

Medivir Q1 REPORT 2025

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

MEDIVIR

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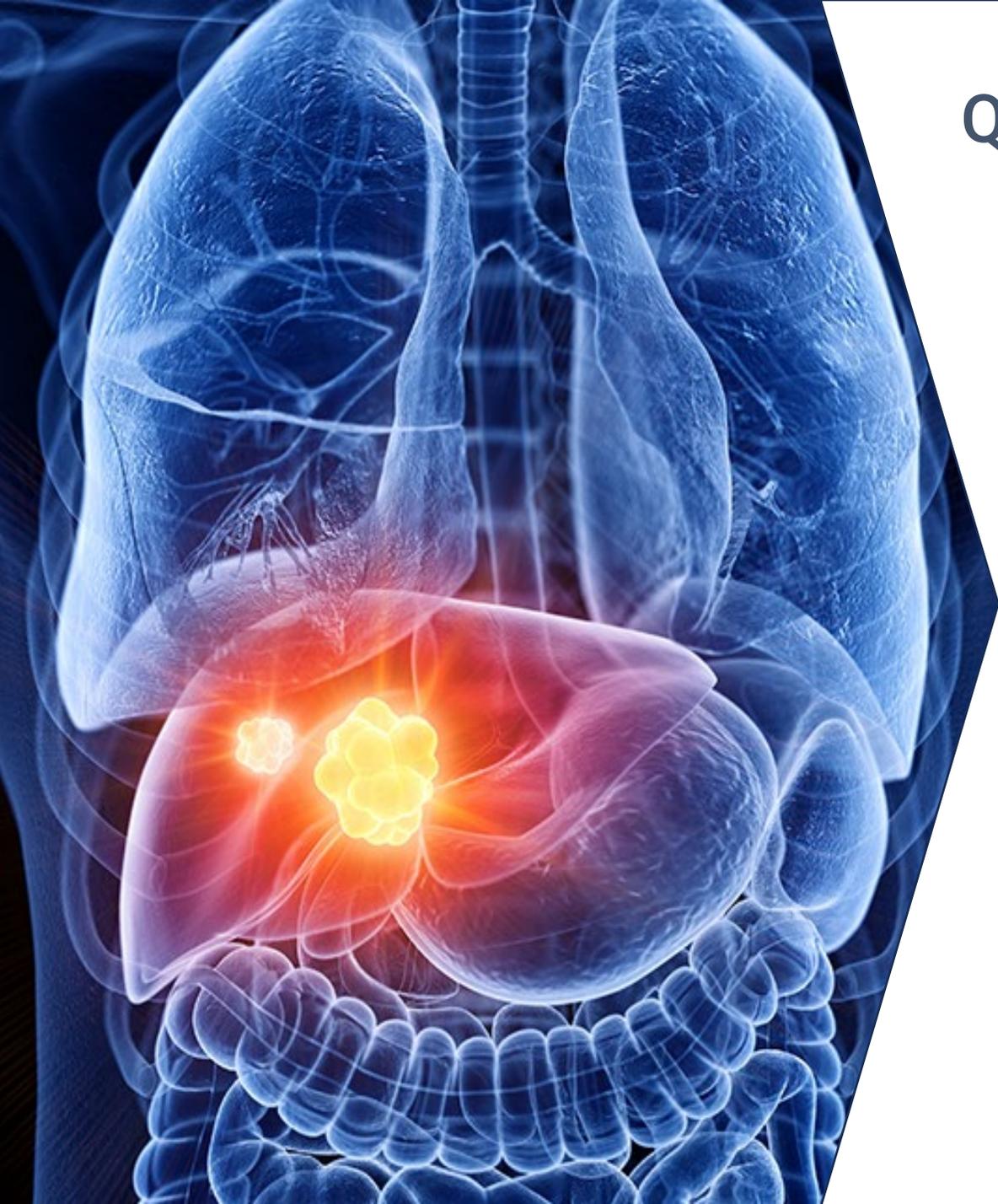
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Q1 Highlights



