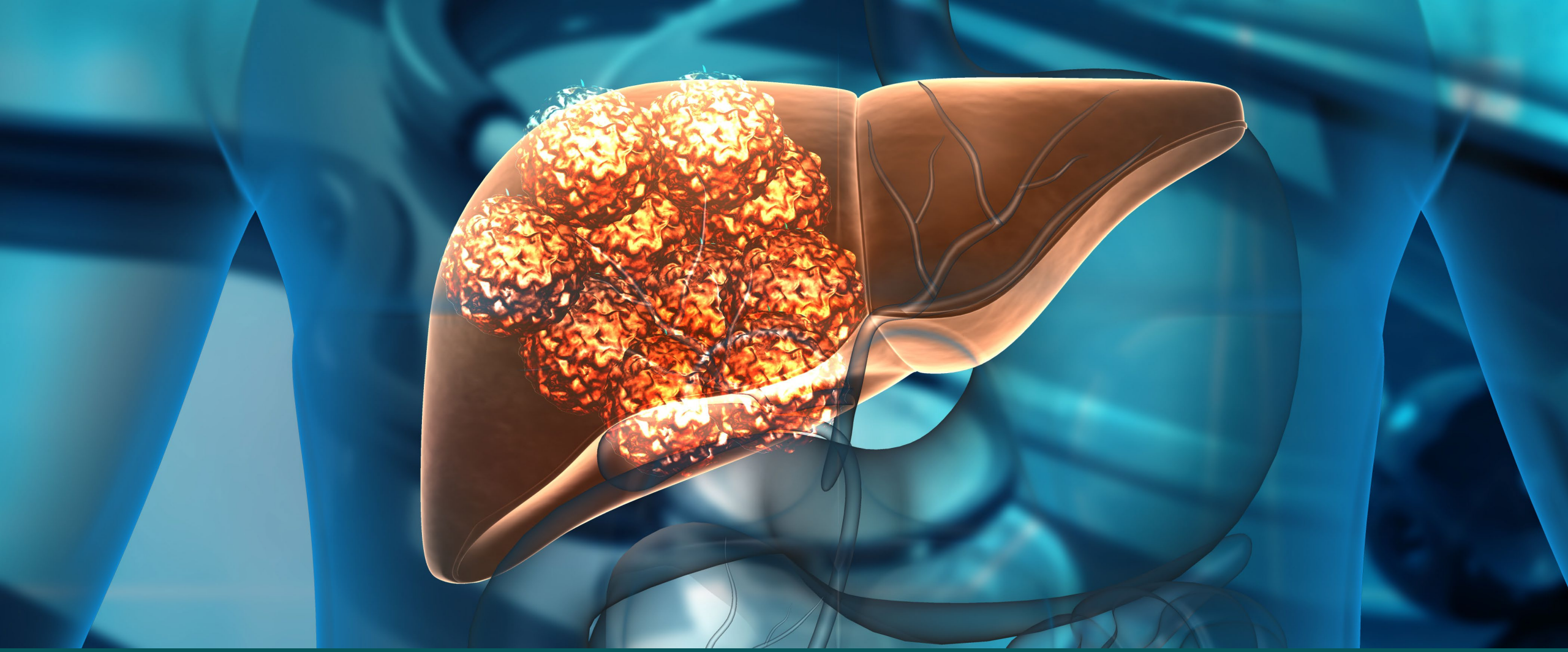

Fostrox – The first oral, liver-targeted treatment for advanced HCC

Jens Lindberg, CEO
Aktiedagarna November 2025

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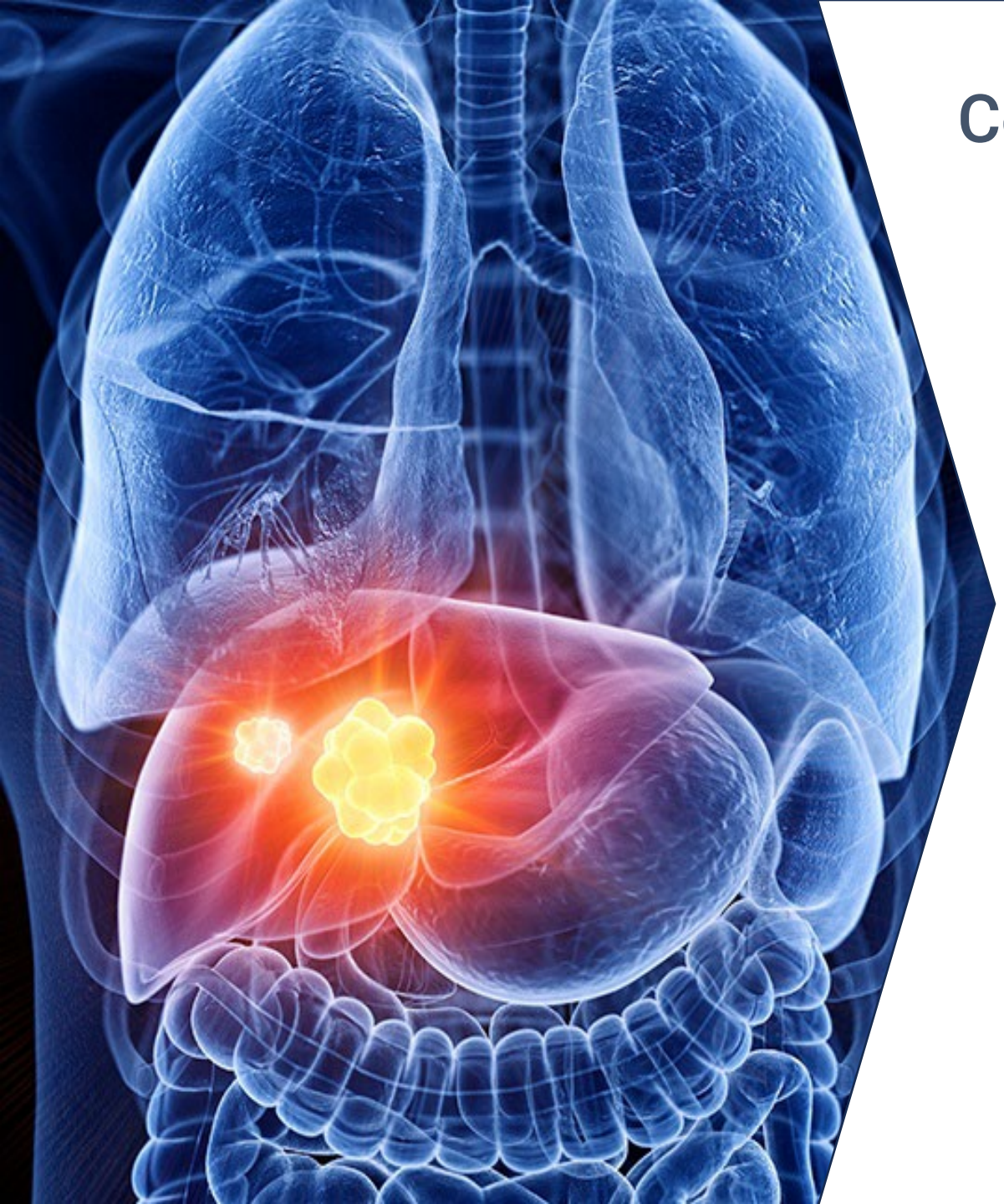

Continued progress

- Right's issue enables rapid generation of randomized, comparative data to confirm benefit of fostrox combination with Lenvima
- Design of planned phase 2 study strengthened by latest data in advanced HCC
- Remetinostat out-license generates significant potential value upside for phase 3 ready molecule

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Medivir enters exclusive licensing agreement with Biossil, Inc. for remetinostat

Medivir enters exclusive licensing agreement with Biossil, Inc. for remetinostat

2025-10-23

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 it has entered into an exclusive licensing agreement, through which Biossil, Inc. will receive global, exclusive development rights for remetinostat, a clinical-stage topical HDAC inhibitor. Biossil is a Toronto-based AI-native drug developer focused on developing novel therapies for heterogenous diseases with urgent unmet medical needs.

