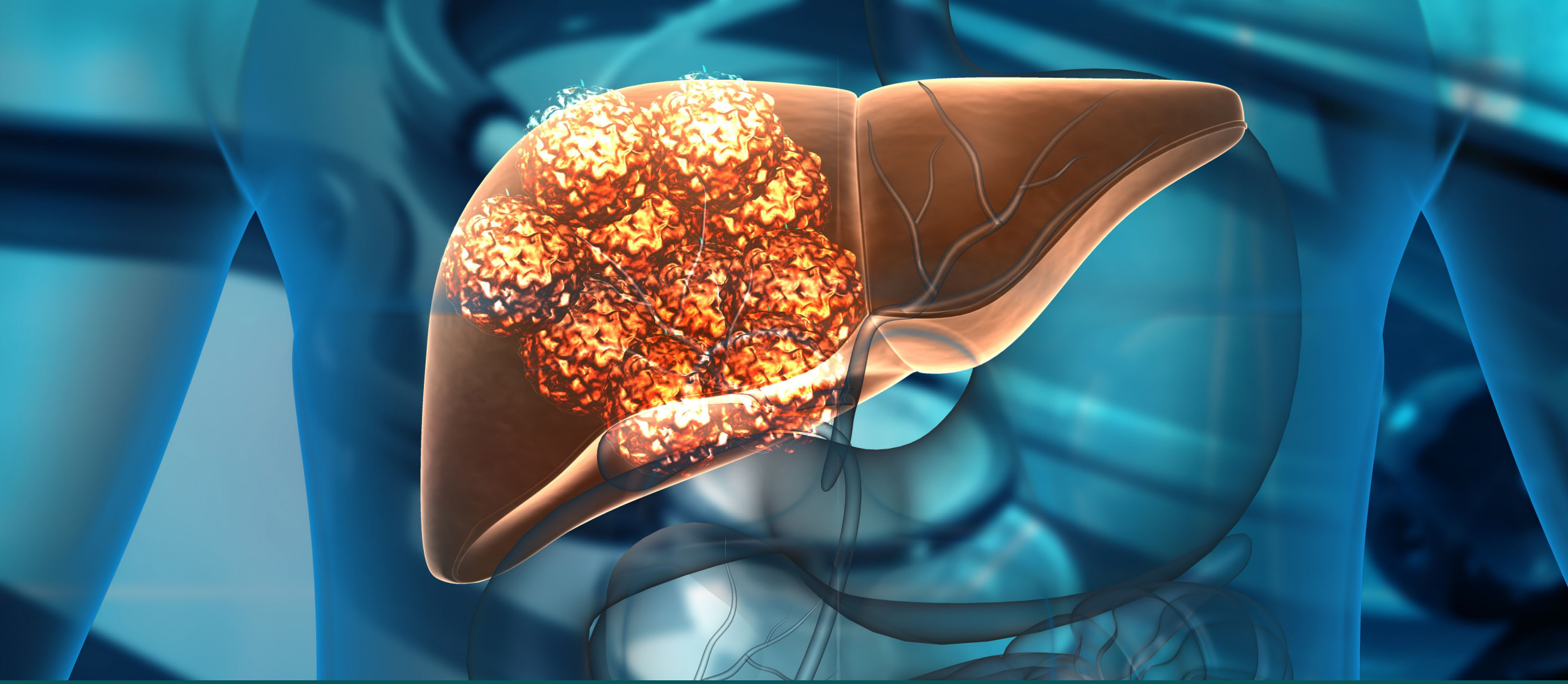
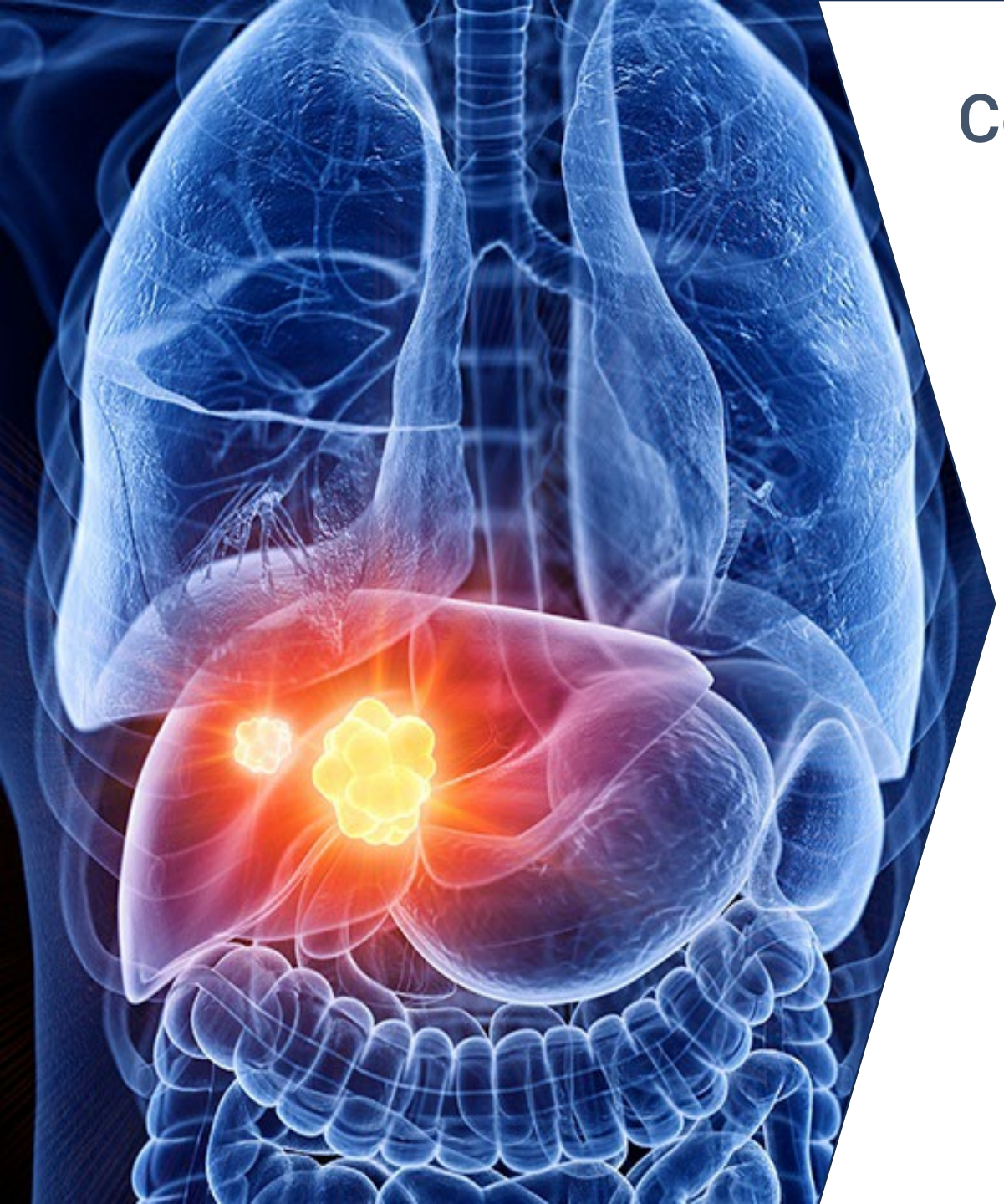