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

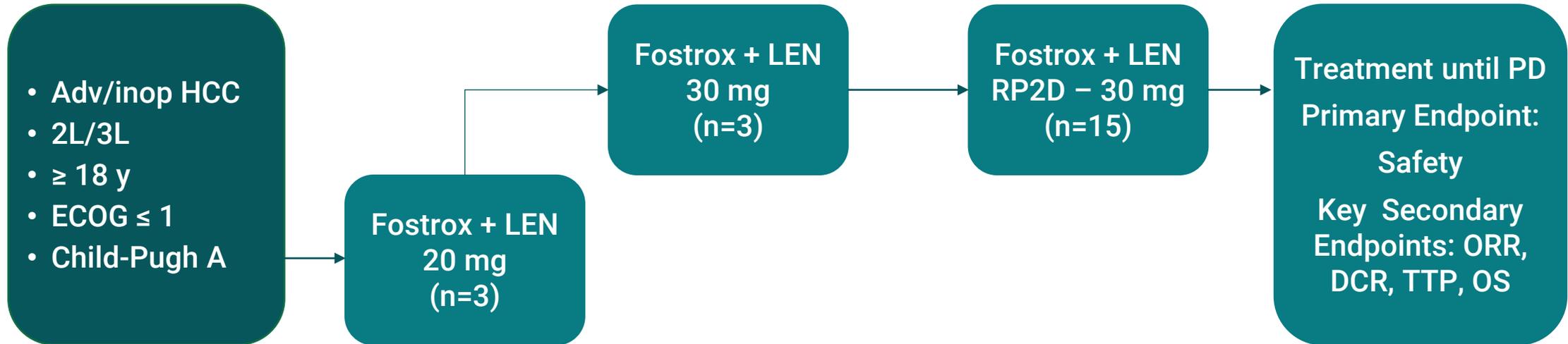


CSO
Fredrik Öberg

Final results from phase 1b/2a study of fostrox + Lenvima[®] 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



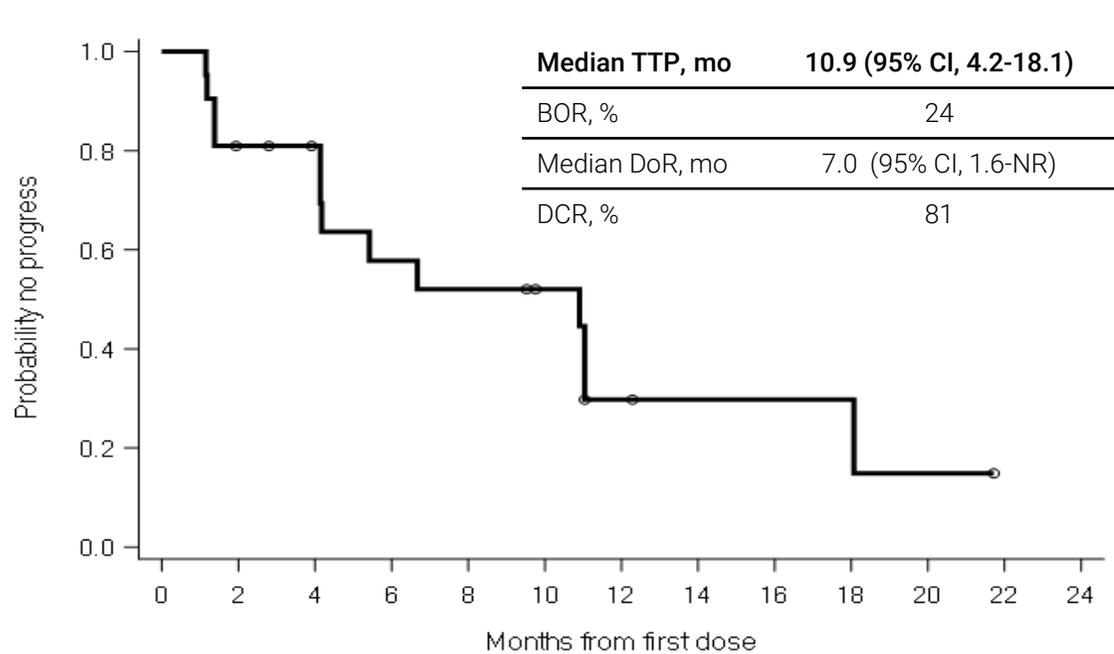
LEN: Oral QD continuous
(8 or 12 mg)



