, glowing molecular structure. It consists of numerous interconnected nodes, represented by small spheres in shades of red, white, and blue, connected by thin, light-colored lines. The overall effect is a dense, three-dimensional network that resembles a chemical or biological molecule, set against a dark blue gradient background.

**Medivir AB**

**Introducing smart, targeted chemotherapy  
for patients with advanced liver cancer (HCC)**

**March 6, 2024**

**Jens Lindberg, CEO**

**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 The Information is not for publication, release or distribution in the United States, Australia, Canada or Japan, or any other jurisdiction in which the distribution or release would be unlawful.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.

# Medivir – Swedish biotech focused on development of innovative treatments for cancer

## Company in brief

Founded	1988
Listed	Nasdaq OMX
Location	Stockholm
FTE	10
Cash position	SEK 169,5M (Q4 23)

### Fostrox

Unique, proprietary clinical asset in phase 1b/2a

- Unique, liver targeted therapy inducing tumor selective cell death in primary liver cancer (HCC) patients
- Promising early & durable clinical benefit in combination with Lenvima in 2<sup>nd</sup> line HCC
- Opportunity for accelerated approval & first-to-market 2027 in target population where no other treatments are approved

### Partnering programs

Potential upside without further investment

- Birinapant, out-licensed to IGM Biosciences, has completed phase 1 dose escalation with aplitabart
- TNG348 (Tango Therapeutics) initiated phase 1 in Jan 2024
- MET-X (Infex Therapeutics), intent to enter phase 1 in 2024

## Pipeline overview

IN-HOUSE PROGRAM – FOSTROX							
PROJECT	DISEASE AREA	PATIENT POPULATION	PRE-CLIN	PH 1	PH 2	PH 3	NEXT EVENTS
Fostrox	HCC	Monotherapy POC	Completed	Ongoing			<ul style="list-style-type: none"> <li>▪ Fostrox + Lenvima data read-out</li> <li>▪ Fostrox + Lenvima ph 2b initiation</li> </ul>
		Fostrox + Lenvima	Completed	Ongoing	Planned		
		Fostrox + Keytruda	Completed				

### PARTNERING PROGRAMS

PROJECT	PARTNER	DISEASE AREA	PRE-CLIN	PH 1	PH 2	PH 3	MAR-KET	POTENTIAL NEXT EVENT(S)
Xerclear	GSK	Herpes	Completed	Ongoing				▪ Reg. in China
Remetino-stat	TBD	CTCL/BCC/ SCC	Completed	Ongoing				▪ Partnering
MIV-711	TBD	Osteoarthritis	Completed	Ongoing				▪ Partnering
Birinapant	IGM	Solid tumors	Completed	Ongoing				▪ Dose expansion
TNG348	Tango	Cancer	Completed	Ongoing				▪ Phase I start
USP-7	Ubiquigent	Cancer	Completed					▪ Partnering
MET-X	INFEX	Infection	Completed	Ongoing				▪ Phase I start

