

Medivir Q1 REPORT 2025

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

**MEDIVIR**

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An anatomical illustration of a human torso, focusing on the abdominal cavity. The liver is highlighted in a vibrant red and orange glow, with a prominent, bright yellow, multi-lobed tumor mass visible on its surface. The surrounding organs, including the lungs, stomach, and intestines, are depicted in a semi-transparent blue, allowing the liver and tumor to stand out as the central focus of the image.

## Q1 Highlights



Final phase 1b/2a data presented at EASL Liver Cancer Summit



European patent for fostrox + lenvatinib approved, providing protection until 2041 as preparations for phase 2b study FOcuS-2 continues



Infex Therapeutics signs licensing agreement for MET-X development in India

# Today's presenters



**CEO**  
**Jens Lindberg**



**CMO**  
**Pia Baumann**



**CFO**  
**Magnus Christensen**

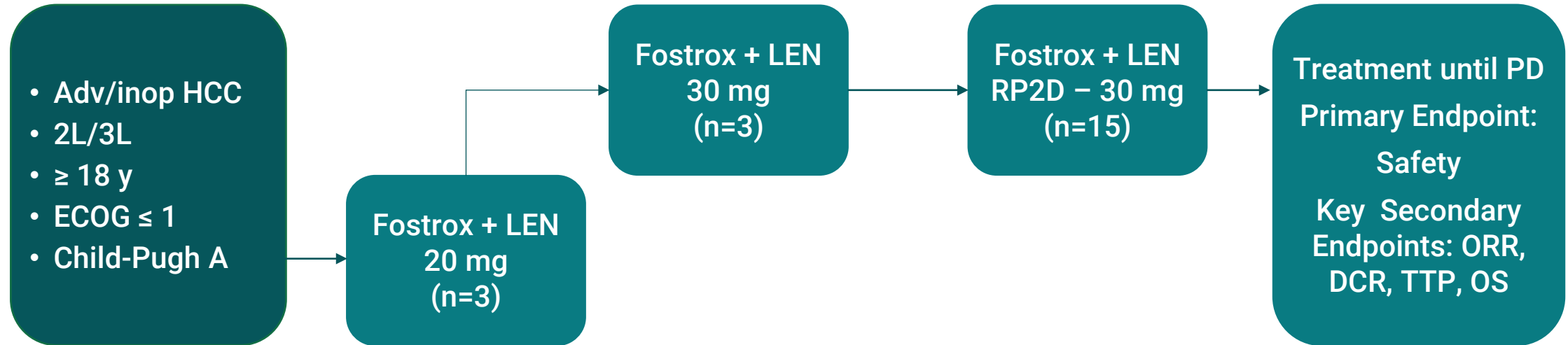


**CSO**  
**Fredrik Öberg**



# Final results from phase 1b/2a study of fostrox + Lenvima<sup>®</sup> presented at EASL Liver Cancer Summit

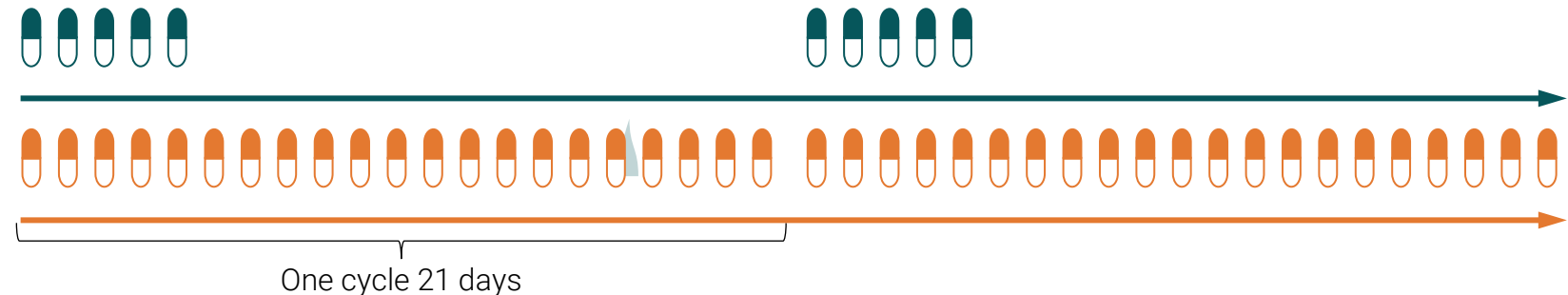
# Global phase 1b/2a study with fostrox + Lenvima