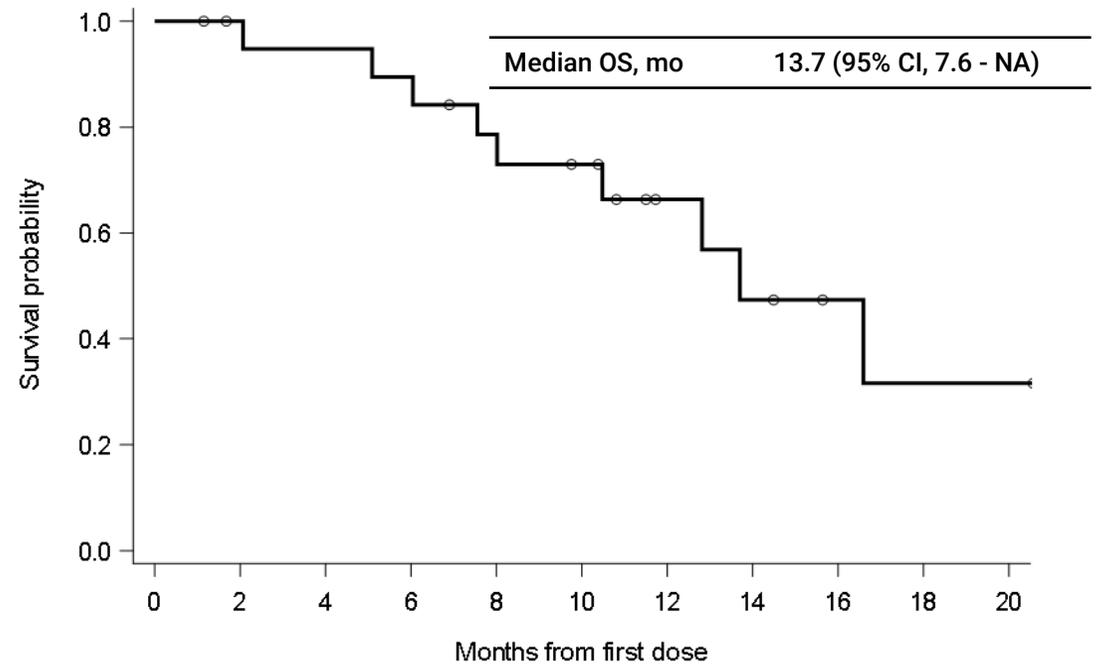
One cycle 21 days

Fostrox + Lenvima shows longer median TTP and OS than previously seen in second-line HCC¹