Completed

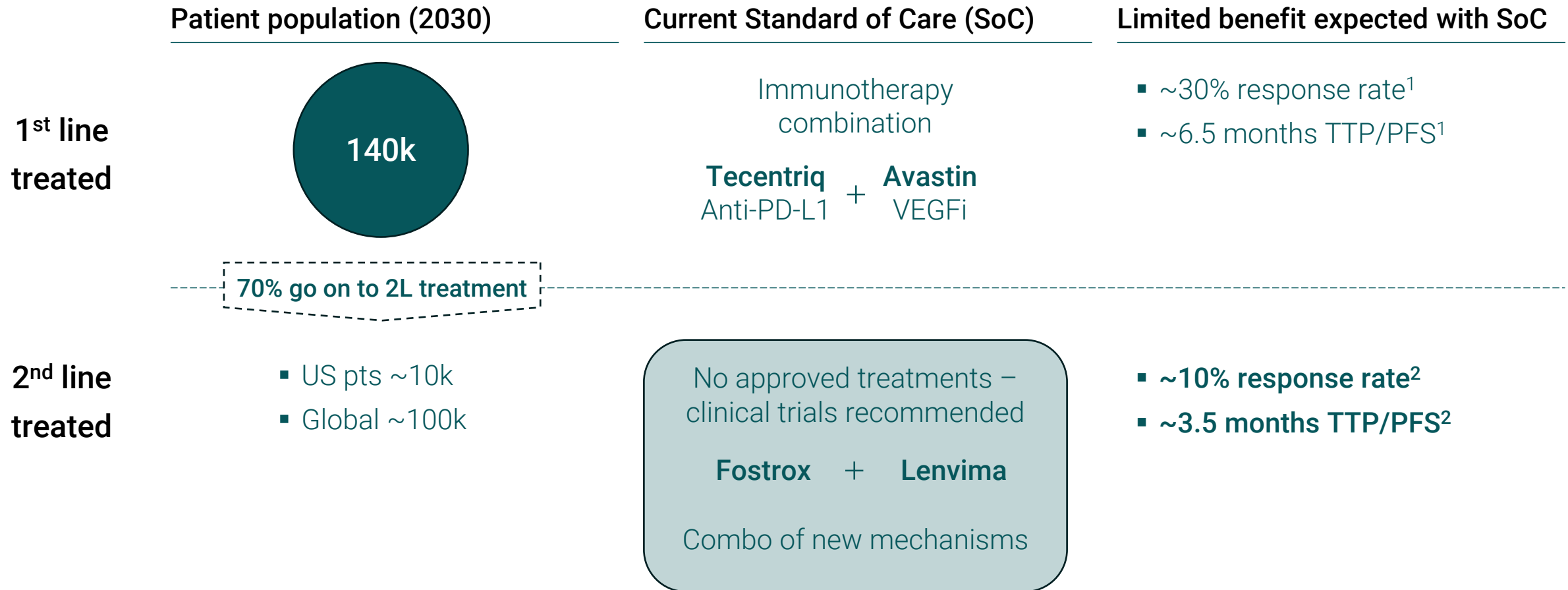
Ongoing

Planned

MEDIVIR

# Primary Liver Cancer (HCC)

## 2L – fast-to-market strategy in underserved population



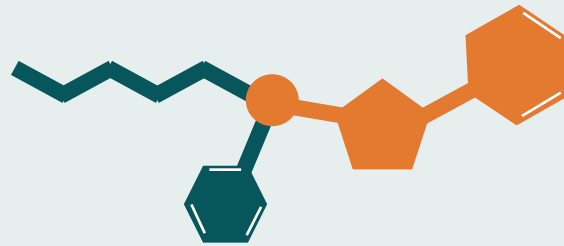
<sup>1</sup> Finn et al., N Engl J Med 2020; 382:1894-1905

<sup>2</sup> Based on previous 2<sup>nd</sup> line HCC studies with kinase inhibitors

<sup>3</sup> Global Data 2021, population estimate 2030

# Fostrox – smart, liver targeted chemotherapy

Pro-drug tail for organ-specific targeting



Toxin to induce tumor-selective cell death

1. Oral administration
2. Targeted (>100-fold) liver exposure vs IV chemotherapy<sup>1</sup>
3. Selective DNA damage and cell death in tumor cells<sup>2</sup>

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

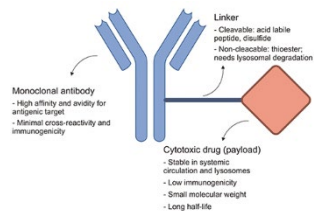
<sup>2</sup>Öberg F. et al, EASL PO-221, 2022

# 2 different approaches to smart, targeted chemotherapy

Selectively delivering chemotherapy to cancer cells while minimizing damage to healthy cells

## Antigen-specific targeting

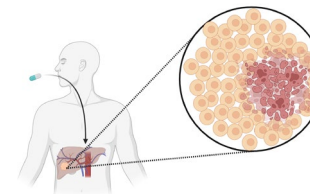
### ADC



- For cancers with high expression of target antigen selectively on tumor cells
- Breast (HER2)

## Organ-specific targeting

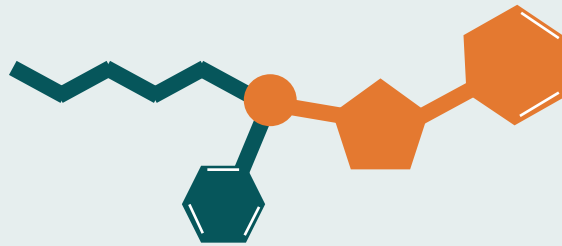
### Fostrox



- For heterogenous cancers without specific target antigen on select tumor cells
- Liver

