

Medivir Q2 REPORT 2025

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

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Q2 Highlights



ASCO & ESMO-GI data presentations confirm fostrox frontrunner position in 2L HCC



Japan patent for fostrox + lenvatinib approved, providing protection until 2041, complementing previous approvals in EU and Australia



Concentra acquiring IGM Biosciences, birinapant returned to Medivir

Today's presenters



CEO
Jens Lindberg



CMO
Pia Baumann



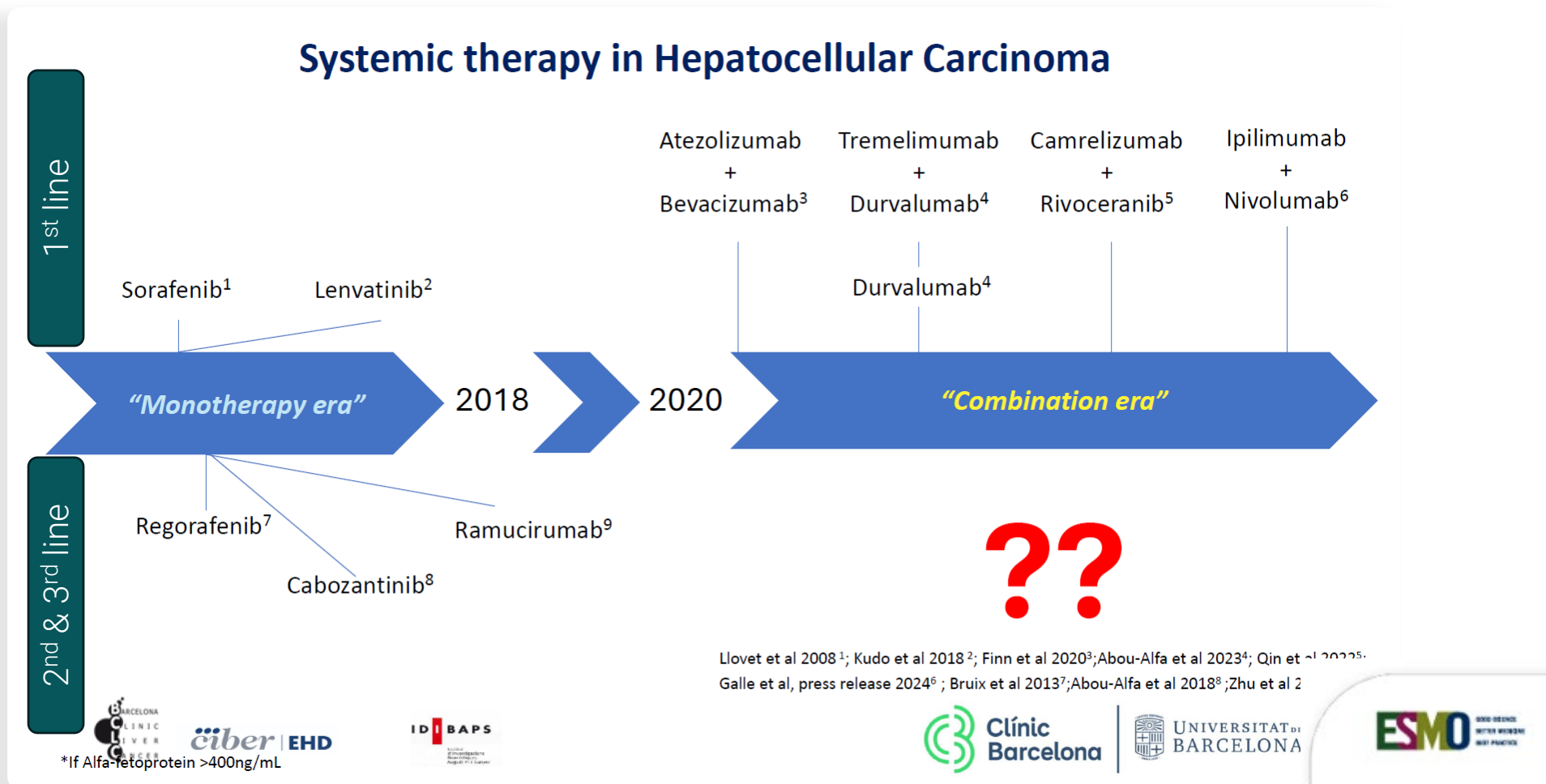
CFO
Magnus Christensen



CSO
Fredrik Öberg

**ASCO & ESMO-GI data presentations confirm
fostrox frontrunner position in 2L HCC.**

ASCO and ESMO-GI presentations confirm gap in clinical data and lack of consensus in 2nd line advanced HCC