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



At risk – All pts 21 16 14 10 9 7 3 2 2 2 1 0

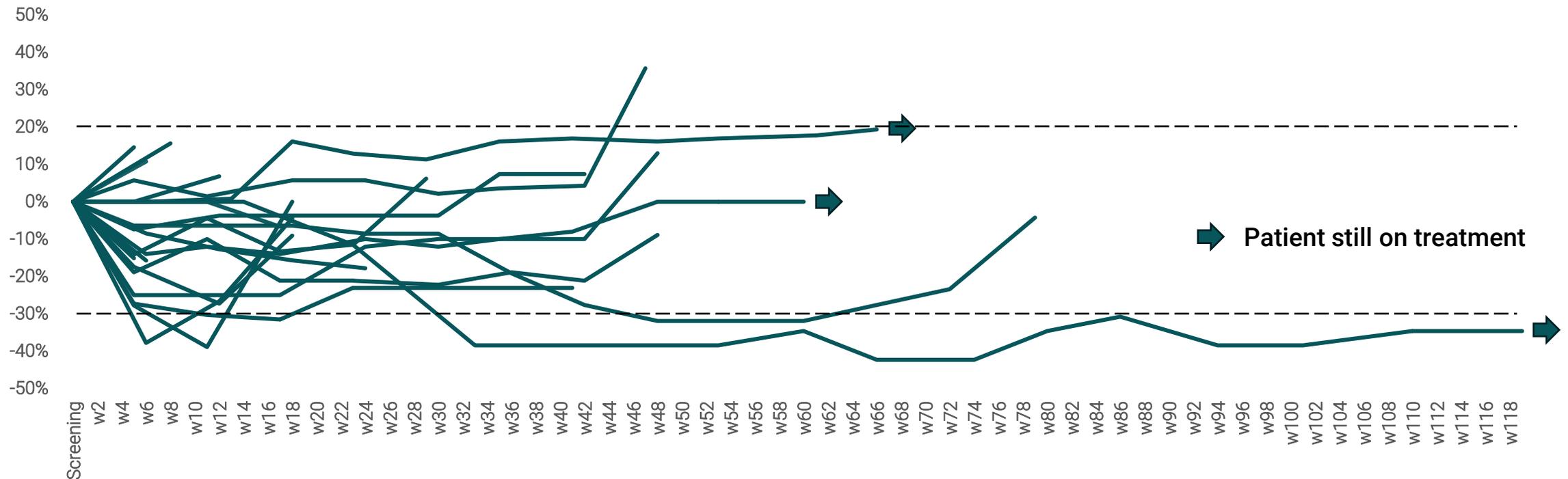


At risk – All pts 21 19 18 17 14 12 7 5 3 2 2

¹Evans et al., EASL Liver Cancer Summit 2025, P02-13.

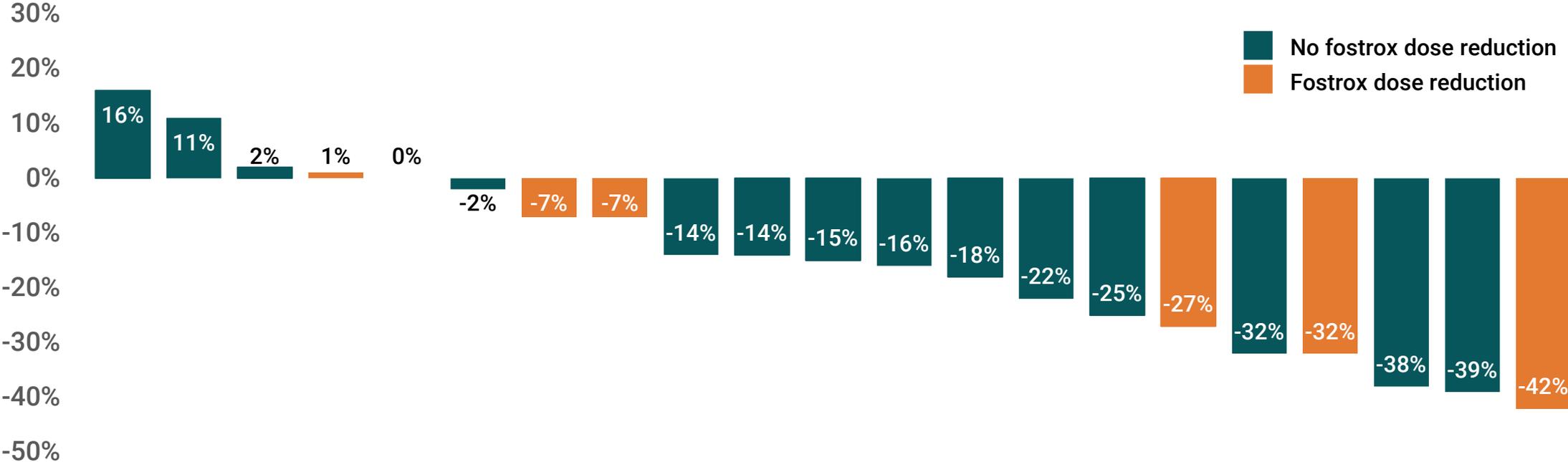
Target lesion tumor reduction was seen in >75% of patients and median duration of clinical benefit was 11.3 months