# But how does it work?

Pro-drug tail for organ-specific targeting



Toxin to induce tumor-selective cell death

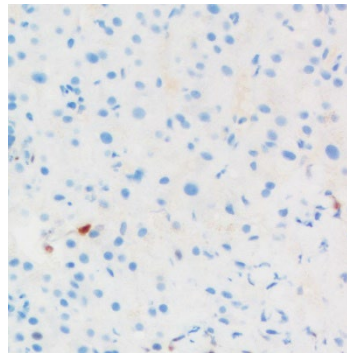
1. Tablet swallowed & molecule travels via portal vein to the liver
2. Pro-drug tail cleaved of & toxin is rapidly activated
3. Toxin starts killing cancer cells in the liver, sparing healthy cells

# Fostrox – Patient biopsies confirming selective DNA damage & cell death in tumor cells while sparing normal liver tissue

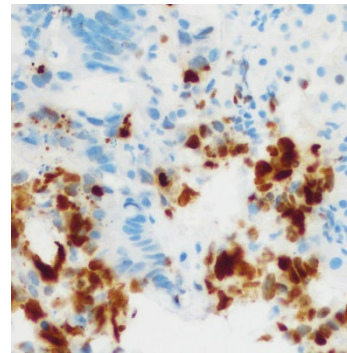
Tumor selective induction of DNA-damage<sup>1</sup>