Positive phase 2 data in basal cell carcinoma (BCC) and cutaneous T-cell lymphoma (CTCL)

Global, exclusive, licensing agreement to develop and commercialize remetinostat

Total, potential milestone payments of approximately USD 60 million
Mid-single digit royalties on future net sales & sub-licensing revenue share.

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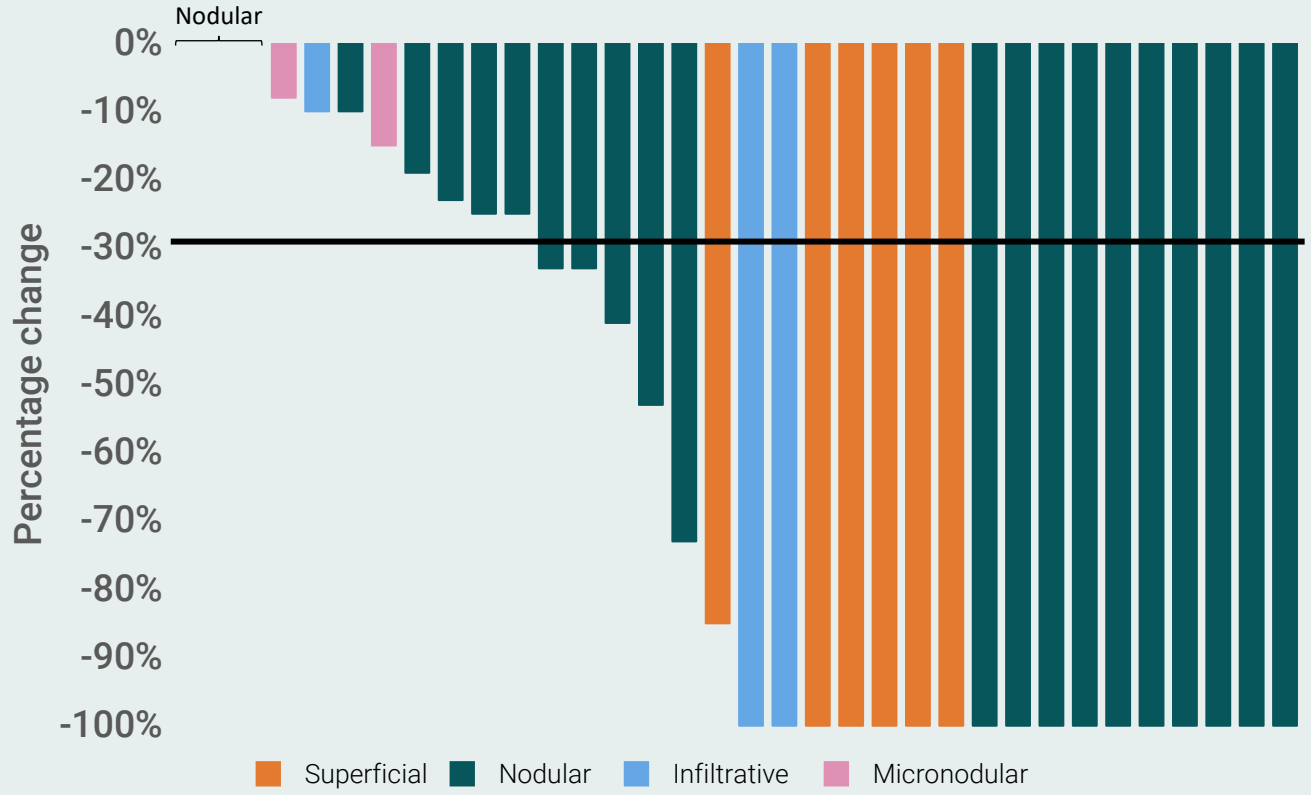
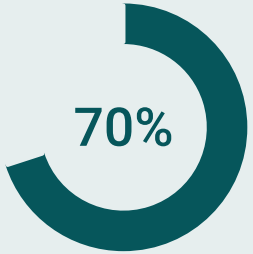
Remetinostat is an effective topical treatment for reducing BCC disease burden in a clinically significant manner

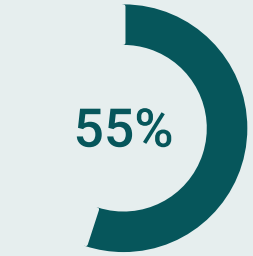
Encouraging efficacy across all subtypes of BCC lesions