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



¹Evans 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

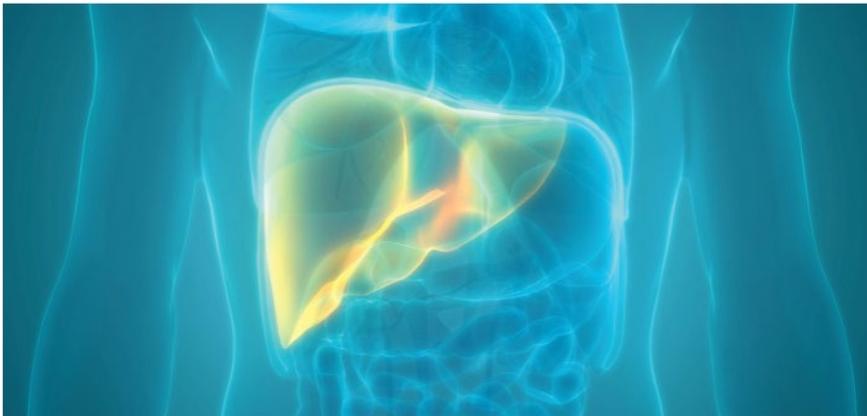
Growth in Fatty Liver Disease expected to drive an alarming increase in liver cancer cases¹

JAMA Network | **Open** 

Original Investigation | Gastroenterology and Hepatology

Estimated Burden of Metabolic Dysfunction-Associated Steatotic Liver Disease in US Adults, 2020 to 2050