Improving life for advanced liver cancer (HCC) patients

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

MEDIVIR



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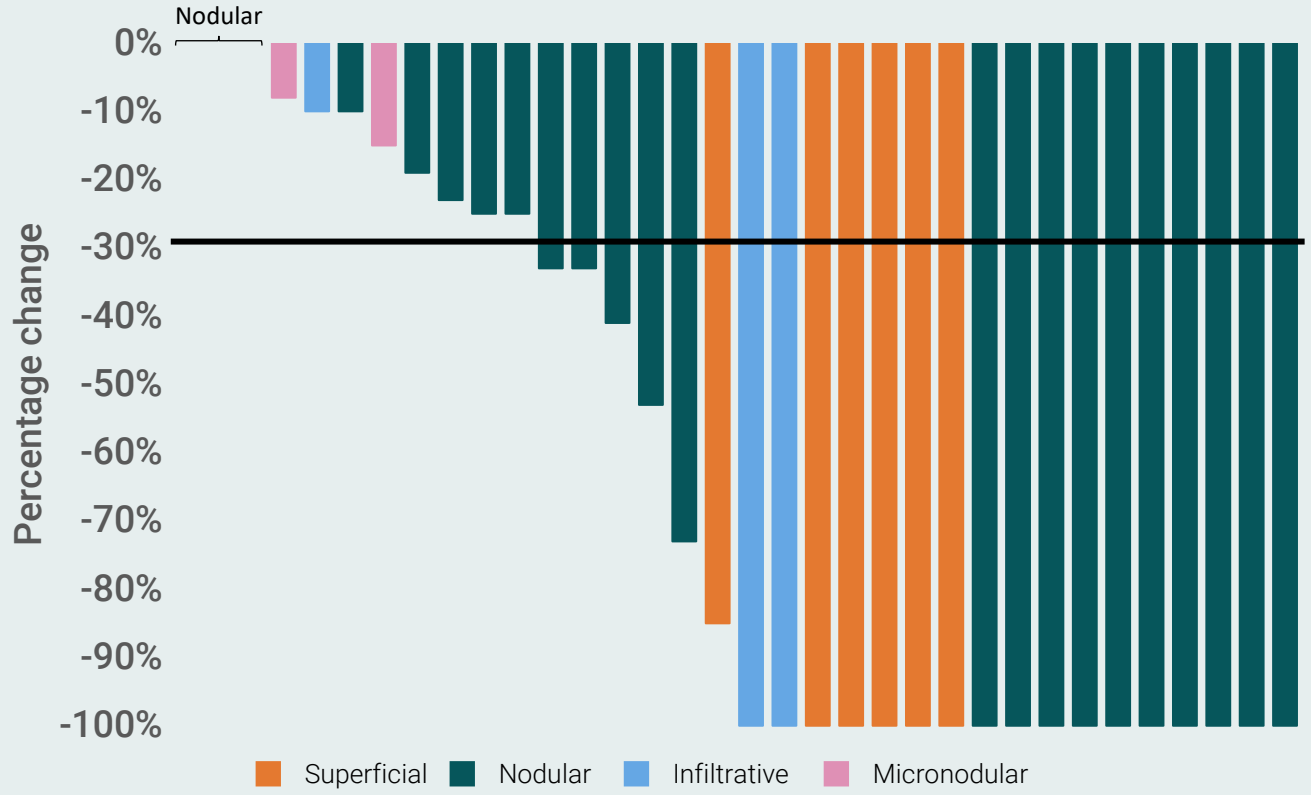
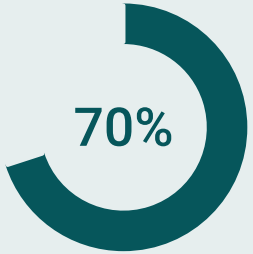
Remetinostat is an effective topical treatment for reducing BCC disease burden in a clinically significant manner

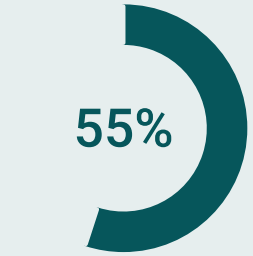
Encouraging efficacy across all subtypes of BCC lesions