>50% of lesions achieving complete pathological resolution across full cohort



Overall response rate



Complete pathological resolution

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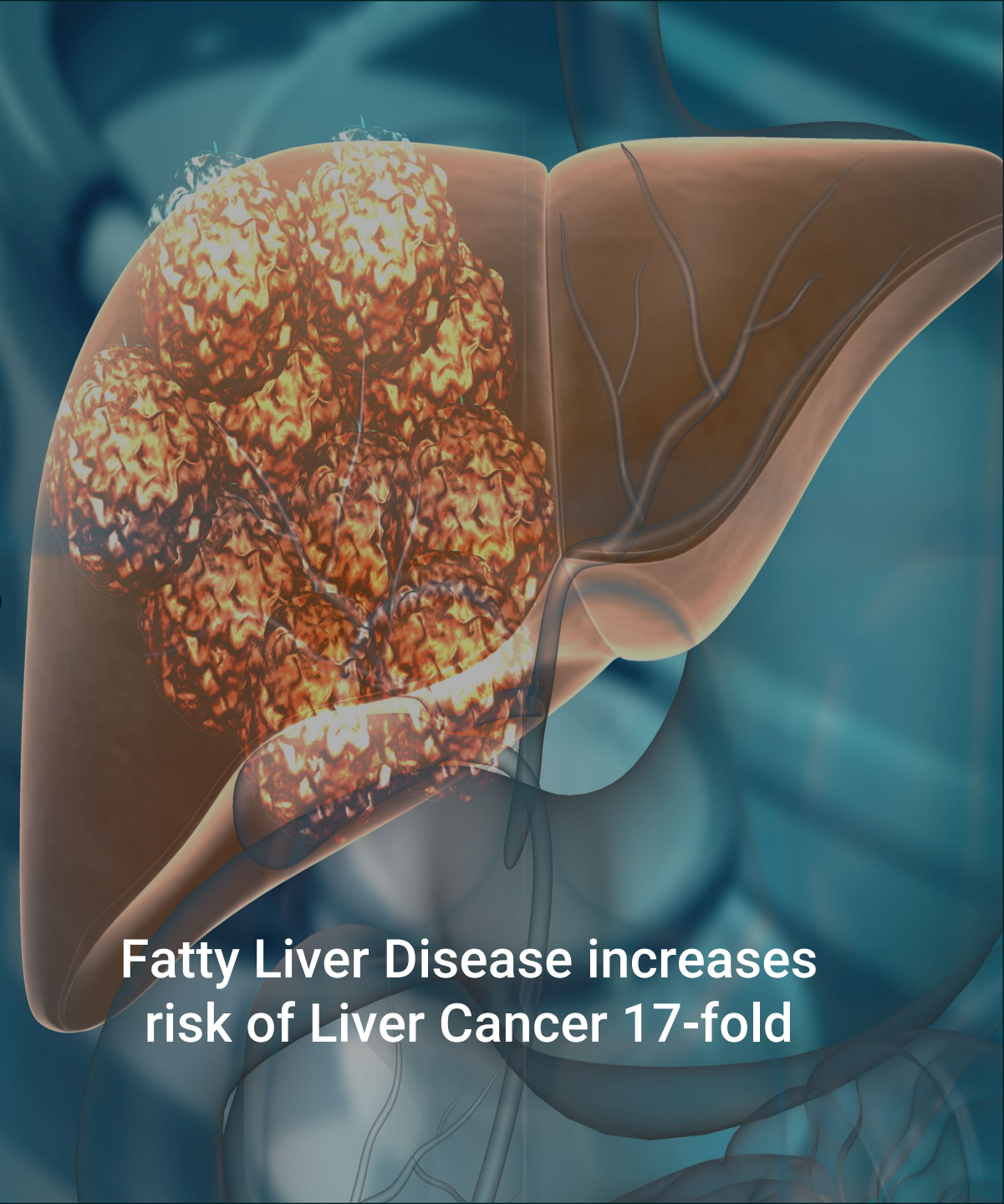
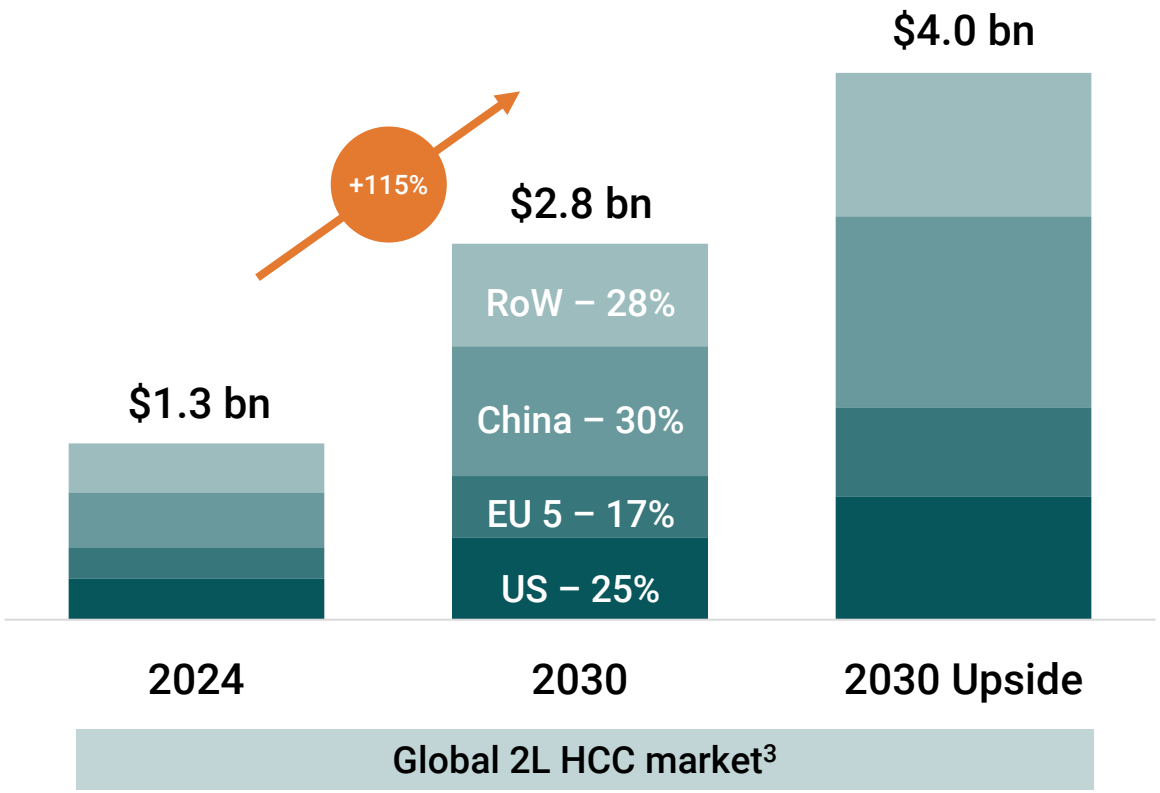
[1]J. Kilgour et al, Clinical Cancer Research published online 6 August 2021

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 ~$3bn commercial opportunity[3]



Growth driven by:

- HCC to increase **+122% in the US** and +**82% in China**[2] by 2030, caused by fatty liver disease
- With improved 1L treatment, more patients will be **fit enough for 2L, 50% → 70%**

2030 Upside:

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

[1]Rumguy et al. Journal of Hepatology 2022
[2]Huang et al., Nature Reviews, Gastroenterology & Hepatology, Vol 18, 2021
[3]GlobalData 2021 and internal analysis

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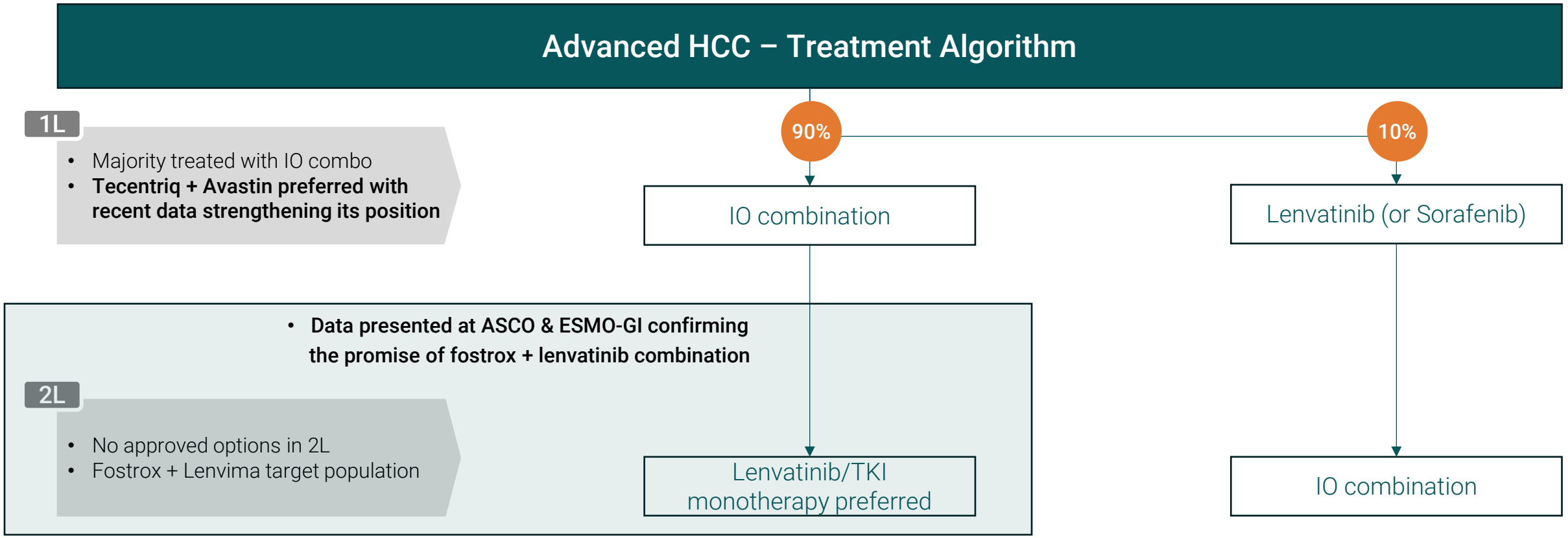
Fostrox + Lenvima targets 2L population where no treatments are approved today