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

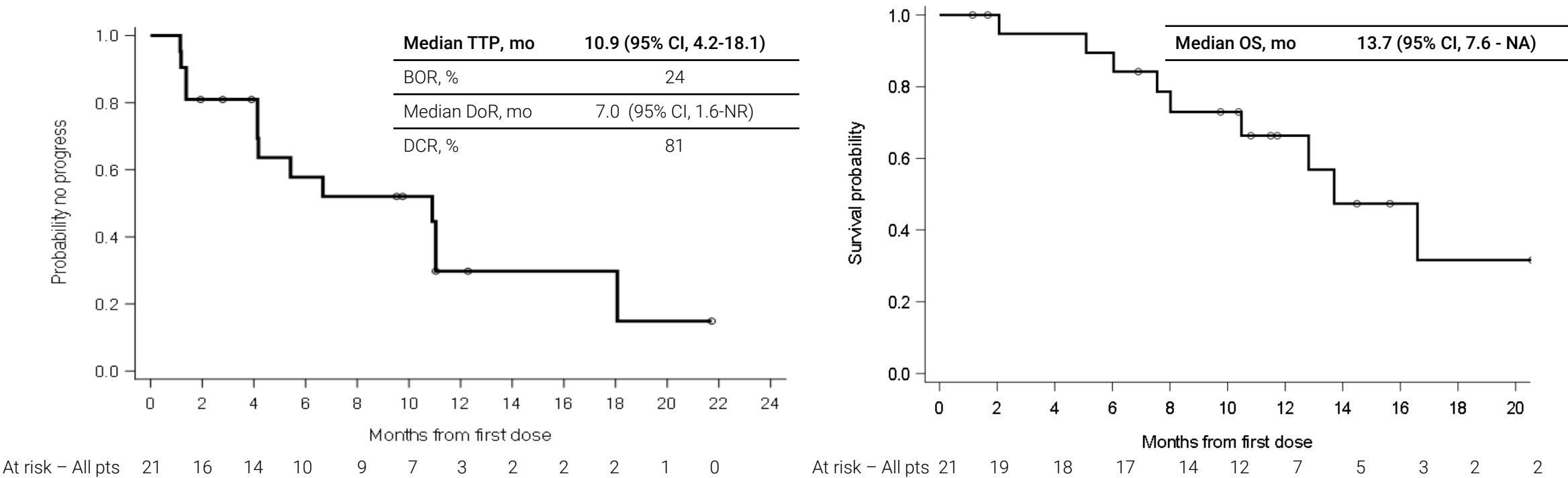
**Fostrox:** Oral QD  
5 days in 21-day cycles