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



Overall response rate

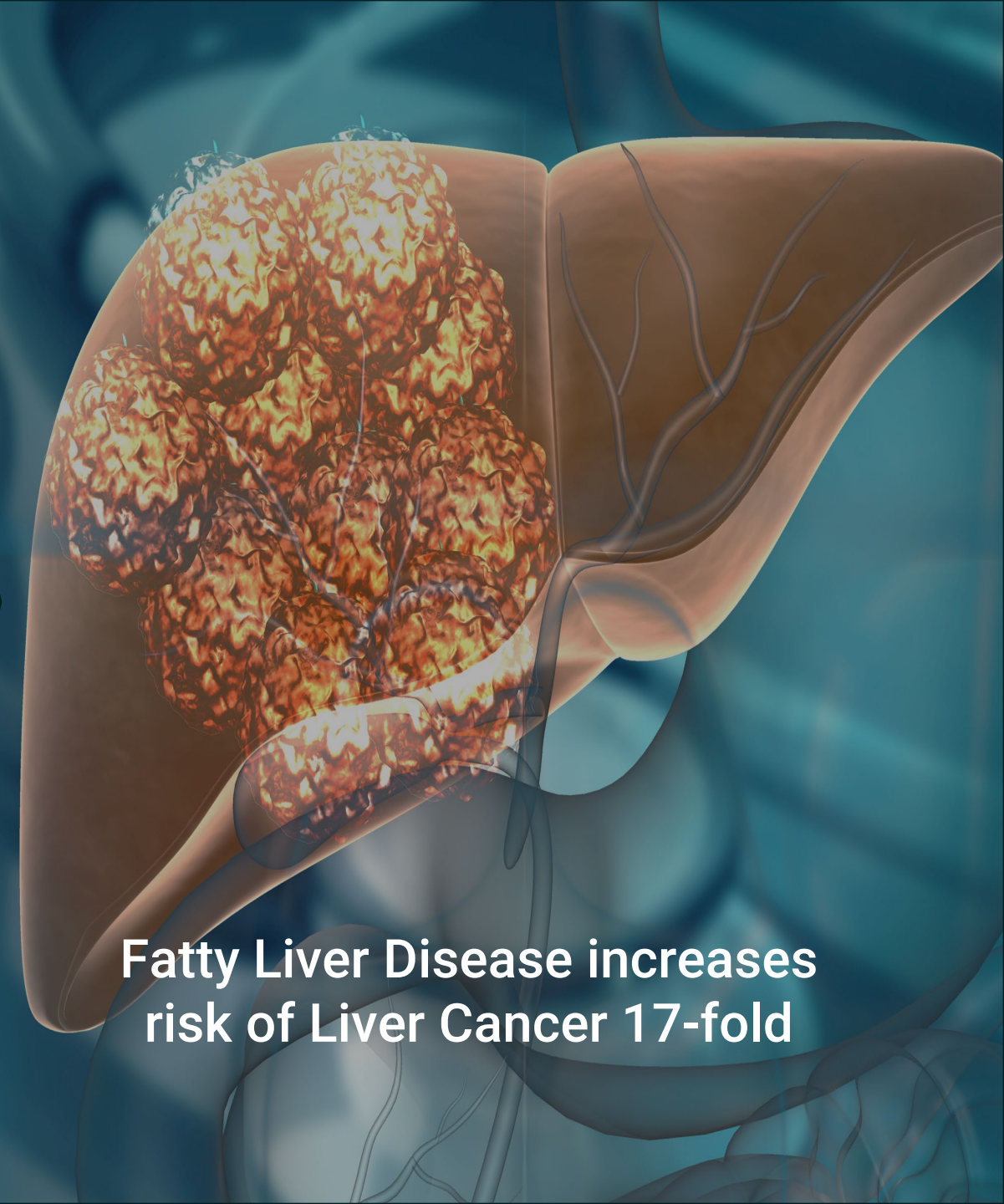


Complete pathological resolution

MEDIVIR

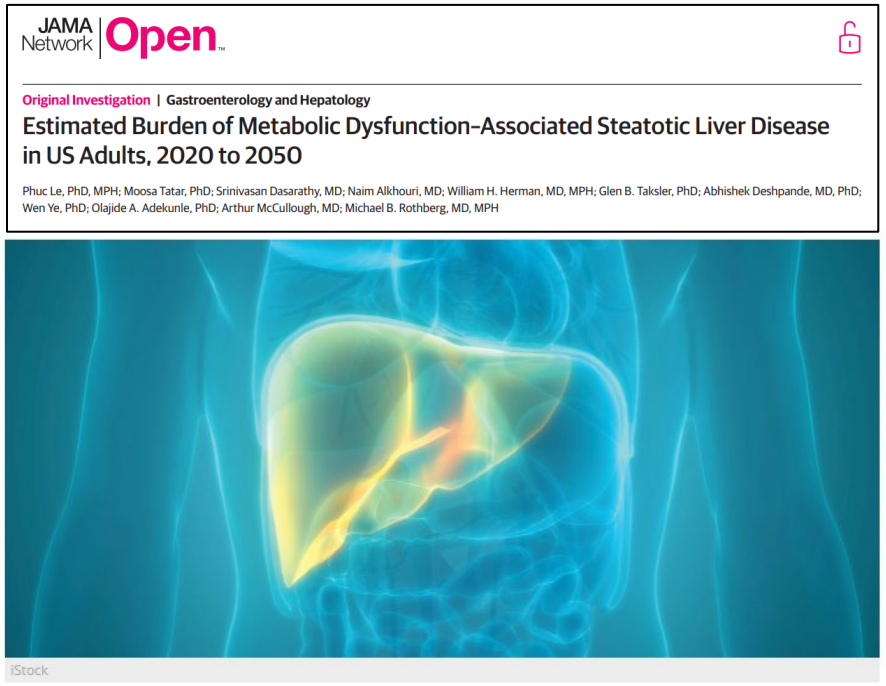
[1]J. Kilgour et al, Clinical Cancer Research published online 6 August 2021

45% of US adults are obese
More than 25% have Fatty Liver Disease



Fatty Liver Disease increases
risk of Liver Cancer 17-fold

Growth in Fatty Liver Disease expected to drive an alarming increase in liver cancer cases[1]



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 Alkhouri, 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

iStock

SCIENCE NEWS

Fatty Liver Disease Is Expected to Skyrocket By 2050

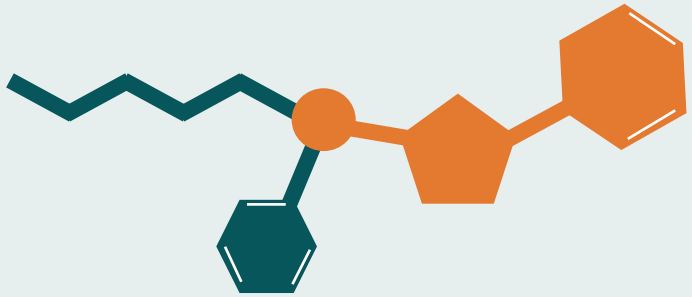
A model predicts the rise in MASLD and MASH will drive an alarming increase in liver failure, liver cancer and liver transplants.

- 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

[1]JAMA Network Open. 2025;8(1):e2454707

Fostrox – designed to selectively kill tumor cells in the liver

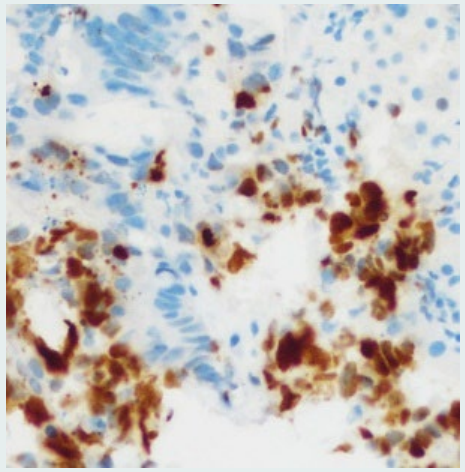
Prodrug transports inactive payload to the liver, where it is rapidly activated by liver enzymes[1]