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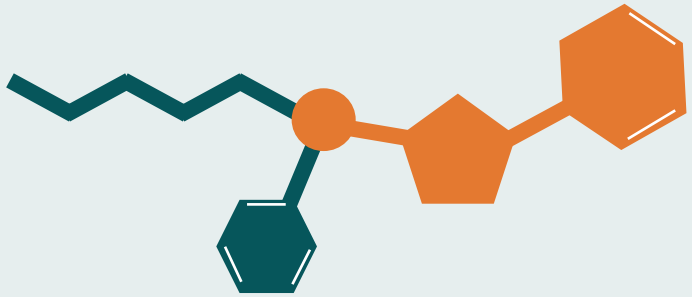
Fostrox – designed to selectively kill tumor cells in the liver

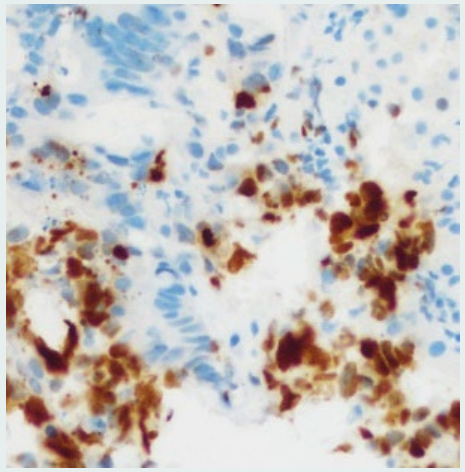
Prodrug transports inactive payload to the liver, where it is rapidly activated by liver enzymes[1]



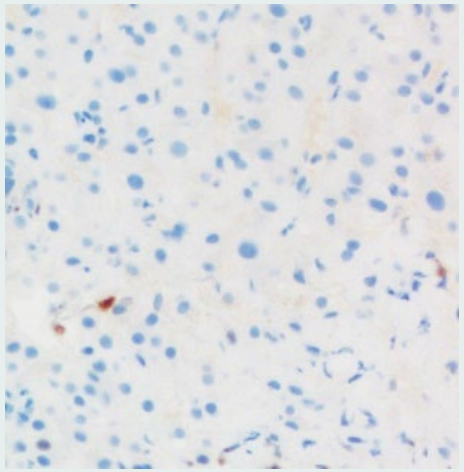
Liver-guided delivery – prodrug

Tumor-selective payload – troxacitabine

Kills tumor cells[2,3,4]



Spares healthy cells[2,3,4]



[1]Bethell, R. et al P-035, ILCA 2016
[2]Kukhanova, M et al J Biol Chem 1995
[3]Albertella, M. et al EASL Summit P01-05, 2018
[4]Öberg F. et al, EASL PO-221, 2022

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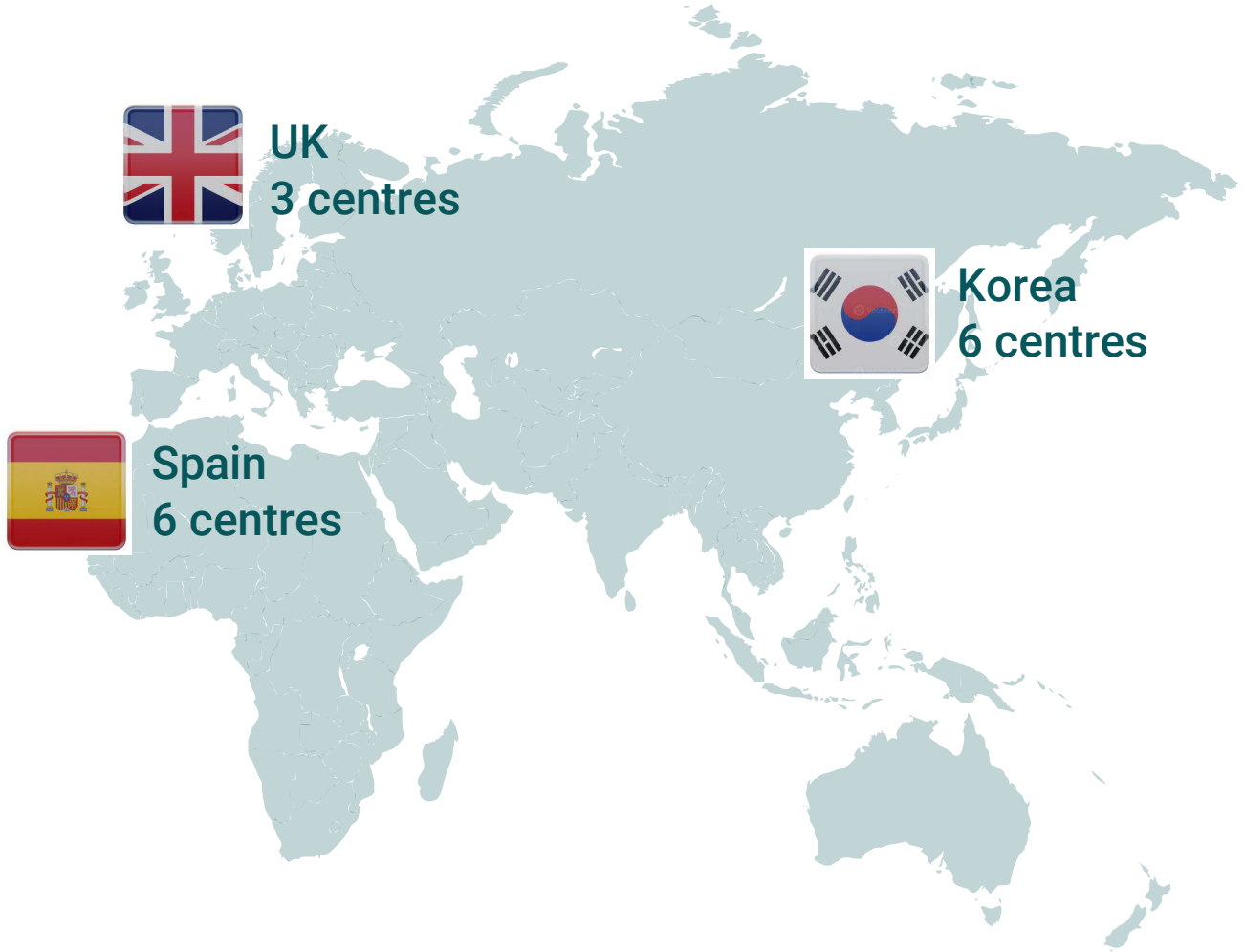
Global phase 1b/2a study with fostrox + Lenvima (TKI) positive, final data presented at EASL in February



Poster P02-13 presented by Dr. Jeff Evans, Glasgow, at EASL Liver Cancer Summit in February in Paris

EASL LIVER CANCER SUMMIT 2025
Paris, France 20-22 February

Final safety and efficacy results from the phase 1b/2a study of fostrox plus lenvatinib in second/third line advanced hepatocellular carcinoma progressed on immunotherapy

T.R. Jeffry Evans[1], Hong Jae Chon[2], Do Young Kim[3], Ho Yeong Lim[4], Teresa Macarulla[5], Carlos Gomez Martin[6], Victor Moreno[7], Min-Hee Ryu[8], Pia Baumann[9], Sujata Bhoi[9], Malene Jensen[9], Karin Tunblad[9], Hans Wallberg[9], Fredrik Öberg[9], Maria Reig[10], Jeong Heo[11]

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Introduction

Fostrox is a liver targeted oral prodrug of troxacitabine that selectively inhibits DNA replication in liver tumors[1].