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



# Fostrox + Lenvima shows longer median TTP and OS than previously seen in second-line HCC<sup>1</sup>

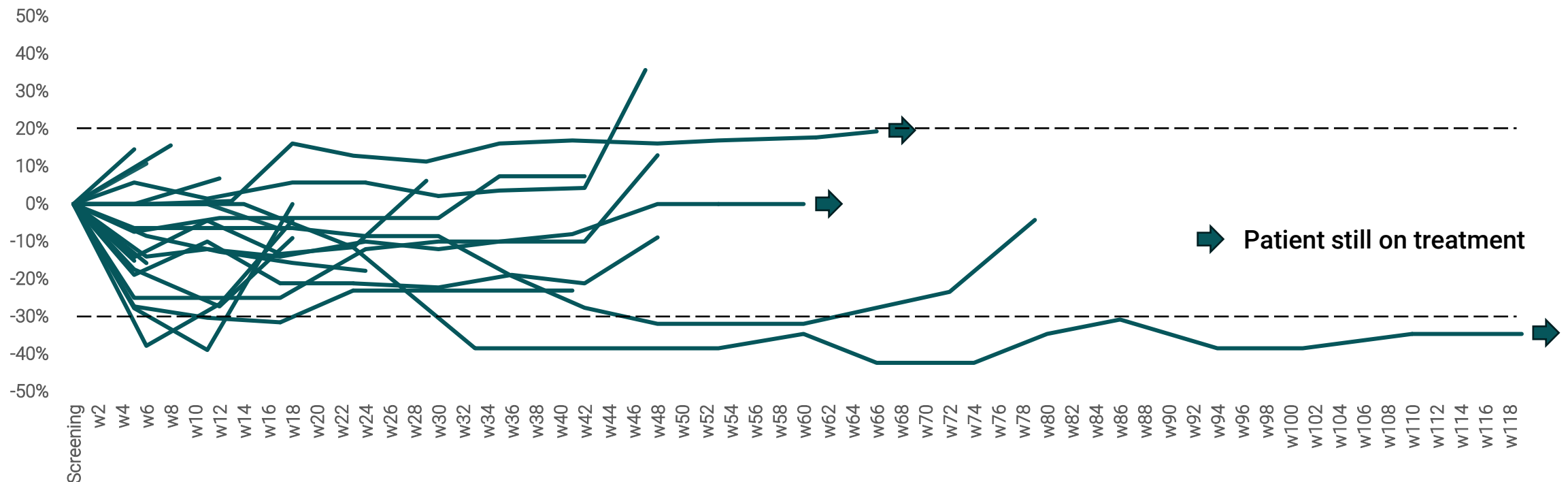
Median TTP & OS with fostrox + LEN – investigator review, RECISTv1.1



<sup>1</sup>Evans et al., EASL Liver Cancer Summit 2025, P02-13.

# Target lesion tumor reduction was seen in >75% of patients and median duration of clinical benefit was 11.3 months

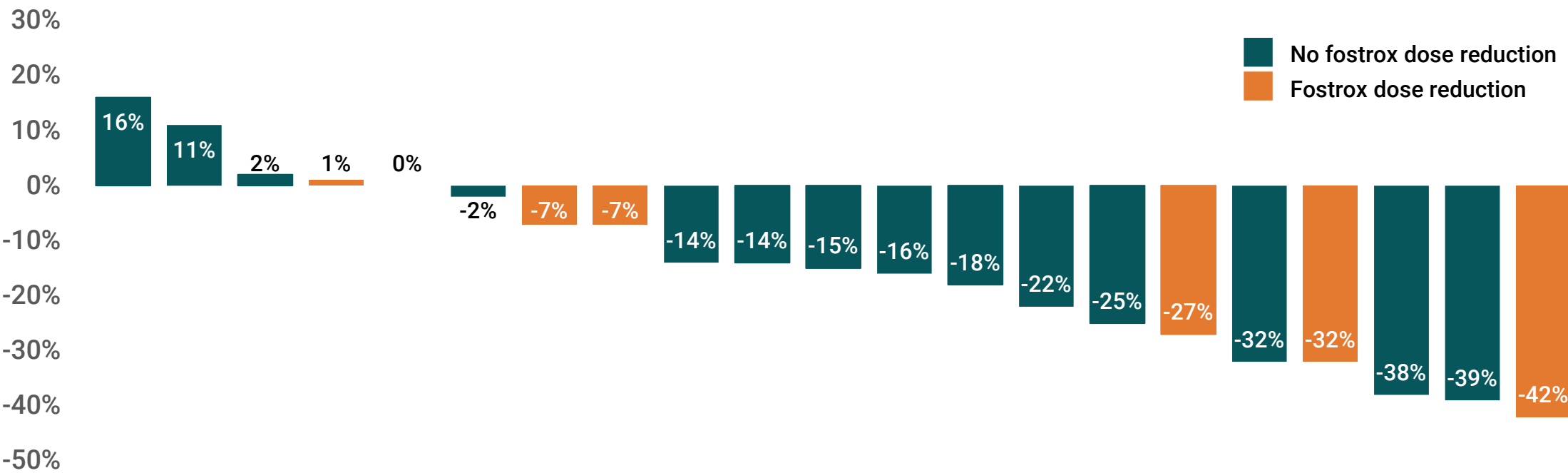
Percentage change in total target lesion size over time – investigator review, RECISTv1.1





# Fostrox dose reduction, required in 29% of patients, didn't impact response to treatment

Best % change in target lesion size related to fostrox dose reduction – investigator review, RECISTv1.1



<sup>1</sup>Evans et al., EASL Liver Cancer Summit 2025, P02-13.