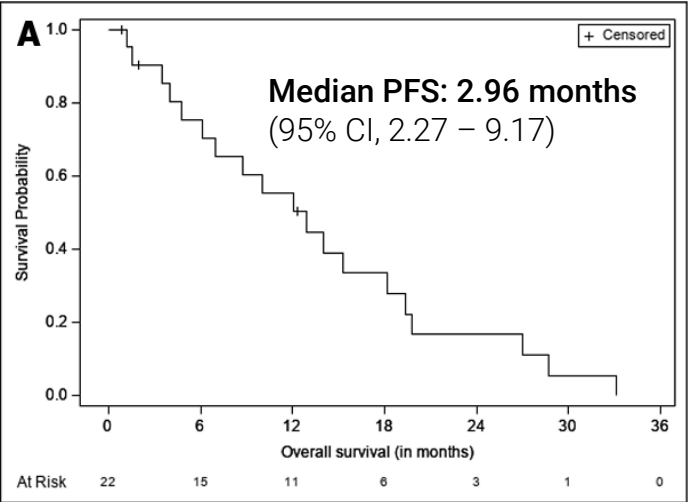


#174P: AURORA – A Phase II, non-randomized, single arm, translational study of Cabozantinib for Patients with Hepatocellular Carcinoma (HCC) Refractory to first line Treatment - the IKF/AIO-AURORA trial

Vogel Arndt^{1,2}, Pink Daniel^{3,4}, Ehmer Ursula⁵, Waldschmidt Dirk⁶, Damm Marko⁷, Ettrich Thomas⁸, Marquardt Jens U⁹, Al-Batran Salah E^{10,11}, Klagges J¹⁰, Saborowski Anna¹

First Line Therapies	
Lenvatinib	4 (18.2%)
Atezo + Bevacizumab	16 (72.7%)
Durva+ Tremelimumab	2 (9.1%)

- 22 patients with progression on prior treatment enrolled at 7 sites in Germany
- Treated with cabozantinib 60 mg once daily

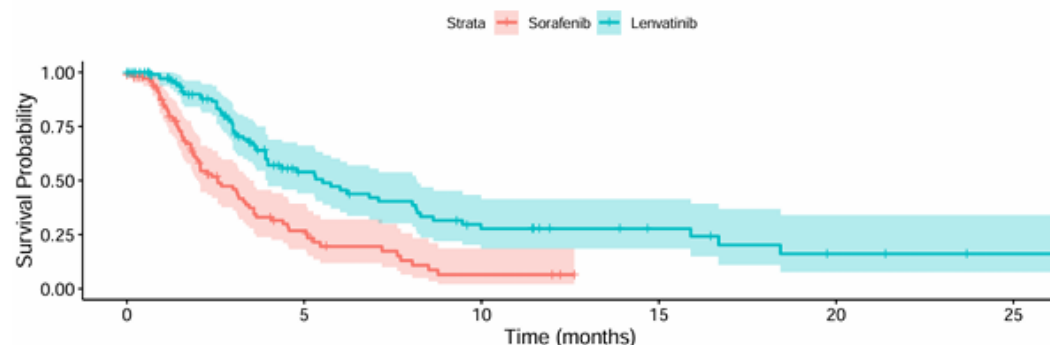


Time on Treatment	2.89 months
Overall survival	12.94 months
Progression free survival	2.96 months
Objective response rate*	
• PR	1 (4.5%)
• SD	8 (36.4%)
• PD	7 (31.8%)

#175P: Lenvatinib versus sorafenib as second-line treatment post-atezolizumab plus bevacizumab for hepatocellular carcinoma: the LEVIATHAN Study.

P. Lombardi^{1,2,#}, H. Yang^{3,#}, G.F. Manfredi^{1,4}, C. Celsa^{1,5}, B. Stefanini^{1,6}, T.U. Marron⁷, M. Pinter⁸, F. Piscaglia^{6,9}, C.Y. Lin^{10,11}, W.F. Hsu¹², A. Dalbeni¹³, G. Masi^{14,15}, M. Schönlein¹⁶, P.R. Galle¹⁷, M. Kudo¹⁸, L. Rimassa^{19,20}, M. Pirisi^{4,21}, H. J. Chon^{3,#}, D. J. Pinato^{1,22#}.