Fostrox monotherapy was investigated in a phase 1a/1b dose escalating and expansion study in advanced solid tumors with an encouraging safety, tolerability profile and preliminary anti-tumor activity in hepatocellular carcinoma (HCC)[2].

Based on these results, a phase 1b/2a study of fostrox in combination with lenvatinib (LEN) in second line in locally advanced unresectable or metastatic hepatocellular carcinoma (HCC) (NCT03781934) was initiated and end of treatment data are reported here.

Aim

The aim of the phase 1b/2a study was to establish a recommended phase 2 dose of fostrox in combination with LEN and to evaluate safety & tolerability together with preliminary anti-tumor activity data.

Method

Figure 1: Study design of phase 1b/2a fostrox + LEN in advanced HCC

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

Table 1: Patient characteristics

	N = 21
Median age (range)	63 yrs (42 - 82)
Gender, Female / Male (%)	24 / 76
ECOG Performance status 0/1 (%)	71 / 29
Child Pugh A (%)	100
Viral/Non-viral (%)	76* / 24
Extra hepatic lesion(s) Y/N (%)	67 / 33
AFP ≥400 ng/mL at baseline Y/N (%)**	48 / 52
Region, Asia / Europe (%)	67 / 33
Prior treatment lines; 2nd line/3rd line (%)	81 /19
Prior atezo/bevacizumab in 1L (%)	86
Prior local therapy (TACE, RFA etc)	76
PD on prior treatment (%)	100
Primary refractory on prior therapy (%)***	24
Starting dose fostrox, 20mg / 30mg (%)	14 / 86

Results

Safety and tolerability*

Table 2: Treatment emergent/related adverse events seen in >20% of patients

Adverse Events*	TEAE: No of pts (%)			TRAE Grade ≥ 3*: No of pts (%)	
	Grade 1/2	Grade 3	Grade 4	Fostrox	LEN
Hematologic AE					
Thrombocytopenia	13 (62)	5 (24)	2 (10)	5 (24)	6 (29)
Neutropenia (no febrile)	9 (43)	8 (38)	2 (10)	8 (38)	6 (29)
Anaemia	6 (29)	3 (14)		3 (14)	3 (14)
Leukocyte decrease	6 (29)	2 (10)		2 (10)	2 (10)
Other AE					
Hypothyroidism	11 (52)				
Diarrhea	11 (52)	1 (5)			1 (5)
Hand-foot syndrome	10 (48)	1 (5)			1 (5)
Fatigue	9 (43)				
Asthenia	2 (10)	2 (10)		1 (5)	2 (10)
Anorexia	8 (38)				
Proteinuria	7 (33)	2 (10)			1 (5)
Hypertension	8 (38)	3 (14)			2 (10)
Cough	5 (24)				
Pruritus	5 (24)				

* There was no grade 5 fostrox related AE and one grade 5 LEN related death (renal failure)

- With a median follow-up of 10.5 months (range 1.2 – 27.8 months) the combination of fostrox + LEN was shown to be safe and well tolerated with no unexpected new adverse events reported.
- Most common adverse events were laboratory test results with 33 events (out of 880 blood tests) of grade ≥ 3 neutropenia and thrombocytopenia with clinical relevance (fostrox: dose-delay, reduction or discontinuation) in 11 of these 33 occasions.
- No febrile neutropenia or low platelet count with bleeding was reported
- SAEs were reported in 8 patients with 17 events in total
  - No events were related to fostrox
  - 8 events in 6 patients were possibly related/related to LEN (asthenia, ischemic stroke, renal failure, hepatic encephalopathy, diarrhea)
- Fostrox dose reduction due to AE was done in 29% and discontinuation in 5%
- LEN dose reduction due to AE was done in 52% and discontinuation in 10%

*Data cut Nov 30 2024

Clinical efficacy* (investigator review, RECISTv1.1)

Figure 2. Time to progression (TTP)

Median TTP, mo 10.9 (95% CI, 4.2-18.1)
DCR, % 24
Median DoR, mo 7.0 (95% CI, 1.6-NR)
DCR, % 81

Figure 3. Overall survival (OS)

Median OS, mo 13.7 (95% CI, 7.6 – NR)

Figure 4. Percentage change in total target lesion size over time

Figure 5. Best % change in target lesion size related to fostrox dose reduction

Target lesion tumor reduction was seen in >75% of patients and median duration of clinical benefit (CR, PR or SD>24 weeks*) was 11.2 months.

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

Figure 6. Percentage change in AFP over time and best overall response

Figure 7. Best % change in target lesion size related to AFP at baseline

Reduced or stable AFP levels from baseline to 6 weeks were seen in 79% of patients and was associated with imaging response (RECISTv1.1).

Target lesion size reduction was seen independent of AFP level at baseline

Conclusions

- Fostrox + LEN was safe and well tolerated using the RP2D of fostrox 30 mg QD orally for 5 days in a 21-day cycle in combination with standard dose of LEN
- Encouraging efficacy was seen with a best objective response, median time to progression and overall survival of 24%, 10.9 months and 13.7 months, respectively
- The majority of patients had a reduction in AFP levels at 6 weeks which correlated with imaging response, and overall target lesion reduction was independent of baseline AFP levels
- Based on the promising result from this study, a randomized phase 2b study with fostrox + LEN versus placebo + LEN in second line advanced HCC is planned to enroll patients in Europe, Asia and in North America

Acknowledgement

Thanks to all the investigators, research teams, and clinical staff in Korea, Spain and the UK, whose dedication and expertise made this study possible. We also sincerely thank the patients and their families for participating and contribution to advancing medical knowledge in liver cancer.

Contact information

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pia.baumann@medivir.com

Reference

1. Bethell, R. et al 2017, EASL International Liver Congress, Poster SAT-123 (www.medivir.com/media/7196/liver-targeting-with-the-novel-nucleotide-prodrug-thr-beta.pdf)
2. J Hepatocell Carcinoma. 2024 Oct 24;11:2033-2047
3. Am J Cancer Res 2021;11(4):1121-1131

Abbreviations

Hepatocellular carcinoma (HCC), recommended phase 2 dose (RP2D), progressive disease (PD), best objective response (BOR), duration of response (DoR), disease control rate (DCR), time to progression (TTP), duration of clinical benefit (DoCB), Eastern Cooperative Oncology Group Performance Status (ECOG PS), Response evaluation criteria in solid tumors (RECIST 1.1), Computerized tomography (CT), Magnetic Resonance Imaging (MRI), Trans arterial chemoembolization (TACE), radio frequency ablation (RFA), Common Terminology Criteria for Adverse Events (CTCAE), Immunotherapy (IO), target lesion (TL), treatment emergent adverse event (TEAE), treatment related adverse event (TRAE), lenvatinib (LEN), Kaplan Meier (K-M), serious adverse event (SAE), quasar decline daily (QD), alfa feto protein (AFP), overall survival (OS)

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Fostrox + Lenvima phase 1b/2a study design

- Adv/inop HCC
- 2L/3L
- ≥ 18 y
- ECOG ≤ 1
- Child-Pugh A

Fostrox + LEN* 20 mg (n=3)

Fostrox + LEN 30 mg (n=3)

Fostrox + LEN RP2D – 30 mg (n=15)