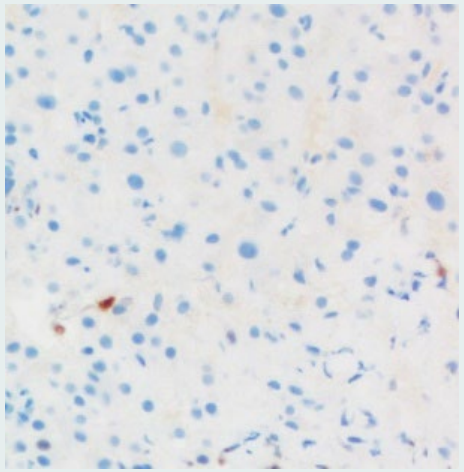
Liver-guided delivery – prodrug

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

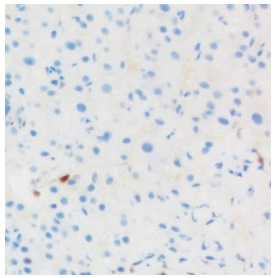
Oral, liver-activated small molecule inducing DNA damage in tumor cells, sparing healthy liver cells[3]

Unique, liver-targeted approach in HCC

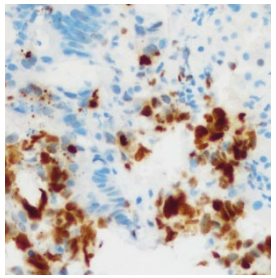
Liver-guided delivery – prodrug

Tumor-selective payload – troxacitabine

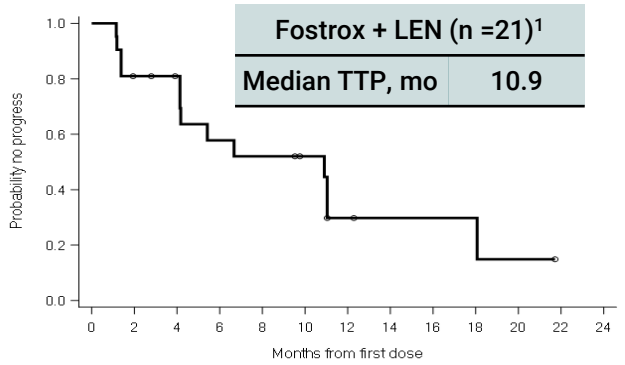
No DNA damage in healthy liver tissue

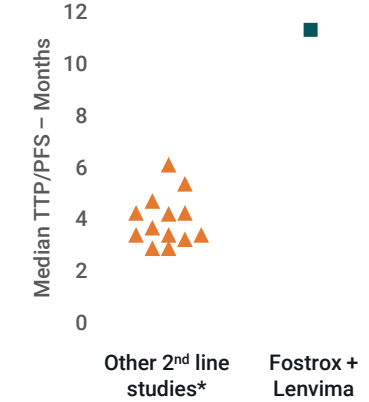


DNA damage in tumor tissue



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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Medivir management team

CEO
Jens Lindberg

- > 25 years of experience from pharmaceutical industry with focus on late-stage development & commercialization in Oncology of drugs like Tagrisso, Lynparza, Imfinzi and Iressa
- Other experience includes interim CEO for Sedana Medical AB and Director Investor Relations at AstraZeneca.
- Member of the Board of Braincool AB.

CMO
Dr. Pia Baumann

- MD PhD with a specialist degree in medical & radiation oncology at Karolinska Institute/University hospital.
- Substantial experience in drug development in the cancer field.
- > 25 years of clinical work at Karolinska and pharmaceutical/ biotech companies, including AstraZeneca, BMS, Takeda, Incyte and ARIAD

CFO
Magnus Christensen

- > 25 years of experience in finance.
- Interim CEO at Medivir, May 2021-January 2022.
- Former CFO at O'Learys Trademark AB.
- Experience of working in listed-, private equity- and private companies.
- Member of the Board of PMD Device Solutions AB.

CSO
Fredrik Öberg

- PhD in Medical Science & Adjunct professor at the Medical Faculty of Uppsala University.
- > 25 years of experience in cancer research.
- During the last 10 years focused on industrial drug discovery and development projects in oncology.
- He has published more than 50 scientific articles and holds several patents.

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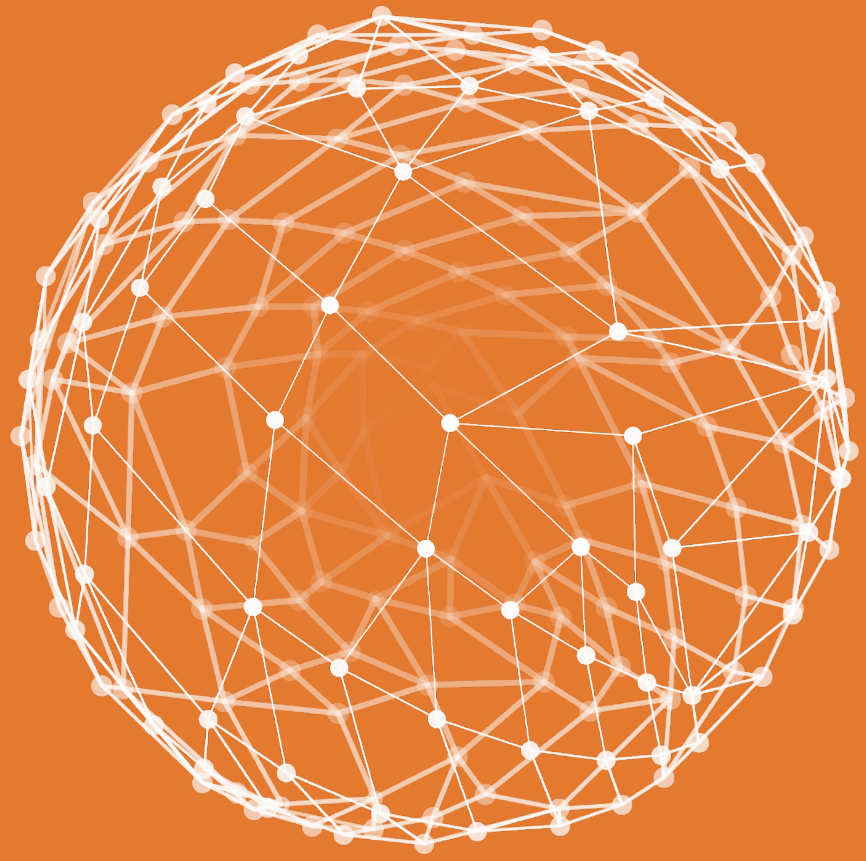
First-to-market opportunity in 2nd line HCC market valued >$2.5bn