Cytotoxic in tumor tissue but not in normal liver tissue<sup>2</sup>

Normal liver tissue

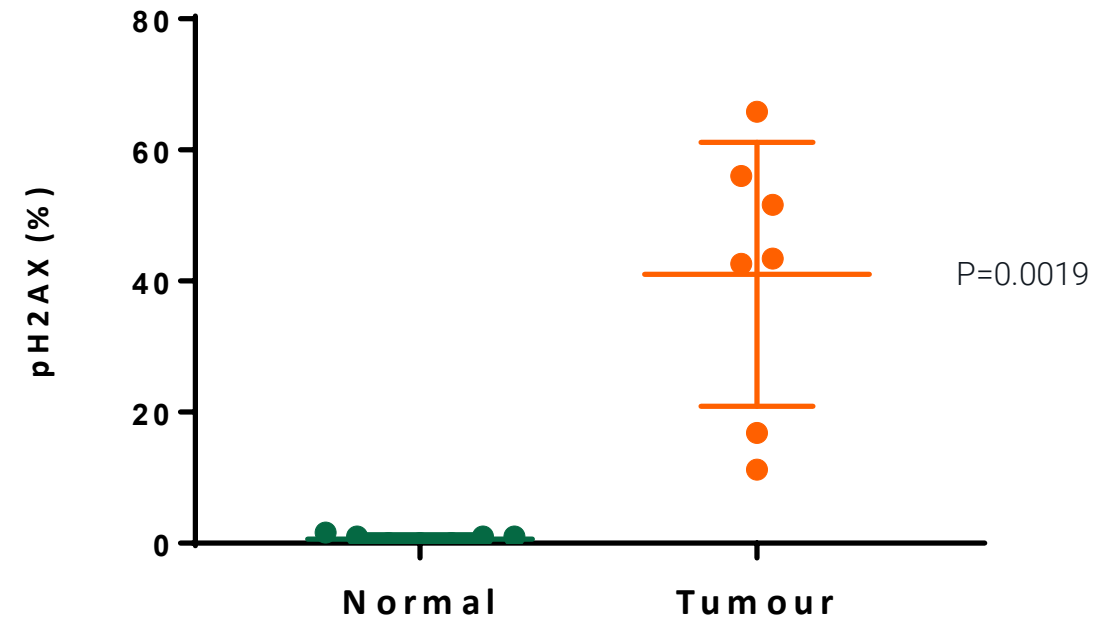


Tumor tissue



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

DNA-damage in normal liver vs tumour



<sup>1</sup>Evans et al ASCO GI, 2021

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

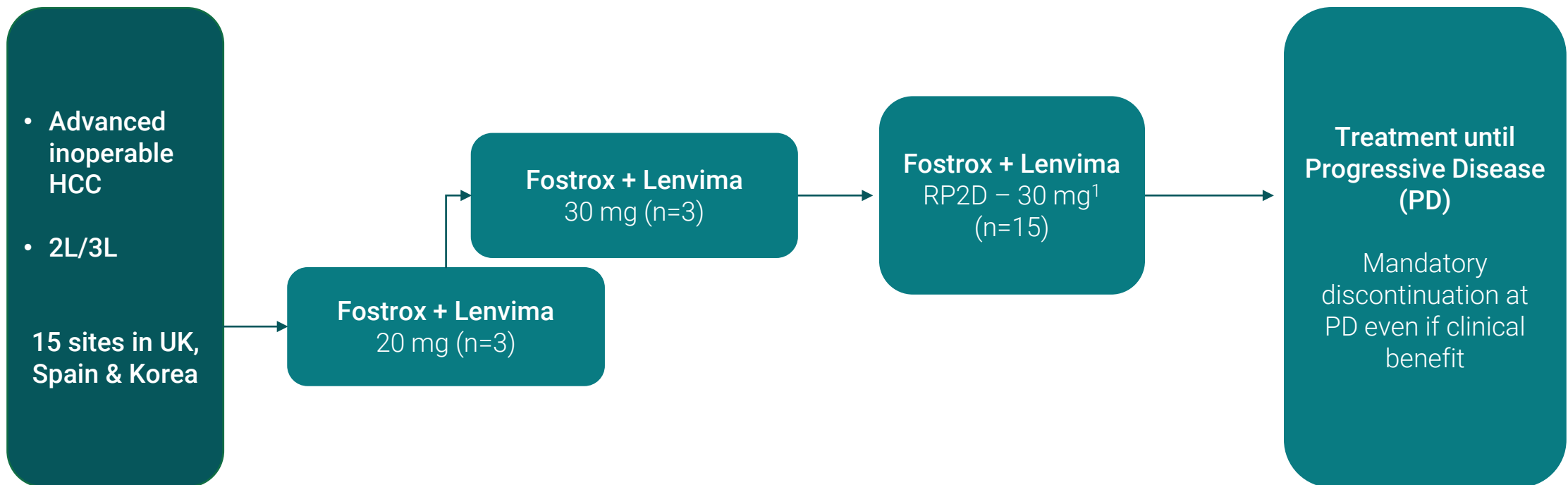


# Fostrox

*a novel combination partner in HCC with promising clinical benefit & safety profile in high unmet need population*

# Phase 1b/2a study fully recruited with >40% of patients still on treatment

Fostrox + Lenvima phase 1b/2a dose expansion study – 21 patients in total



# Generous inclusion criteria

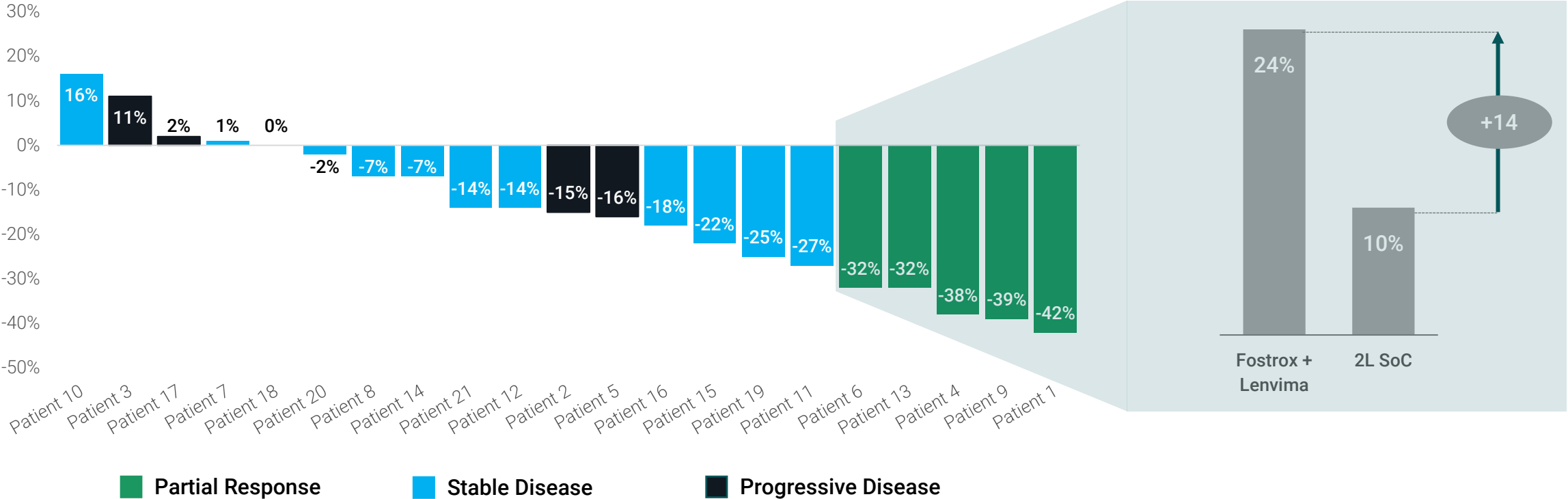
- Third line patients (19%) included
- High share of extrahepatic metastasis (67%)
- Macrovascular invasion all grades allowed
- All patients had tumor progression on prior treatment