Treatment until PD

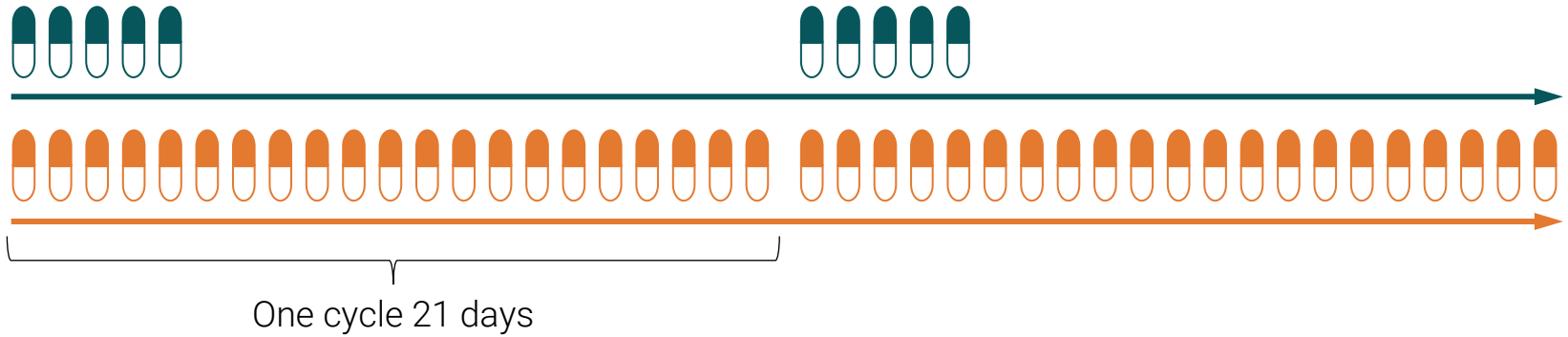
Primary Endpoint: Safety

Key Secondary Endpoints: ORR, DCR, TTP/PFS

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 days cycles

LEN: Oral QD continuous
(8 or 12 mg)



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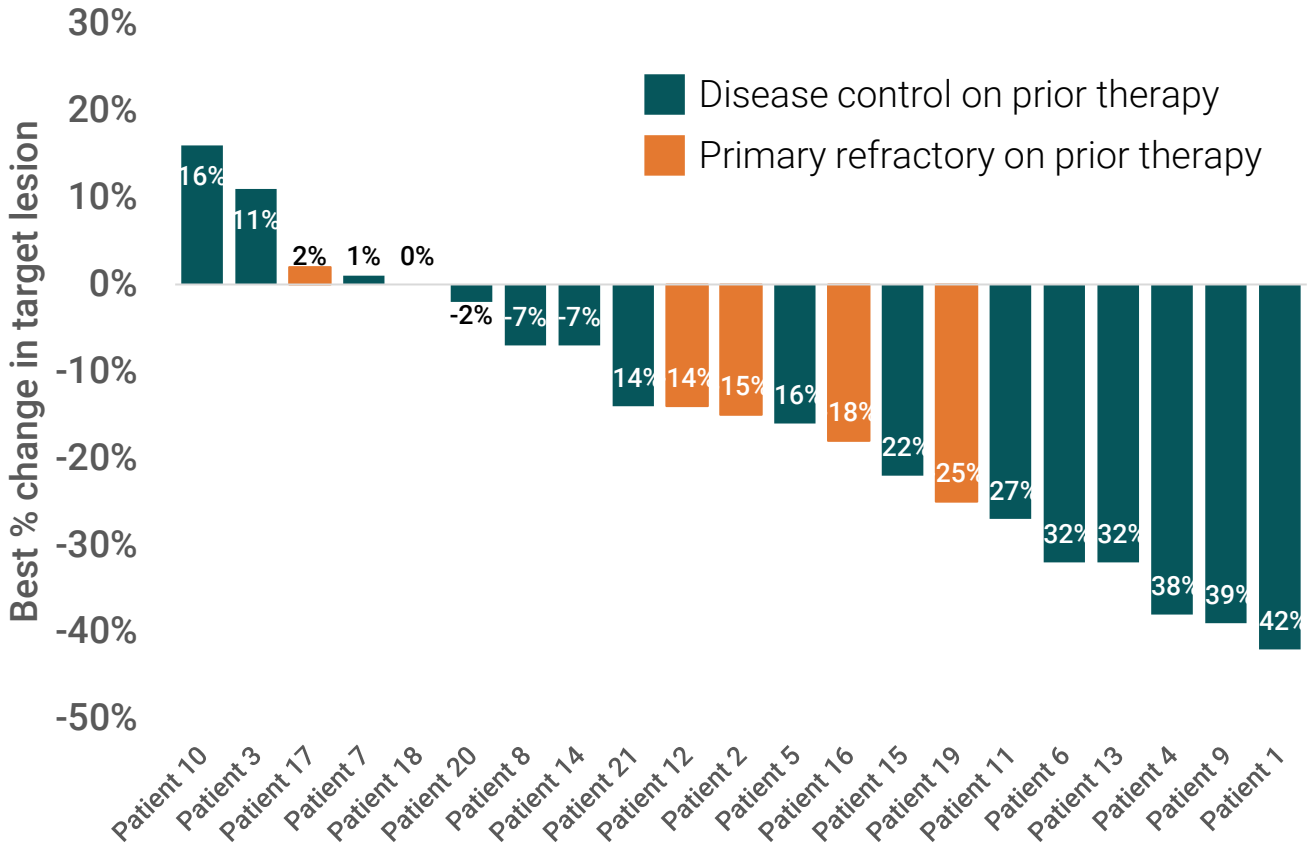
*LEN = lenvatinib

More than 75% of patients experiencing tumor shrinkage[1]

Best percentage change in target lesion size related to treatment response in first line



- Median duration of response 7.0 months
- Longest duration of response still ongoing at 19.5 months
- Patients benefitted from treatment independent of outcome in previous line of therapy

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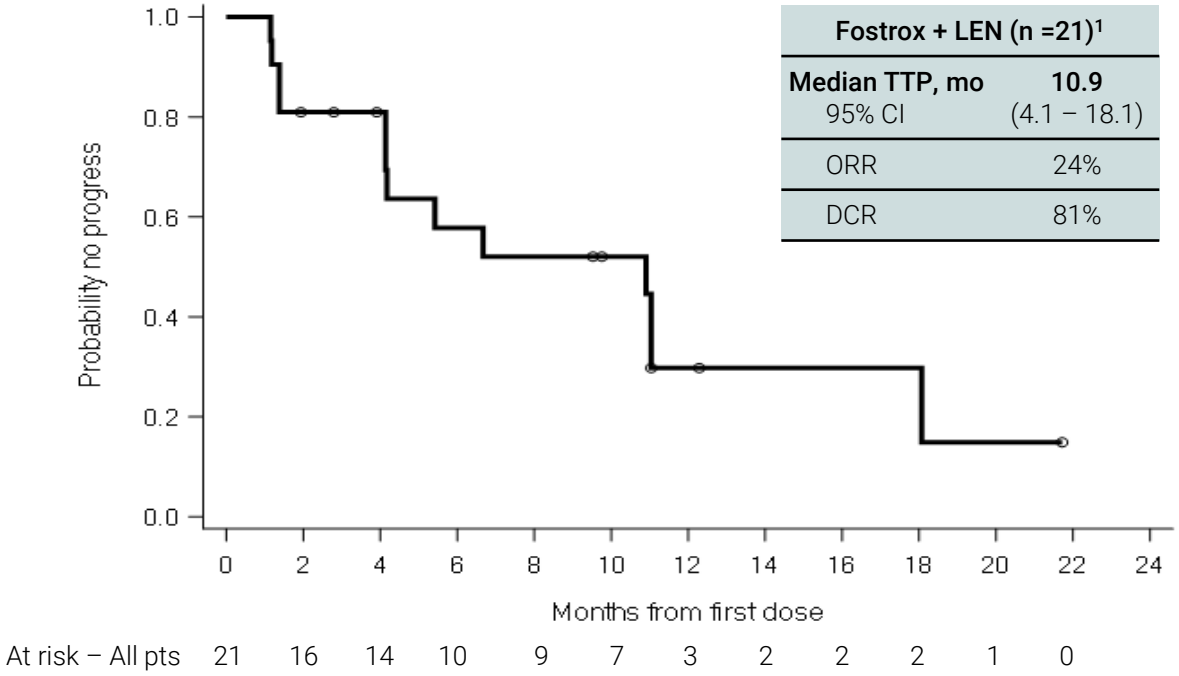
[1]Chon et al., ESMO 2024, Poster 986.