# Key patent approval in Europe for fostrox + Lenvima extending protection until 2041

Medivir receives European patent for fostrox plus lenvatinib in treatment of hepatocellular carcinoma (HCC) and cancer metastases in the liver

2025-03-19

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative treatments for cancer in areas of high unmet medical need, announces today that the European patent authority has granted the company's patent application covering claims for the combination of fostroxacitabine bralpamide (fostrox) with lenvatinib (Lenvima) for the treatment of hepatocellular carcinoma and cancer metastases to the liver. The patent provides protection and market exclusivity until April 2041.



Covers the combination of fostrox + Lenvima for the treatment of HCC and metastases to the liver

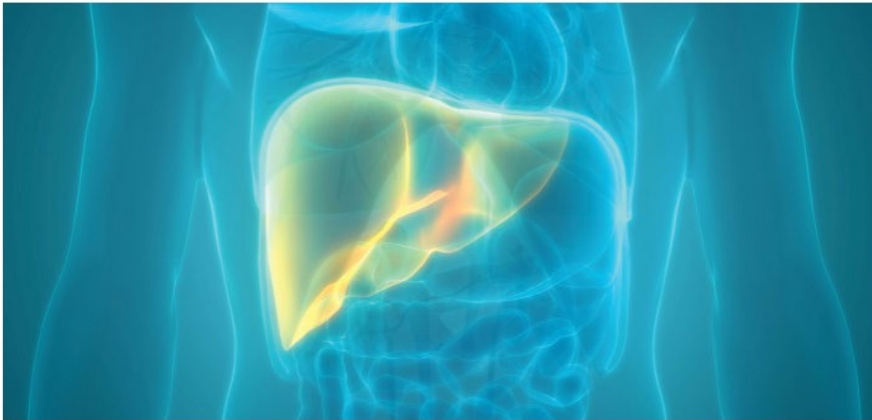
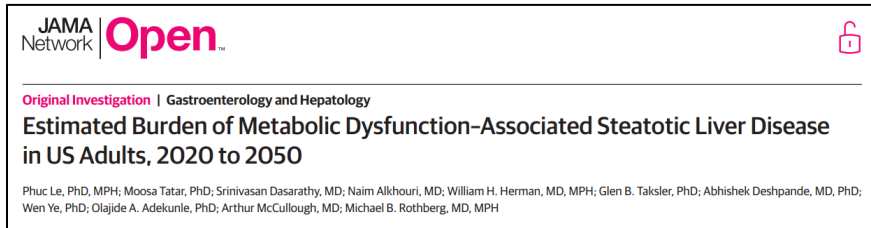


European patent authority approval indicates likelihood of other key regions to follow



Generates critical extension of patent protection until 2041

# Growth in Fatty Liver Disease expected to drive an alarming increase in liver cancer cases<sup>1</sup>



SCIENCE NEWS

## Fatty Liver Disease Is Expected to Skyrocket By 2050

A model predicts the rise in MASLD and MASH will drive an alarming increase in liver failure, liver cancer and liver transplants.



Fatty Liver Disease (MASLD/MASH) expected to rise dramatically over the next 30 years