Patient Characteristics	N = 21
Mean age (range)	62 y (42 - 82)
Gender, Female / Male (%)	24 / 76
ECOG Performance Status 0/1 (%)	71 / 29
Viral/Non-viral (%)	76 / 24
Extra hepatic lesion Y/N (%)	67 / 33
Prior treatment lines; 2L/3L (%)	81 / 19
Prior Tecentriq/Avastin 1L (%)	86

# Objective response (ORR) reported in 24% of the patients<sup>3</sup>, comparing favorably with 2L HCC SoC benchmark<sup>1,2</sup>

Best percentage change in target lesion size, local review RECIST 1.1

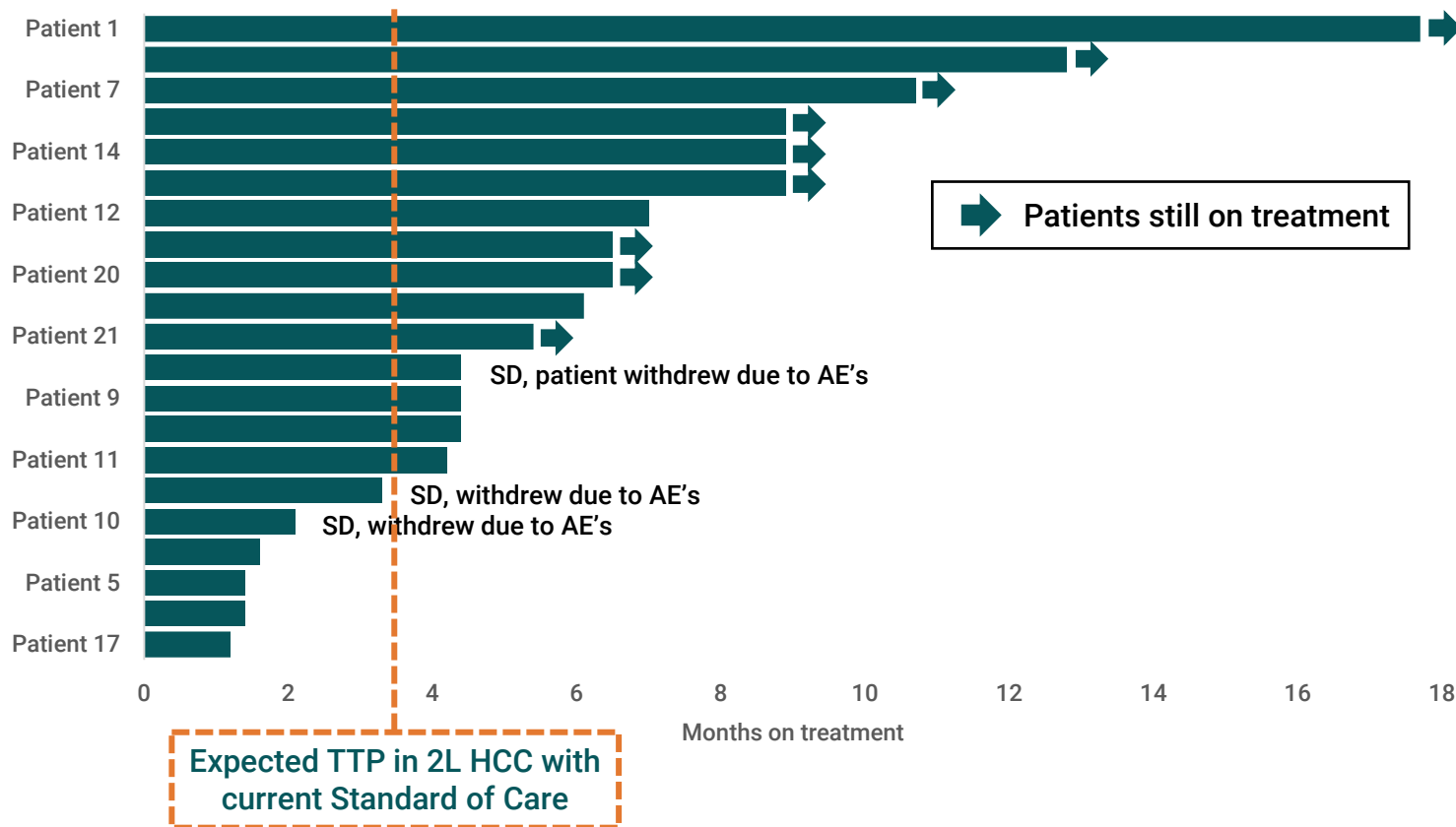
2L ORR benchmark (%)