A Progression-Free Survival by Second Line Treatment (PFS II)



Group	Median PFS (mo)	HR (95% CI)	P-value
Lenvatinib	5.5	Reference	-
Sorafenib	2.6	0.41 (0.29-0.59)	p < 0.001

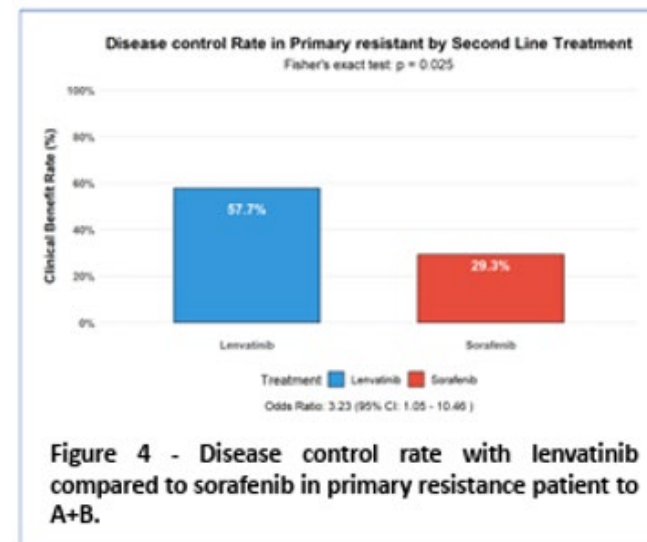


Figure 4 - Disease control rate with lenvatinib compared to sorafenib in primary resistance patient to A+B.

- 230 HCC patients on 2L treatment post atezolizumab + bevacizumab; lenvatinib (n=125) or sorafenib (n=105)
- Study confirmed lenvatinib superiority over sorafenib and similar efficacy for lenvatinib monotherapy as in previous studies:
 - Median PFS of 5.5 months
 - Disease Control Rate of 57.7%

Recent review of HCC studies in 2nd line confirms unmet need with an ORR < 10% and a PFS of around 4 months

Table 3
Selected clinical studies reporting efficacy and safety of subsequent MKI treatments following progression of atezolizumab plus bevacizumab.

Treatment	Sorafenib or lenvatinib	MKIs (predominantly sorafenib)	Sorafenib	Lenvatinib	Cabozantinib	Regorafenib	Pembrolizumab plus regorafenib (prior atezolizumab plus bevacizumab cohort)	Lenvatinib
Authors (year)	Yoo et al. (2021) [39]	Falette-Puisieux et al. (2023) [40]	Chon et al. (2024) [41]	Chon et al. (2024) [41]	Chan et al. (2024) [21]	Yoo et al. (2023) [23]	El-Khoueiry et al. (2024) [22]	Yoo et al. (2024) [44]
Number of patients	49	53	86	40	47	40	68	50
Region	Asia	France	Korea	Korea	Asia	Asia	Global	Korea
Study design	Retrospective	Retrospective	Retrospective	Retrospective	Prospective	Prospective	Prospective	Prospective
BCLC– C (%)	100	92.4	86.6	90.0	94	97.5	78	76
Macrovascular invasion (%)	38.8	43.4	46	52.1	30	–	28	24
Extrahepatic spread (%)	–	77.4	69	72.5	–	–	66	–
mPFS (months)	3.4	2.8	3.5	1.8	4.1*	3.5	2.8	5.4
mOS (months)	14.7	7.0	10.3	7.5	11.8*	9.7	Not reached	8.6
ORR (%)	6.1	–	5.8	7.5	6.4	10.0	5.9	12
DCR (%)	63.3	–	24.4	67.5	83.0	82.5	54.4	84
Gr3/4 TRAE (%)	16.3	28.3	35.0	38.4	–	–	40	–
Most common Gr3/4 TRAE	HFS	–	Proteinuria	HFS, rash	Platelet count decrease	Platelet count decrease	HFS	Hypertension

BCLC: Barcelona Clinic Liver Cancer; DCR: disease control rates; HFS: hand-foot syndrome; mOS: median overall survival; mPFS: median progression-free survival; ORR: objective response rates.

* mPFS and mOS after atezolizumab plus bevacizumab-based therapy.