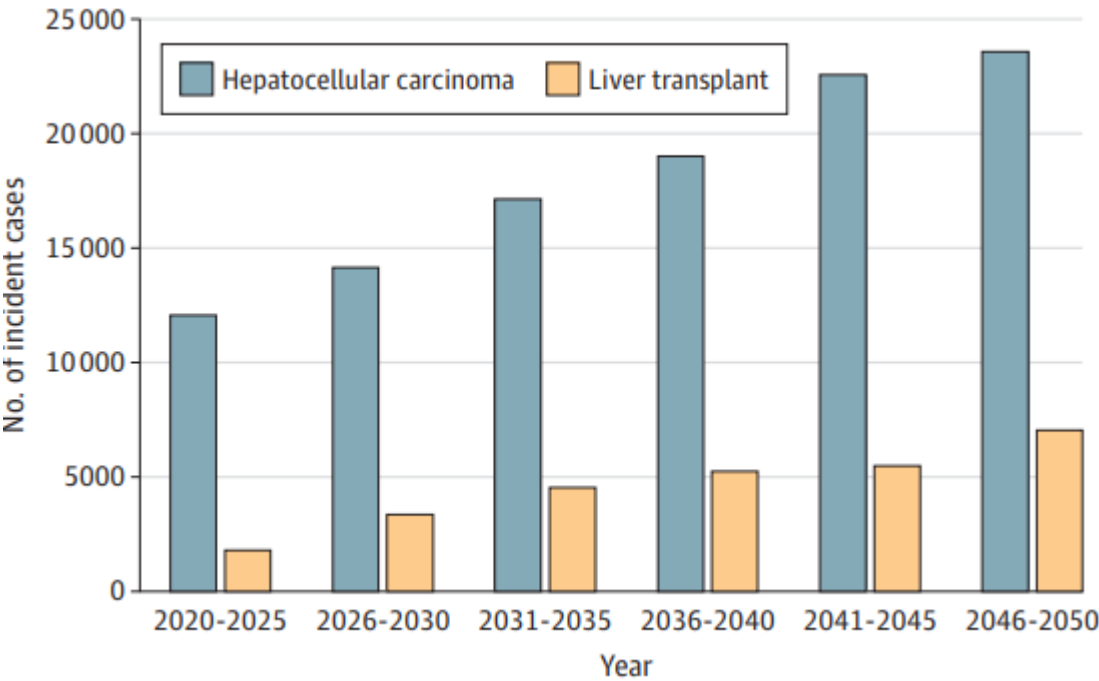
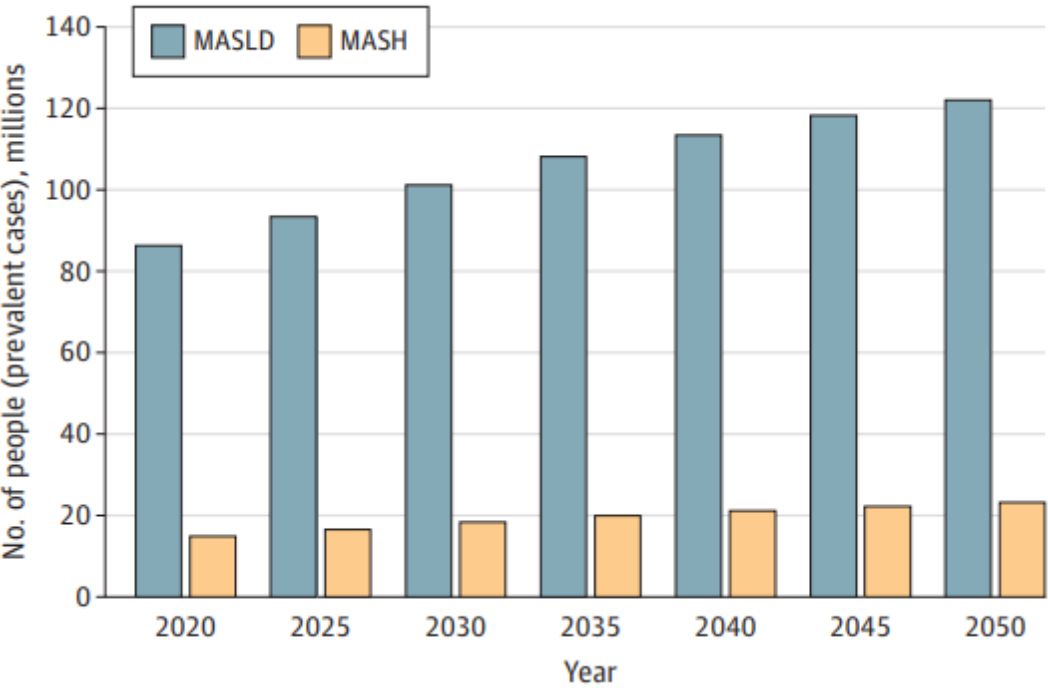


The number of newly diagnosed liver cancer patients each year is expected to double



HCC market growth further spurred by more and better treatments enabling patients to be treated longer