Median TTP 10.9 months, indicating substantially improved efficacy compared with Lenvima alone[1]

Median time to progression (TTP) with fostrox + LEN – investigator review, RECISTv1.1



Fostrox + LEN (n =21)[1]	
Median TTP, mo	**10.9**
95% CI	(4.1 – 18.1)
ORR	24%
DCR	81%

- Median time to progression 10.9 months
- Median follow-up of 10.5 months
- Longst running patient still on treatment after three years (Aug 2025)

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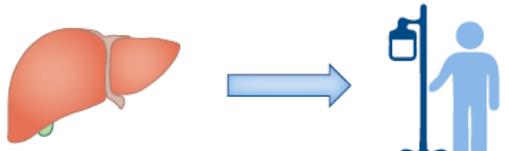
[1]Chon et al., ESMO 2024, Poster 986.

Korean Cancer Study Group prospective study data with Lenvima post Tecentriq + Avastin, aligns with other 2nd line outcome data

Second-line lenvatinib after atezolizumab-bevacizumab in advanced HCC

Study design

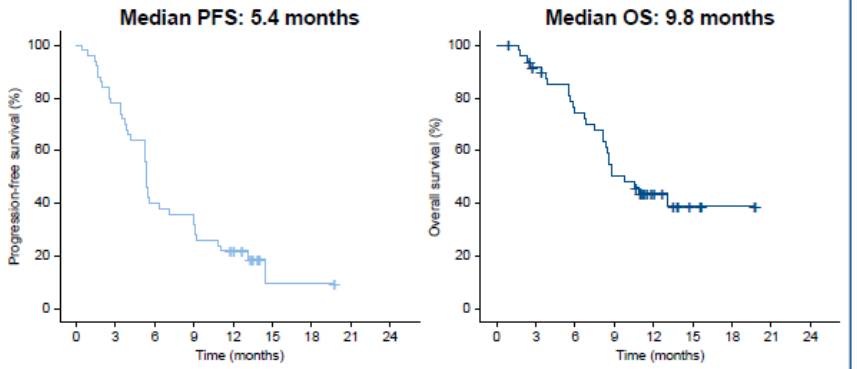
HCC progressed on 1st-line atezolizumab-bevacizumab



2nd-line lenvatinib

- **Investigator-initiated, multicenter, single-arm phase 2 study**
- **50 patients enrolled from 13 sites in Korea**
- **Primary end point:** PFS (>median 4.5 months)
- **Secondary endpoints:** OS, ORR, DCR, DoR, and safety.

Results



- **The most common AE were diarrhea (42.0%), hypothyroidism (32.0%), and anorexia (30.0%).**
- **Grade ≥3 AEs occurred in 46.0% of patients.**

Conclusion

- **Lenvatinib demonstrated promising efficacy and a manageable safety profile as a second-line treatment for patients with HCC progressing on atezolizumab-bevacizumab.**
- **These findings offer prospective evidence supporting lenvatinib as a viable treatment option in the post-atezolizumab-bevacizumab context.**

[1]Kim et al., Journal of Hepatology, Sept 04 2025

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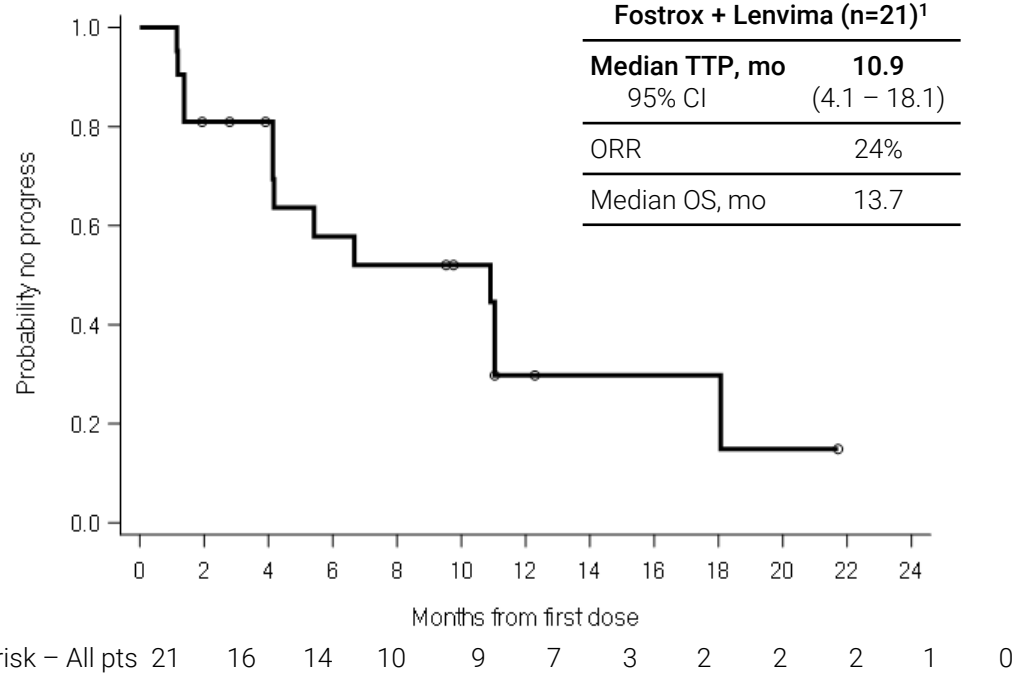
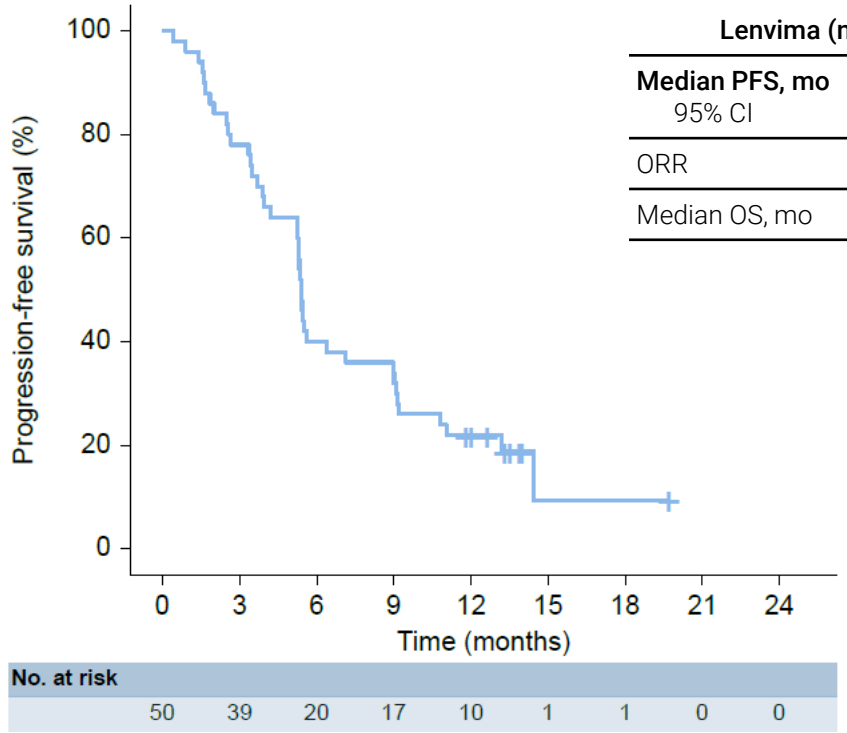
Fostrox + Lenvima phase 1b/2a data showed substantially better outcome data compared to the Lenvima montherapy study