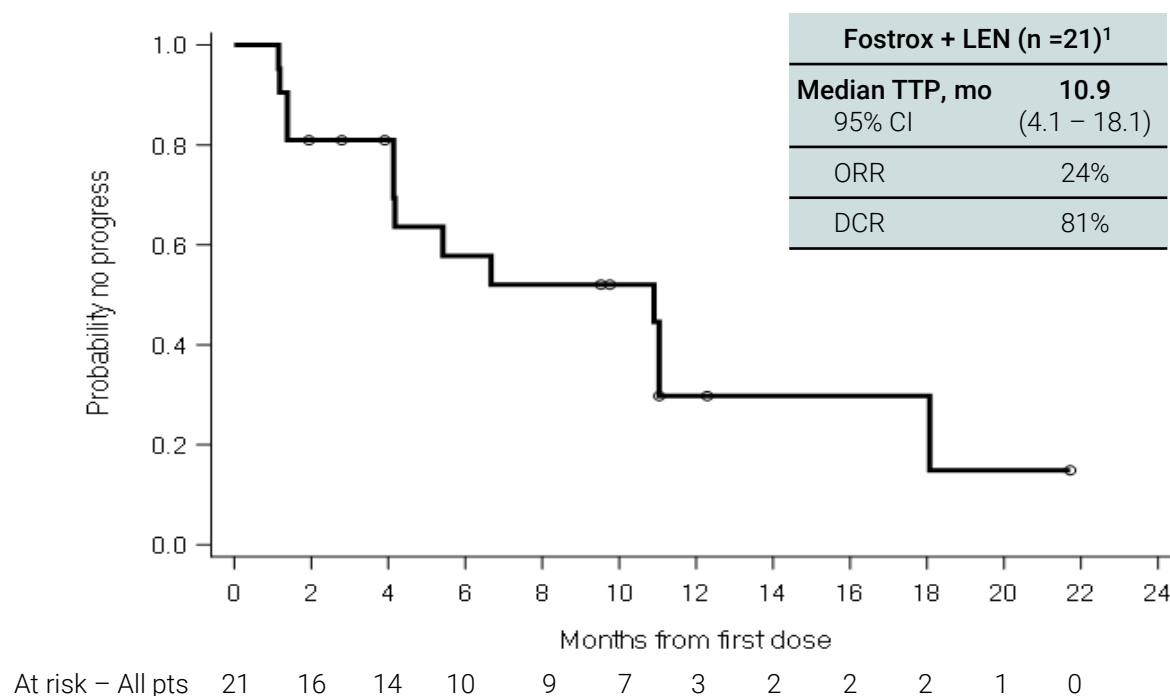
Chan et al., “Treatment for hepatocellular carcinoma after immunotherapy”

Annals of Hepatology, February 2025

	TKIs (lenvatinib, sorafenib etc) Mean results across 8 studies	Fostrox + lenvatinib
ORR	7.7%	24%
DCR	65.6%	81.0%
PFS/TTP	3.4 months	10.9 months

Treatment outcome substantially improved with Fostrox + Lenvima compared to 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)

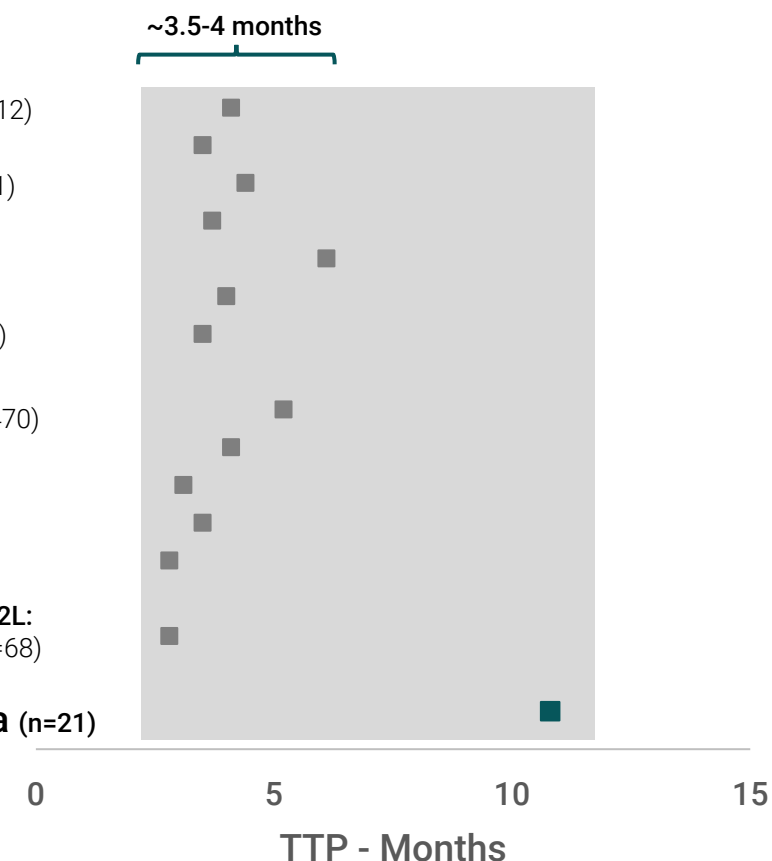
Other TKIs in 2L:

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)

Fostrox + Lenvima (n=21)



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Integrating Quality of Life and Survival in Systemic Therapy for Advanced Hepatocellular Carcinoma

A Network Meta-Analysis

Ciro Celsa, MD, PhD; Gabriele Di Maria, MD; Pasquale Lombardi, MD; Antonio D'Alessio, MD; Claudia A. M. Fulgenzi, MD; Leonardo Brunetti, MD; Giulia F. Manfredi, MD; Bernardo Stefanini, MD; Alba Sparacino, MD; Cristina Rigamonti, MD, PhD; Mario Pirisi, MD, PhD; Charles Latchford, MD; Marco Vaccaro, MD; Marco Enea, MD, PhD; Calogero Cammà, MD, PhD; Giuseppe Cabibbo, MD, PhD; David James Pinato, MD, MRes, PhD

OBJECTIVE

- To compare the HR-QoL effects associated with different first-line treatments for unresectable or advanced HCC
- To integrate treatment-induced survival benefit with impact on patients' HR-QoL.

RESULTS

- Atezolizumab plus bevacizumab had the highest probability of reducing deterioration of global health status and QoL (85%).
- When integrating HR-QoL with overall survival, atezolizumab plus bevacizumab outperformed all other treatments.

CONCLUSIONS AND RELEVANCE

- Atezolizumab plus bevacizumab provides the best balance between QoL preservation and overall survival benefit compared to other systemic therapy options in unresectable or advanced HCC.

Recent data cements current treatment algorithm in, further strengthening the potential for Fostrox to be first in 2L HCC

Advanced HCC – Treatment Algorithm

1L

- Majority treated with IO combo
- **Tecentriq + Avastin preferred with recent data strengthening its position**

90%

IO combination

10%

Lenvatinib (or Sorafenib)

2L

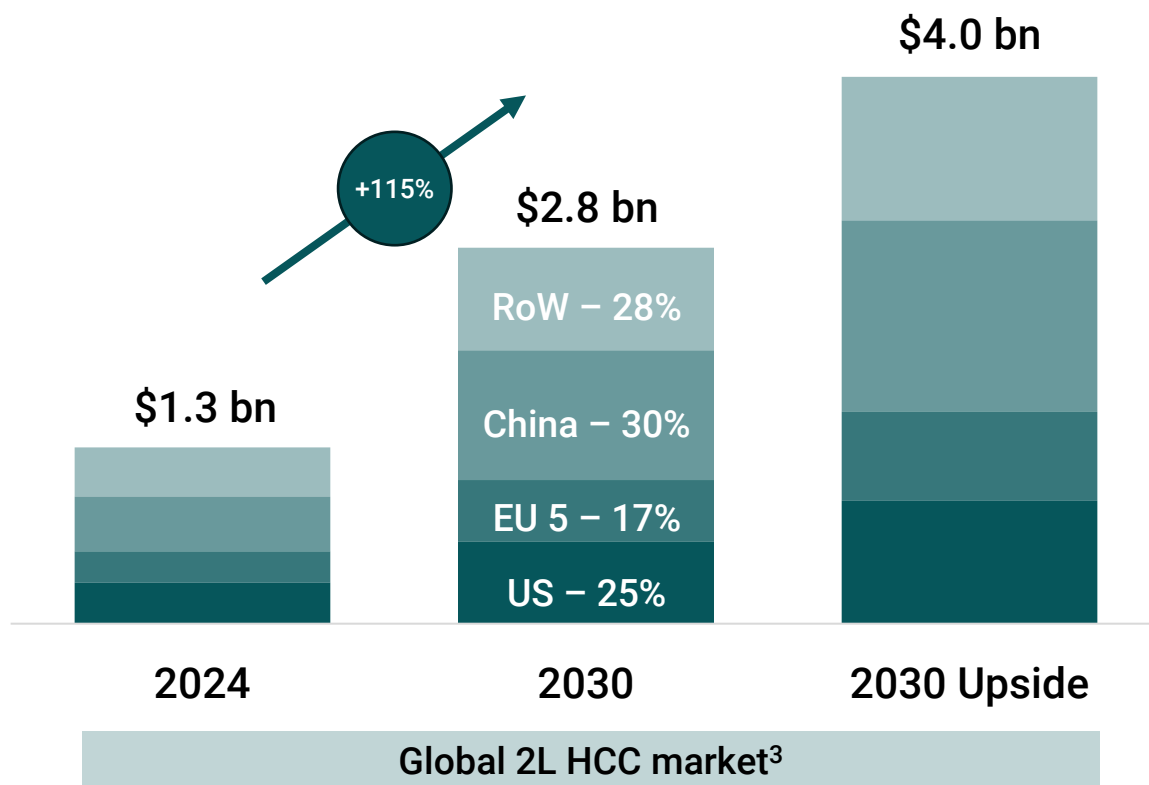
- No approved options in 2L
- Fostrox + Lenvima target population