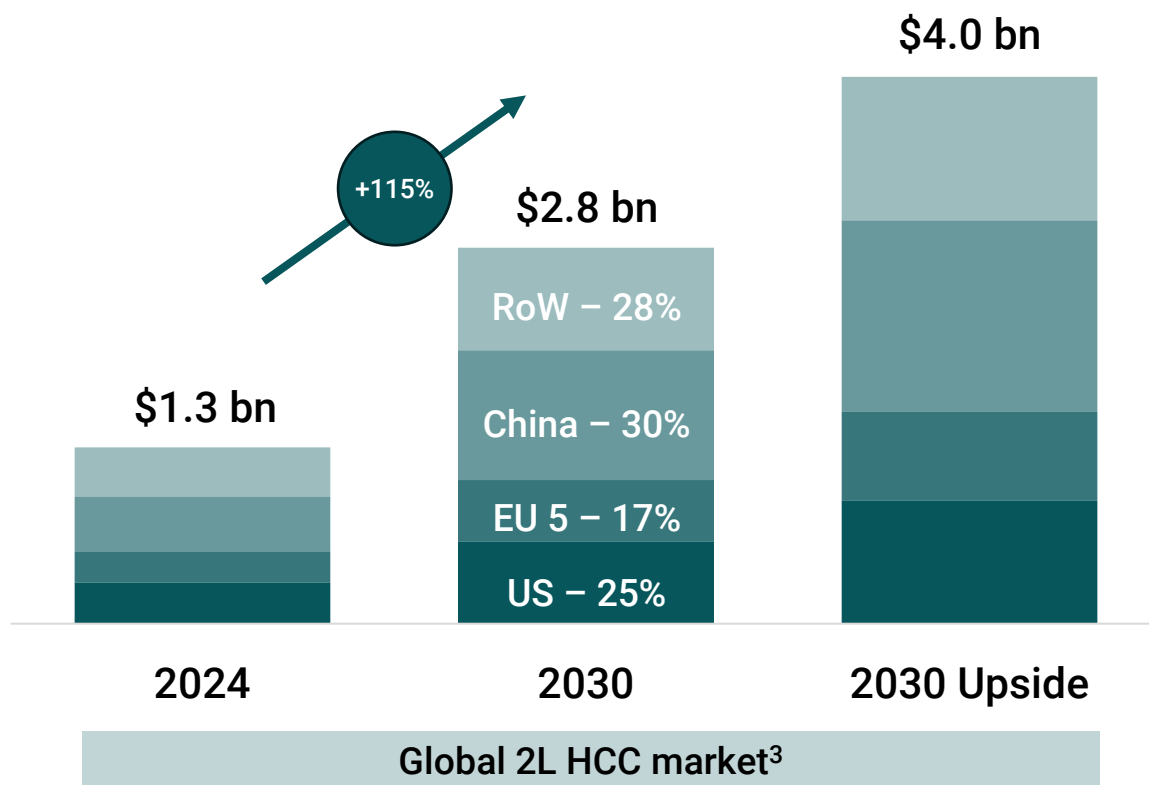
# Growth in Fatty Liver Disease expected to drive an alarming increase in liver cancer cases<sup>1</sup>



<sup>1</sup>JAMA Network Open. 2025;8(1):e2454707



## 2<sup>nd</sup> 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<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

# Infex Therapeutics signs licensing agreement for MET-X development in India



## Infex signs exclusive license agreement with Venus Remedies Ltd to advance MET-X through clinical development and commercialisation in India

February 25, 2025

Infex Therapeutics, a leading anti-infectives specialist, announces that it has signed an exclusive license agreement for the Indian market with Venus Remedies Ltd, an Indian pharmaceutical company,...

Press Releases, Breaking News, Pipeline



- Venus Remedies to conduct phase I trial for MET-X with healthy volunteers in India followed by phase II/III trial of MET-X, subject to successful phase 1
- Infex to receive upfront license fee payments, near-term milestones and tiered double-digit royalty payments on net sales of MET-X in India
- Medivir is entitled to a share of potential future revenue