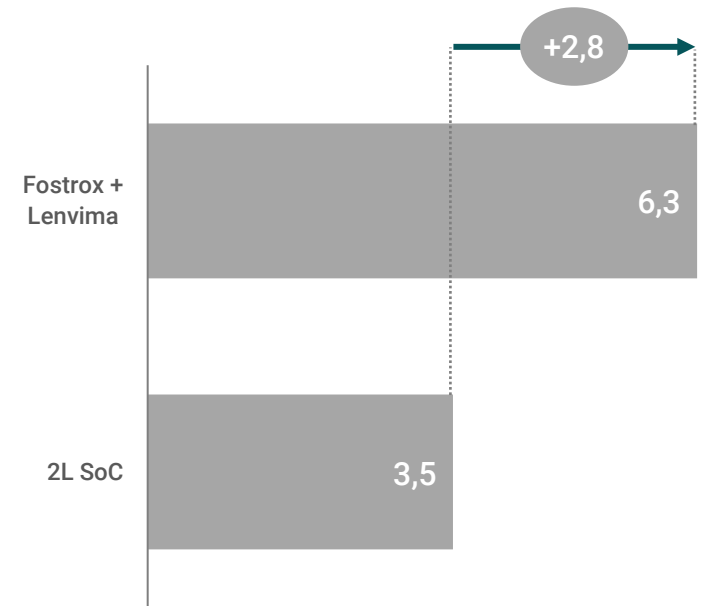
<sup>1</sup>Data from previous 2L phase 3 HCC studies with Stivarga, Cyramza & Cabometyx  
<sup>2</sup>Kobayashi et al., Clinical Cancer Research, Oct 5, 2023 online  
<sup>3</sup>Local review (All 21 patients data cut-off February 14, 2024)

# Promising median time to progression (TTP) of 6.3 months<sup>3</sup>, >40% of patients still on treatment

Local review, time to progression RECIST 1.1



2L median TTP/PFS benchmark (months)<sup>1,2</sup>



<sup>1</sup>Data from previous 2L phase 3 HCC studies with Stivarga, Cyramza & Cabometyx

<sup>2</sup>Kobayashi et al., Clinical Cancer Research, Oct 5, 2023 online

<sup>3</sup>Local review (All 21 patients data cut-off February 14, 2024, >40% of patients still on treatment)

# Long duration of benefit seen in patients with limited effect on prior treatment, updated median TTP 6.3 months\*



\*TTP – Time to Progression, data cut-off February 14, 2024

# Fostrox + Lenvima showed a good safety and tolerability profile enabling patients to stay on treatment long-term

- No new, unexpected safety events
- Fostrox related side effects were mainly haematological and temporary with 70% of patients staying on the full dose
- Lenvima tolerability not affected by fostrox
- Lenvima dose modification/ discontinuation in line with monotherapy