- Data presented at ASCO & ESMO-GI confirming the promise of fostrox + lenvatinib combination

Lenvatinib/TKI
monotherapy preferred

IO combination

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:

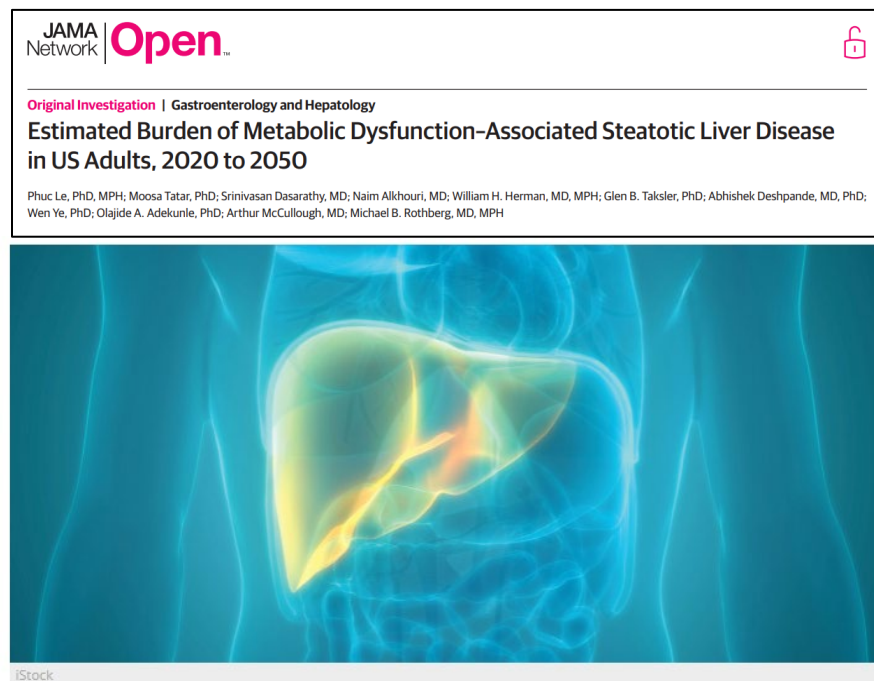
- Average treatment duration increases to 10 months based on fostrox + Lenvima[®] study

¹Rumguy et al. Journal of Hepatology 2022

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

³GlobalData 2021 and internal analysis

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



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

Key patent approval in Japan for fostrox + Lenvima extending protection until 2041, complementing previous approval in EU

Medivir receives Notice of Allowance for fostrox plus lenvatinib combination patent by Japan Patent Office

2025-07-08

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 it has received a Notice of Allowance by the Japan Patent Office (JPO) for the company's patent application covering claims for the combination of fostroxacitabine bralpamide (fostrox) with lenvatinib (Lenvima) for the treatment of hepatocellular carcinoma (HCC) and cancer metastases to the liver.