# Financial highlights Q1

# Financial summary Q1, 2025

## Consolidated Income Statement, summary (SEK m)

	Q1		Full year
	2025	2024	2024
Net turnover	0.6	0.5	3.5
Other operating income	0.2	0.1	1.0
<b>Total income</b>	<b>0.8</b>	<b>0.6</b>	<b>4.5</b>
Other external expenses	-6.1	-20.7	-101.3
Personnel costs	-7.0	-6.5	-27.2
Depreciations and write-downs	-0.7	-0.7	-2.7
Other operating expenses	-0.4	-0.1	-0.6
<b>Operating profit/loss</b>	<b>-13.3</b>	<b>-27.4</b>	<b>-127.3</b>
Net financial items	0.1	1.3	4.0
<b>Profit/loss after financial items</b>	<b>-13.3</b>	<b>-26.1</b>	<b>-123.3</b>
Tax	-	-	-
<b>Net profit/loss for the period</b>	<b>-13.3</b>	<b>-26.1</b>	<b>-123.3</b>

- Net turnover for Q1 was SEK 0.6 million
- Operating loss for Q1 was SEK -13.3 million
- Cash flow from operating activities for Q1 was SEK -26.8 million
- Cash balance end of Q1 was SEK 35.1 million



The background is a deep purple with a bokeh effect of out-of-focus light circles. Numerous thin, white, fiber-optic-like lines radiate from a central point, creating a starburst or explosion effect.

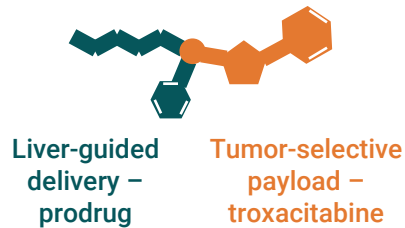
Q/A

# Fostrox (fostroxacitabine bralpamide)

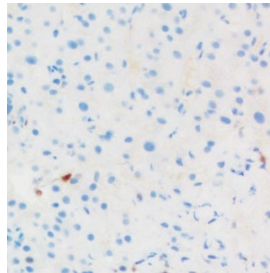
## The first oral, liver-targeted treatment tailored for HCC

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

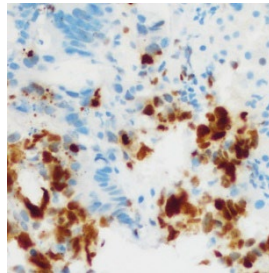
Unique, liver-targeted approach in HCC



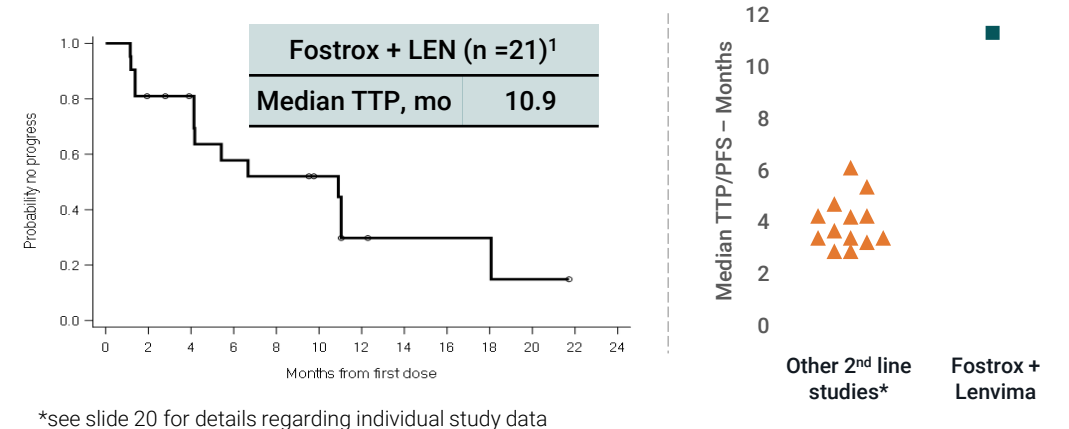
No DNA damage in healthy liver tissue



DNA damage in tumor tissue



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



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

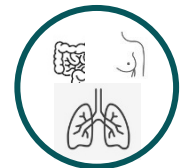


- No 2<sup>nd</sup> line treatments approved in advanced HCC
- Global phase 2b start '25
- Designed to enable breakthrough designation and support accelerated approval process

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

The background is a deep purple with a bokeh effect of out-of-focus light circles. Numerous thin, white, curved lines radiate from the center, creating a sense of motion and depth.

# Thank You!