Phuc Le, PhD, MPH; Moosa Tatar, PhD; Srinivasan Dasarathy, MD; Naim Alkhoury, MD; William H. Herman, MD, MPH; Glen B. Taksler, PhD; Abhishek Deshpande, MD, PhD; Wen Ye, PhD; Olajide A. Adekunle, PhD; Arthur McCullough, MD; Michael B. Rothberg, MD, MPH



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

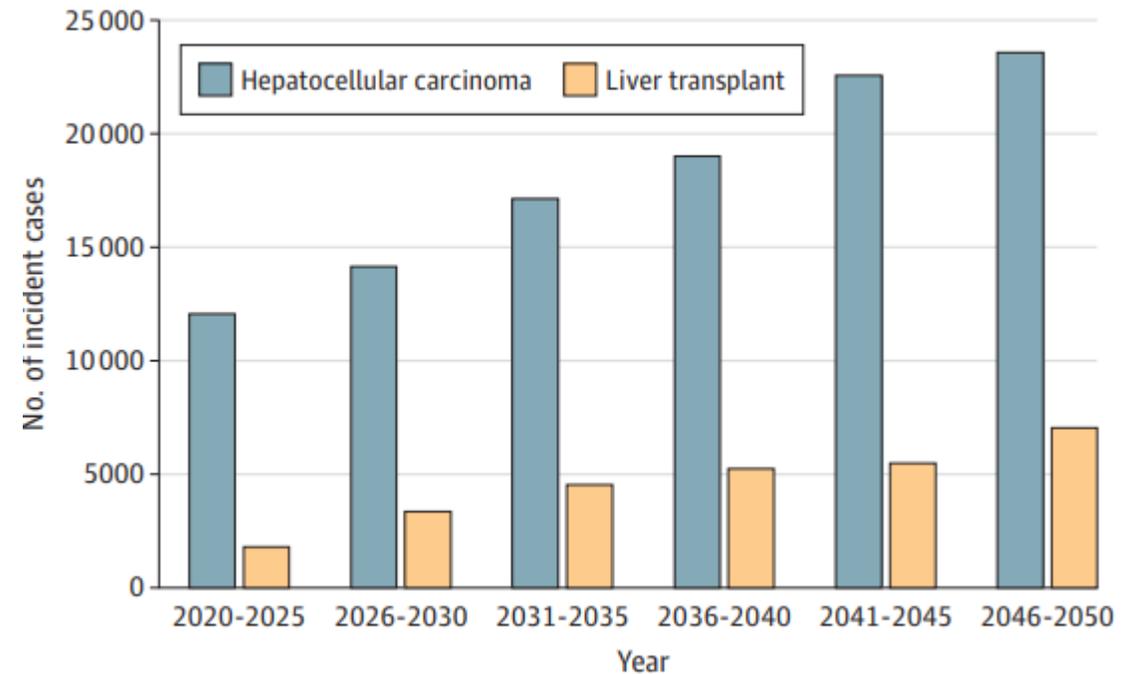
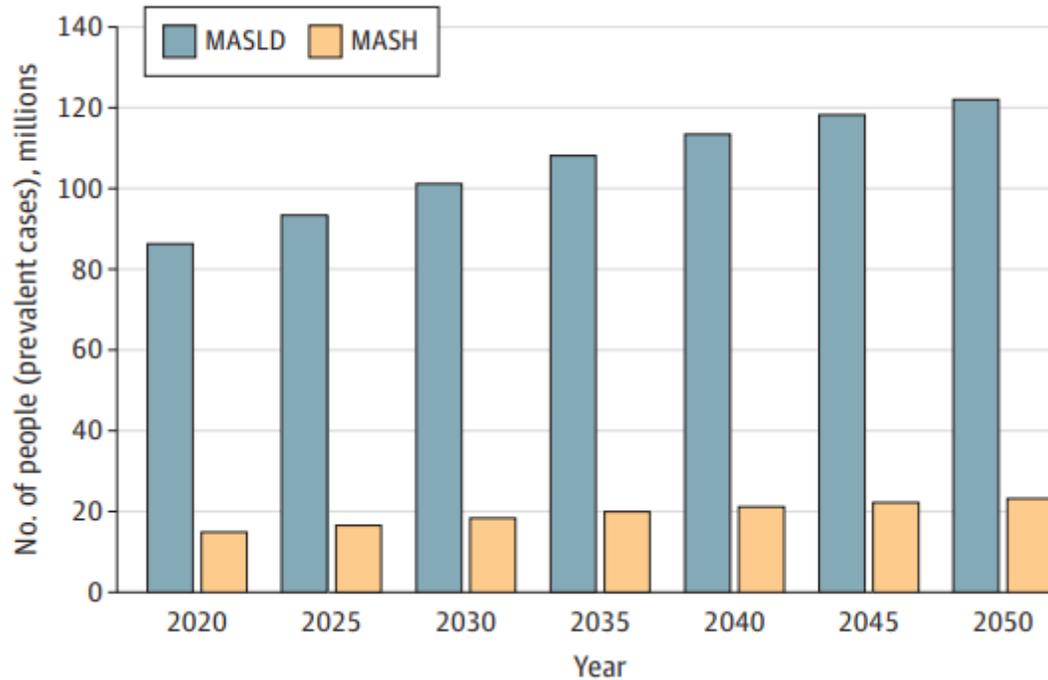