Median TTP – Fostrox + Lenvima[1]



Fostrox + Lenvima (n=21)[1]	
Median TTP, mo 95% CI	**10.9** (4.1 – 18.1)
ORR	24%
Median OS, mo	13.7

Median PFS – Lenvima monotherapy[2]



Lenvima (n=50)[2]	
Median PFS, mo 95% CI	**5.4** (4.2 – 7.1)
ORR	14%
Median OS, mo	9.8

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[1]Chon et al., ESMO 2024, Poster 986
[2]Kim et al., Journal of Hepatology, Sept 04 2025

FLEX-HCC
Fostrox + Lenvatinib Combination for Advanced HCC

Primary Investigator

Dr. Hong Jae Chon

**CHA Bundang Hospital,
Seoul, Korea**

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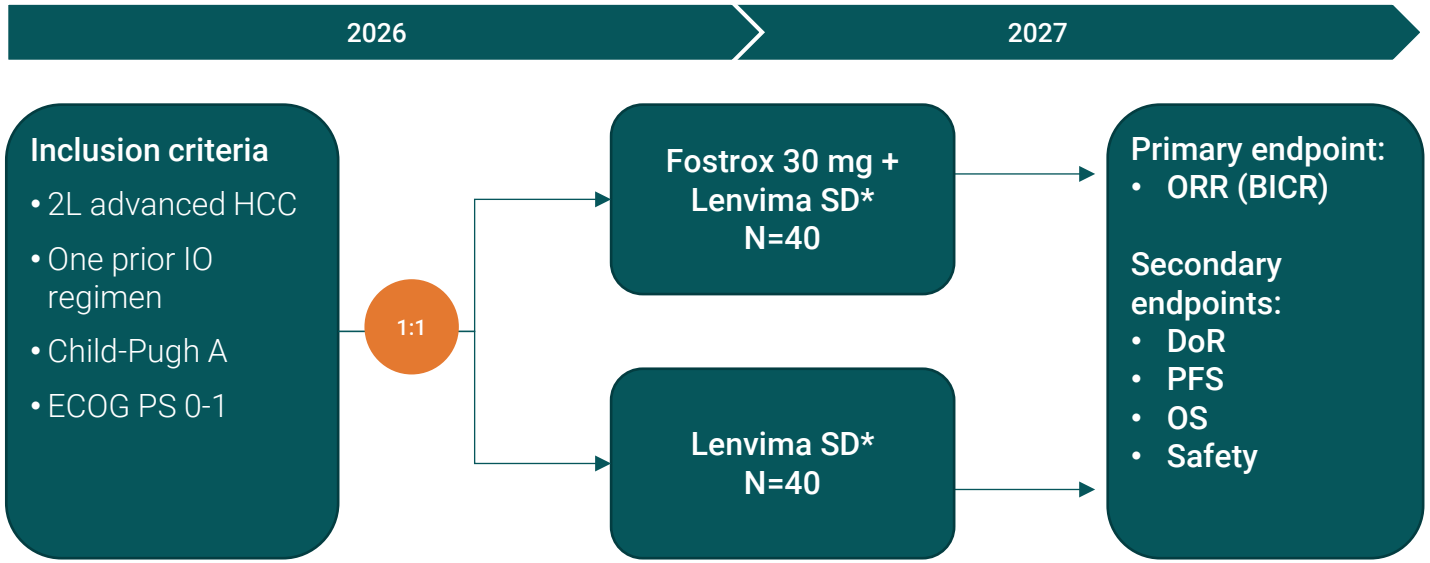
FLEX-HCC: Randomized, comparative phase 2 study to confirm benefit for fostrox + Lenvima combination in 2nd line HCC



*standard weight based dose in HCC

Response assessments every 6 week with CT or MRI

Study design:

- 80 pts randomized: Fostrox + Lenvima vs Lenvima
- 8 sites in Korean Cancer Study Group
- Enrolment: 12 months
- Primary endpoint FU: 3-6 months
- Efficacy evaluated by Blinded Independent Central Review (BICR)

Key benefits:

- Generates robust comparative efficacy and safety data in collaboration with established research consortium
- Enables rapid data read out
- Strengthens design of registrational study

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 thar 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

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Fostrox (fostroxacitabine bralpamide)
The first oral, liver-targeted treatment tailored for HCC

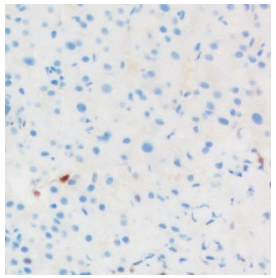
Oral, liver-activated small molecule inducing DNA damage in tumor cells, sparing healthy liver cells[3]

Unique, liver-targeted approach in HCC

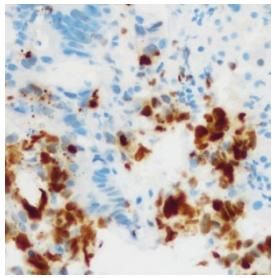
Liver-guided delivery – prodrug

Tumor-selective payload – troxacitabine

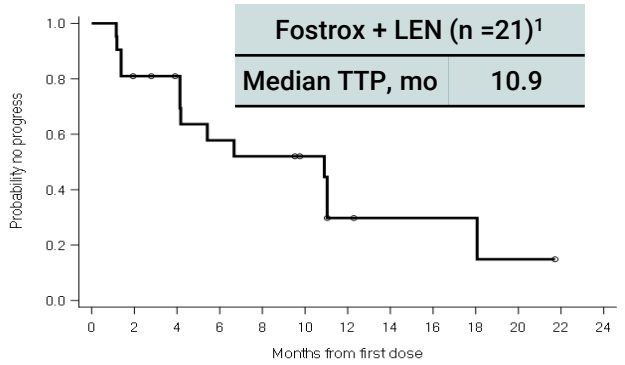
No DNA damage in healthy liver tissue



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
- FLEX-HCC Phase 2 designed to rapidly confirm comparative benefit of fostrox in combination with Lenvima

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 US[4]

Significant upside in liver metastasis from other solid tumors

[1]Chon et al., ESMO, 2024, Poster 986
[2]Based on data from previous 2L phase 3 HCC studies with Stivarga, Cyramza & Cabometyx and investigator initiated prospective & retrospective 2L studies with Lenvatinib
[3]Evans et al ASCO GI, 2021
[4]Ma et al., Cancer, June 15, 2019; 2089-2098

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Thank You!