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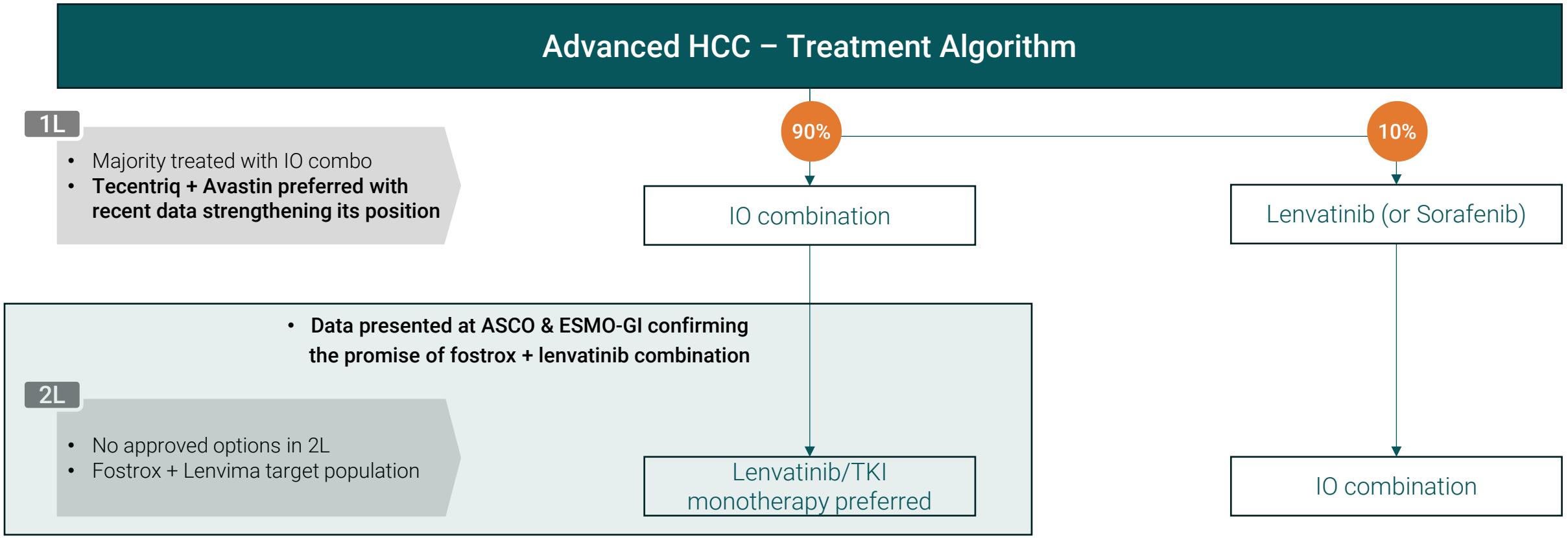
Fostrox + Lenvima targets 2L population where no treatments are approved today



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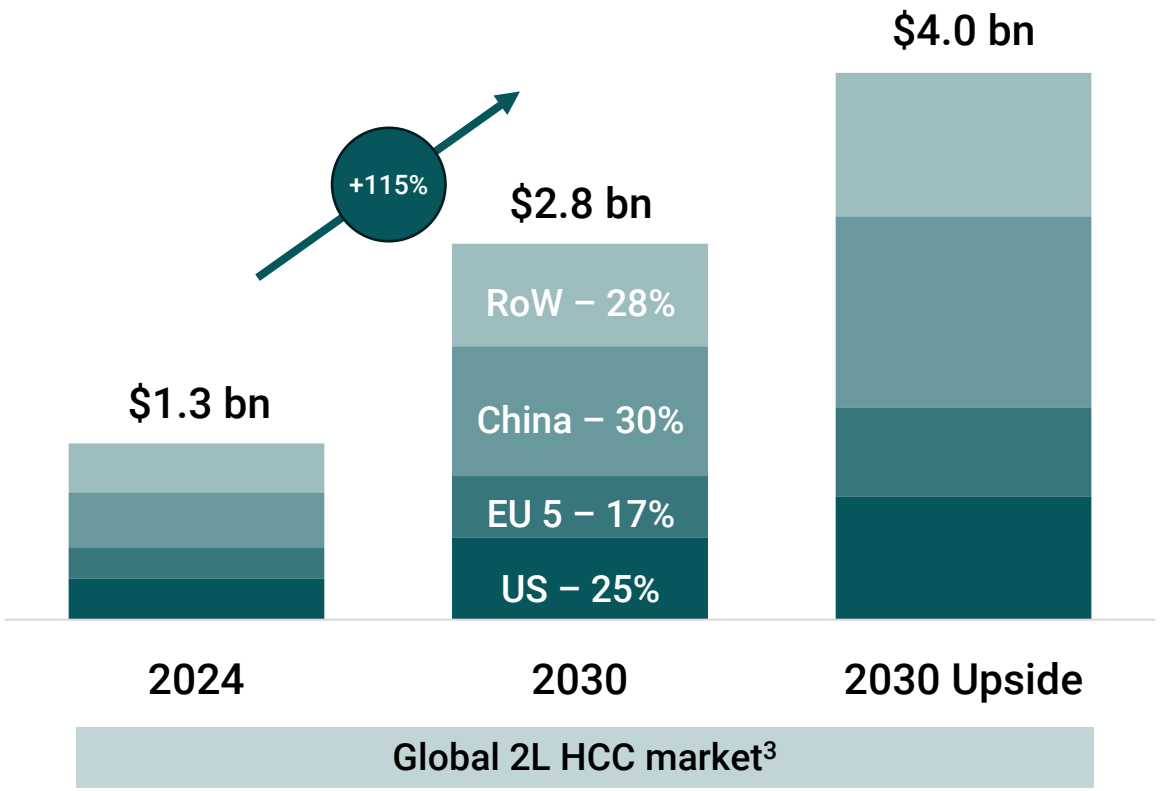
2nd line HCC – a large and growing commercial opportunity with significant need for new treatment options[3]



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%**
- 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