The number of newly diagnosed liver cancer patients each year is expected to double

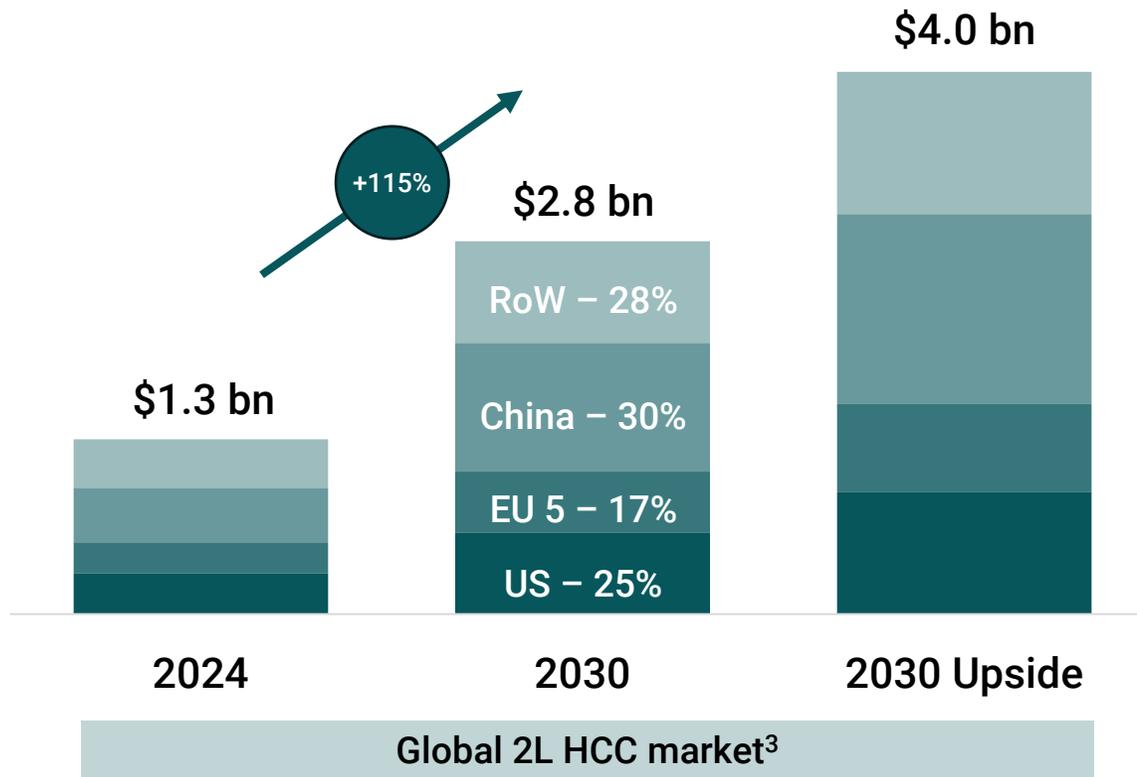


HCC market growth further spurred by more and better treatments enabling patients to be treated longer

Growth in Fatty Liver Disease expected to drive an alarming increase in liver cancer cases¹



2nd line HCC – a large and growing commercial opportunity with significant need for new treatment options³



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

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
Total income	0.8	0.6	4.5
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
Operating profit/loss	-13.3	-27.4	-127.3
Net financial items	0.1	1.3	4.0
Profit/loss after financial items	-13.3	-26.1	-123.3
Tax	-	-	-
Net profit/loss for the period	-13.3	-26.1	-123.3

- 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

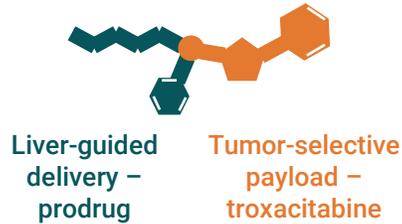
Q/A

Fostrox (fostroxacitabine bralpamide)

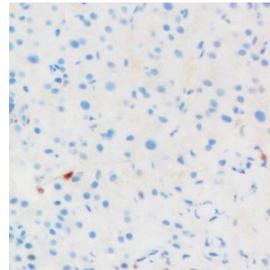
The first oral, liver-targeted treatment tailored for HCC

Oral, liver-activated small molecule inducing DNA damage in tumor cells, sparing healthy liver cells³

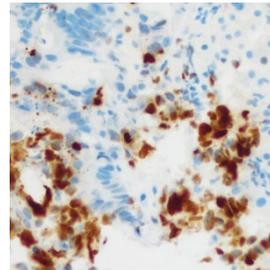
Unique, liver-targeted approach in HCC



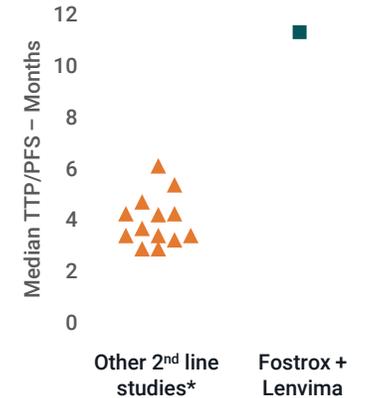
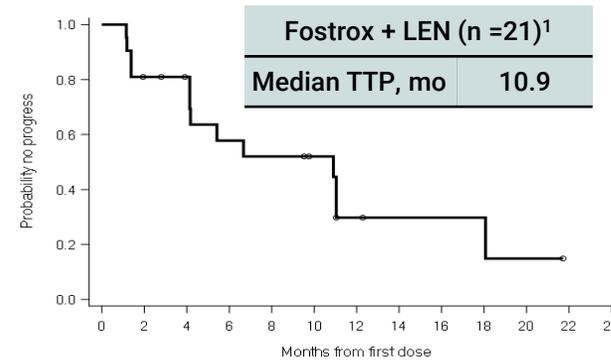
No DNA damage in healthy liver tissue



DNA damage in tumor tissue



10.9 months time to progression, substantially better than SoC^{1,2}



*see slide 20 for details regarding individual study data

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



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

Market opportunity in 2nd line HCC >\$2.5bn, with significant upside potential

>\$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!