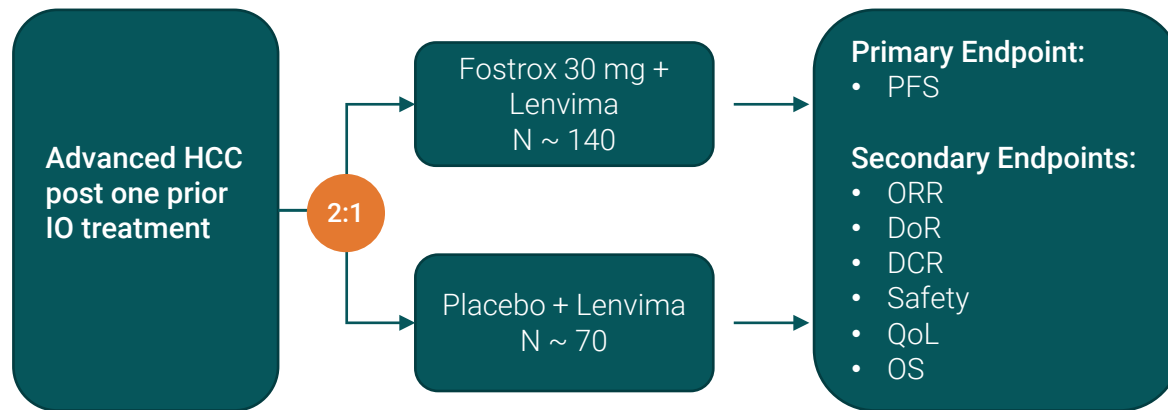
	Lenvima monotherapy <sup>1</sup>	Fostrox + Lenvima <sup>2</sup>
Fostrox dose modification	-	29%
Fostrox discontinuation	-	5%
Lenvima dose modification	62%	57%
Lenvima discontinuation	20%	10%

<sup>1</sup>REFLECT study in 1L advanced HCC, lenvatinib vs sorafenib

<sup>2</sup>Data cut-off February 14, 2024, >40% of patients still on treatment

# Next step pivotal phase 2b; randomized design with PFS as primary endpoint to enable accelerated approval 27/28

Phase 2b: planned, randomized, double-blind study design



## Key factors supporting accelerated approval process

- ✓ Strong KOL support for proposed 2L phase 2b study
- ✓ Serious, orphan disease with high unmet medical need
- ✓ Appropriate patient safety database
- ✓ Study design to be confirmed in FDA interactions

- Enrolment 18 months
- Planning for 7 initial countries (SK, UK, ES, DE, PL, JP, US)



# Second line market worth more than \$2.5bn annually by 2030

## Patient population (2030)

## Key treatment assumptions

## Total market potential in 2L

2<sup>nd</sup> line  
treated

**100k**  
patients

- Treatment duration
  - ~6-7 months
- Cost of therapy
  - ~3-10.000/month

**~\$2.5bn**  
by 2030 & growing

<sup>1</sup> Finn et al., N Engl J Med 2020; 382:1894-1905

<sup>2</sup> Based on previous 2<sup>nd</sup> line HCC studies with kinase inhibitors

<sup>3</sup> Global Data 2021, population estimate 2030

# Making good progress in preparing for pivotal phase 2b

## Phase 2b: acceleration activities underway to enable initiation 24/25

---

- Q4 23 – Capital raise to enable acceleration of activities to prepare for phase 2b
- Q4 23 – Formulation & process development for commercial manufacture
- Q1 24 – Scientific Advisory Council & extensive KOL engagement ahead of FDA interactions
- H1 24 – FDA Type C engagement to confirm study design and file for IND & fast track designation
- H1 24 – CRO selection & initiate study feasibility

## Key steps moving towards 2025

---

1. Confirm study design with FDA for accelerated approval study
2. Establish development & commercialization partnership with focus on Asia
3. Finalise details for phase 2b

# Fostrox – Potential to transform 2<sup>nd</sup> line HCC



A smart, liver-targeted chemotherapy that selectively kills liver cancer cells, while sparing healthy cells



Fostrox + Lenvima outperforming Standard of Care benchmark in 2L HCC; data keeps improving as >40% of patients are still on treatment



Fast-to-market opportunity with lead indication in highly underserved population; market potential >\$2.5bn

**Thank You!**