[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

Absence of effective treatment options in 2nd line HCC

Treatment algorithm – major need for new 2nd line options

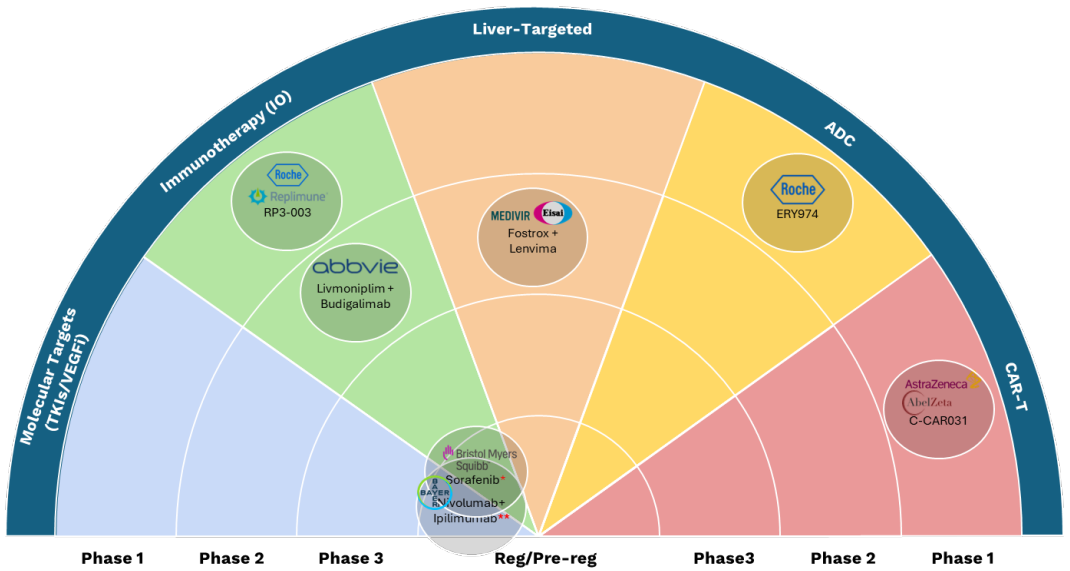
1st line treatment

- **IO combinations Standard of Care** – Tecentriq + Avastin
- Numerous studies ongoing evaluating various other IO combinations

2nd line treatment

- **No approvals or scientific evidence** to support treatment choice in 2nd line
- Few ongoing studies in 2nd line

Competitive landscape in 2nd line HCC highlights lack of novel mechanisms in development with fostrox + Lenvima at the forefront



"We are becoming greedy, trying to have 8 different regimens in the 1L setting and none of us know what to do after.

If I had my way, the focus should really be on 2L treatment and beyond"

Rachna T Schroff, University of Arizona Cancer Center
Late Breaking Abstract session at ESMO, September 2024

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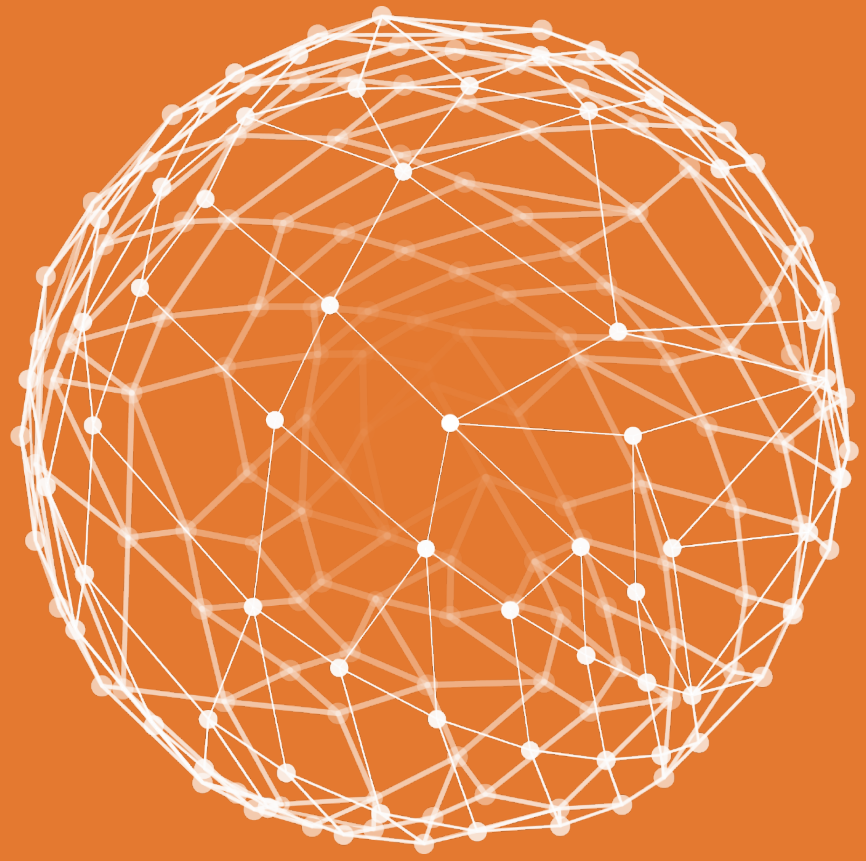
*Sorafenib was the first approved 1st-line treatment for HCC. Although approved for 2nd-line use, guidelines recommend against it due to a lack of evidence showing efficacy after immunotherapy combinations.
**Nivolumab + Ipilimumab were approved for patients post-sorafenib but are now moving into 1st line HCC treatment (positive phase III, awaiting approval (source)).

Fostrox – tailored for the specific needs of HCC



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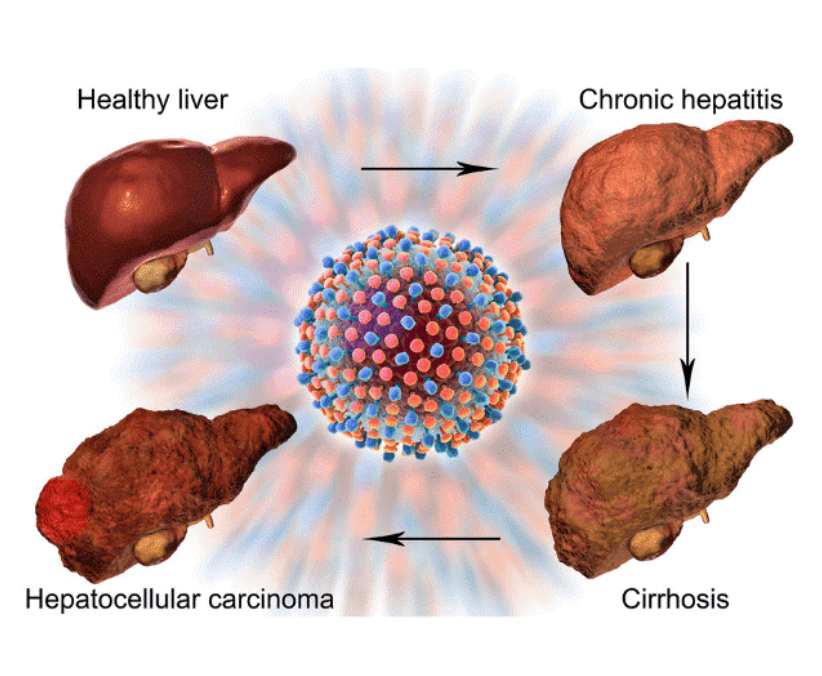
Targeted treatment approach critical in liver cancer (HCC)