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



Now approved in Japan, EU and Australia which indicates likelihood of other key regions to follow



Generates critical extension of patent protection until 2041

Financial highlights Q2

Financial summary Q2, 2025

Consolidated Income Statement, summary

(SEK m)

	Q2		Q1 - Q2		Full year
	2025	2024	2025	2024	2024
Net turnover	1.5	1.1	2.1	1.6	3.5
Other operating income	0.3	0.1	0.5	0.3	1.0
Total income	1.8	1.2	2.6	1.9	4.5
Other external expenses	-17.0	-30.3	-23.2	-51.0	-101.3
Personnel costs	-7.1	-7.6	-14.1	-14.1	-27.2
Depreciations and write-downs	-0.7	-0.7	-1.4	-1.4	-2.7
Other operating expenses	-0.2	0.0	-0.5	-0.1	-0.6
Operating profit/loss	-23.2	-37.3	-36.5	-64.7	-127.3
Net financial items	-0.2	1.4	-0.1	2.7	4.0
Profit/loss after financial items	-23.3	-36.0	-36.6	-62.0	-123.3
Tax	-	-	-	-	-
Net profit/loss for the period	-23.3	-36.0	-36.6	-62.0	-123.3

- Net turnover for Q2 was SEK 1.5 million
- Operating loss for Q2 was SEK -23.2 million
- Cash flow from operating activities for Q2 was SEK -26.2 million
- Cash balance end of Q2 was SEK 38.2 million

The background is a deep purple with a bokeh effect of out-of-focus light circles. A dense cluster of thin, white, fiber-optic-like lines radiates from the center, creating a starburst or explosion effect.

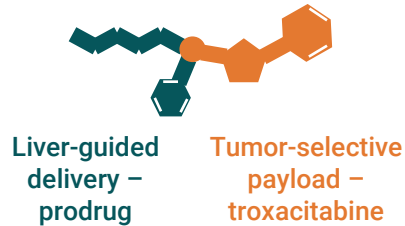
Q/A

Fostrox (fostroxacitabine bralpamide)

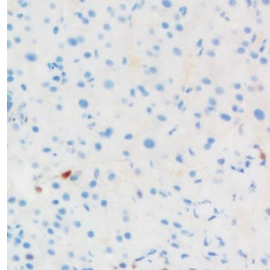
The first oral, liver-targeted treatment tailored for HCC

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

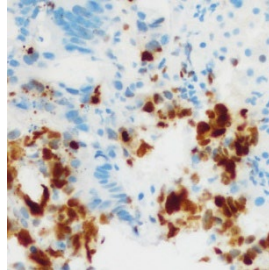
Unique, liver-targeted approach in HCC



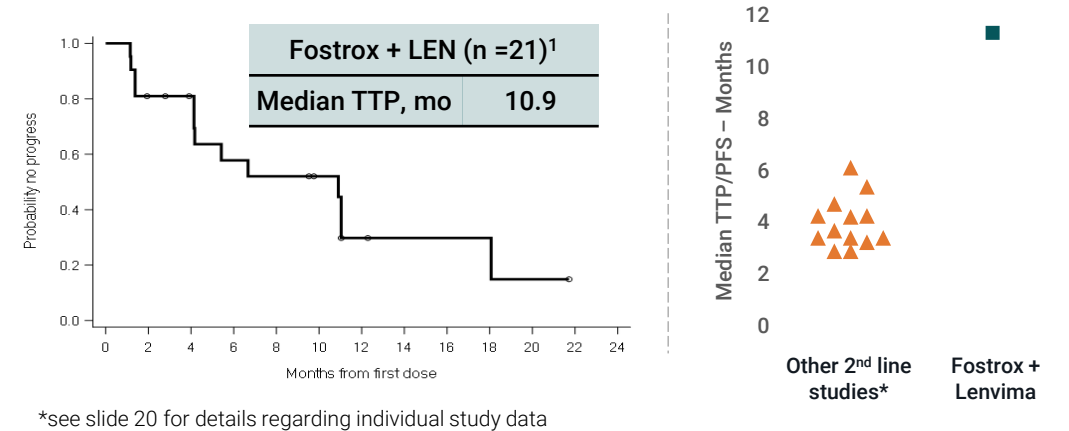
No DNA damage in healthy liver tissue



DNA damage in tumor tissue



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



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



- No 2nd line treatments approved in advanced HCC
- 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

The background is a deep purple with a bokeh effect of out-of-focus light circles. From the center, numerous thin, white fiber optic-like lines radiate outwards, some ending in small, bright white dots.

Thank You!