~80% of patients have impaired liver function due to underlying liver disease[1,2]

Key objective – target cancer cells, minimize effects on healthy cells

Tumor growth primarily occurs locally in the liver[1]

Critical to achieve selective targeting of tumor cells while sparing healthy cells

[1] Senthilnathan et al., Hepatology, 2012 May; 55(5): 1432-1442
[2] Llovet et al., Nature Reviews Gastroenterology & Hepatology, Vol 20, Aug 2023, 487-503

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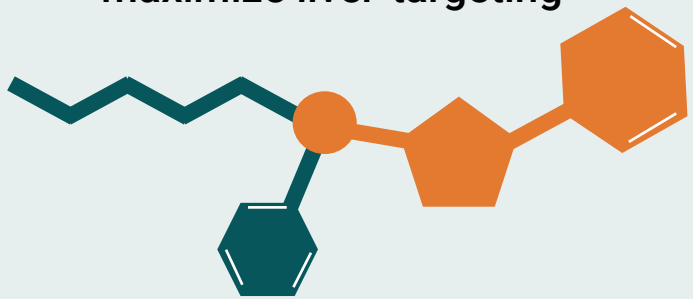
Fostrox – tailored for HCC to achieve targeted DNA damage in liver tumor cells with minimal impact on healthy liver cells

The same, proven & highly successful approach used in HCV to maximize liver-targeting[2]



Liver-guided delivery – prodrug

Tumor-selective payload – troxacitabine

- **Combining prodrug & payload enables oral administration & targeted (>100-fold) liver exposure vs IV chemotherapy[1]**
- **Molecule stable in GI tract & in blood, rapidly activated by enzymes in the liver[2]**
- **Payload selected as it causes DNA damage selectively in liver tumor cells, sparing healthy liver cells[3,4,5]**

[1]Bethell, R. et al , SAT-123, EASL 2017
[2]Bethell, R. et al P-035, ILCA 2016
[3]Kukhanova, M et al J Biol Chem 1995
[4]Albertella, M. et al EASL Summit P01-05, 2018
[5]Öberg F. et al, EASL PO-221, 2022

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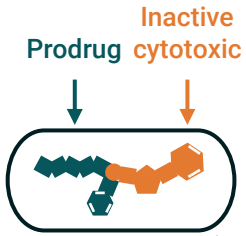
Fostrox MoA – tailored for HCC to achieve targeted DNA damage in liver tumor cells with minimal impact on healthy liver cells



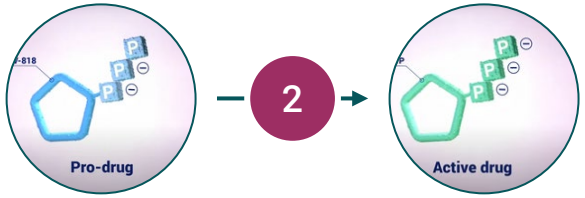
Fostrox taken as oral tablet

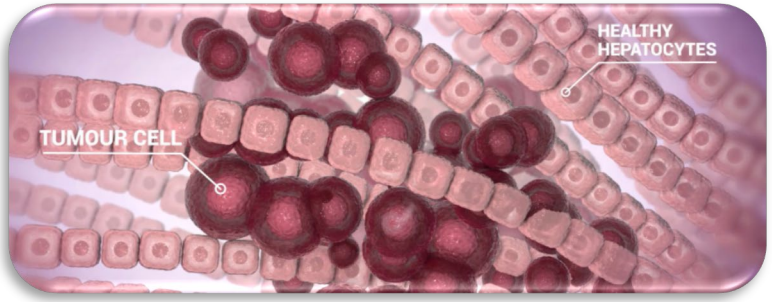
Prodrug transports inactive payload via first-pass metabolism to the liver[1]

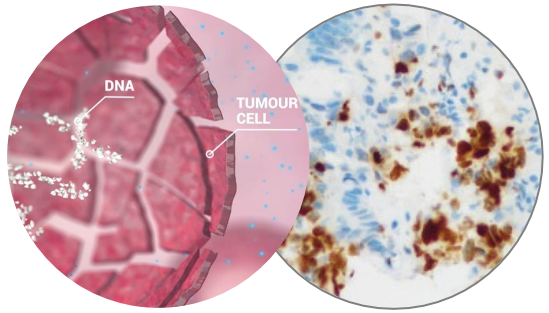
Mechanism of Action video

Rapidly activated by liver enzymes

Trapped inside liver cells for maximum liver exposure and minimal systemic spread[2,3,4]

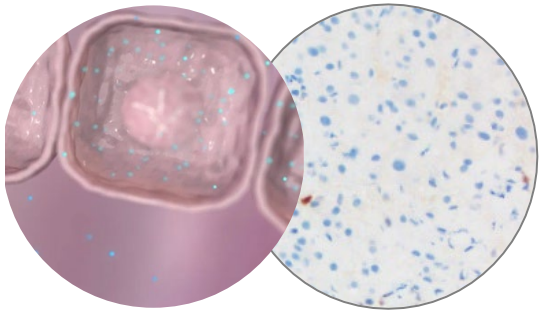






Cell death in tumor cells

Causes selective cell killing effect in tumor cells, sparing healthy liver cells as they very rarely divide[2,3,4]



No impact on healthy cells

[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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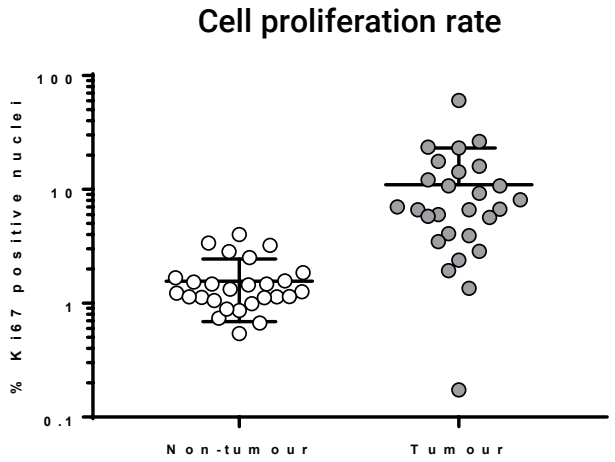
100-fold higher liver targeting vs IV administration & selective DNA damage in tumor cells enabling highly targeted mechanism

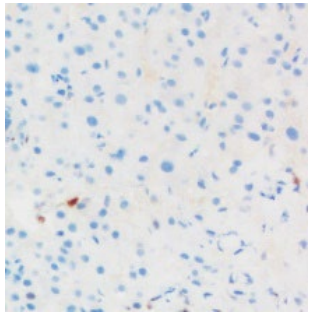
>100-fold higher liver targeting with fostrox than iv troxacitabine in rats

Compound	Route	Dose (µmol/kg)	AUC_{Liver} (nmol*h/g)	AUC_{Plasma} (µmol*h/L)	AUC ratio (Liver/ Plasma)
Troxa-citabine	*iv*	80	<1.2	80	**<0.016**
Fostrox	*oral*	80	10	5.4	**1.9**

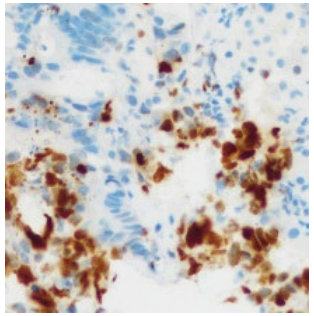
Liver tumor cells divide significantly more often than non-tumor cells[1]



Fostrox induces DNA damage in tumor cells, sparing normal liver tissue[2]



Normal liver tissue*



Tumor tissue*

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

[1]Albertella, M. et al EASL Summit P01-05, 2017
[2]Öberg F. et al, EASL PO-221, 2022
*Induced DNA damage indicated by pH2AX IHC staining (brown color) in patient biopsies

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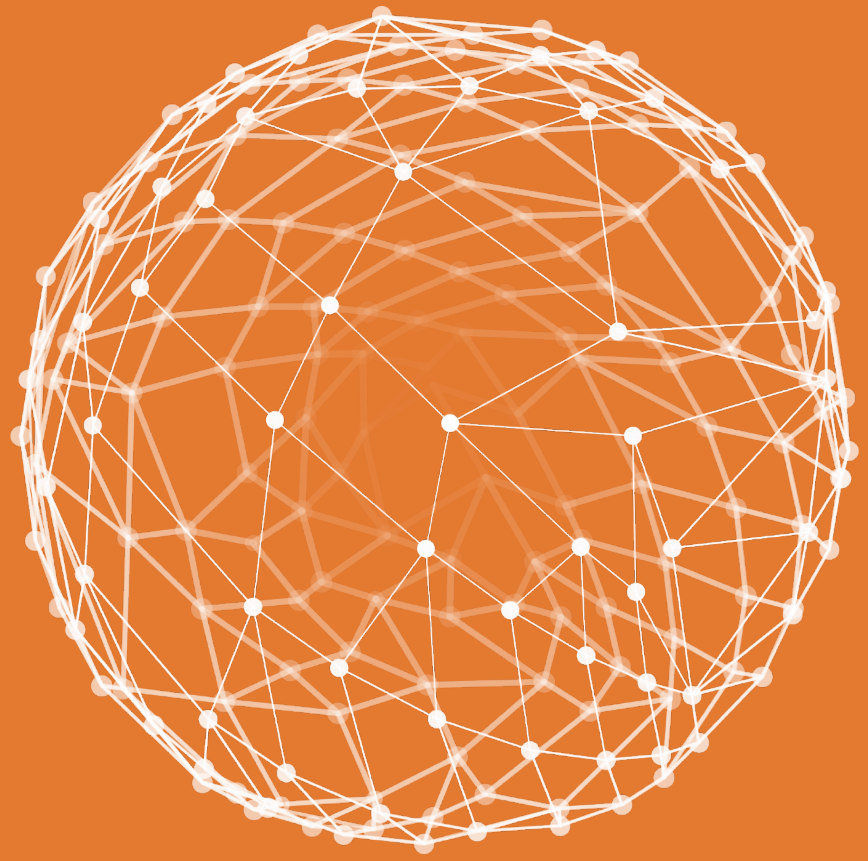
Fostrox + Lenvima shows promise of improved outcomes in 2L HCC



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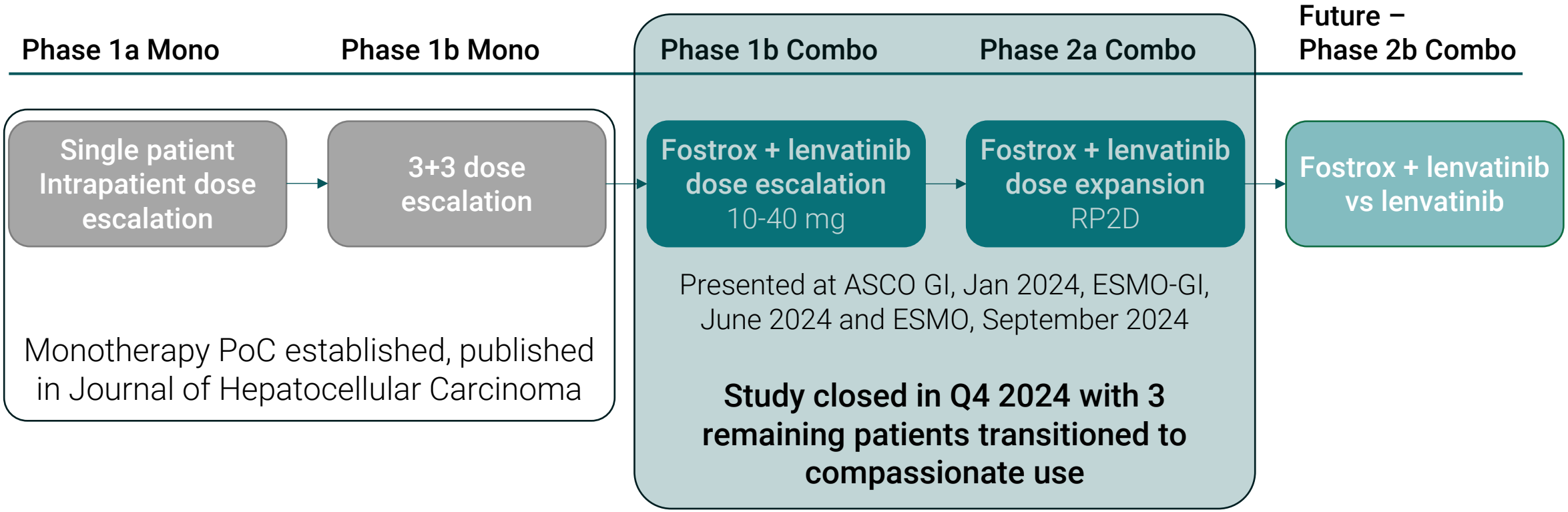
Fostrox Clinical Development Program; monotherapy PoC established, focus on combination approach in 2L HCC



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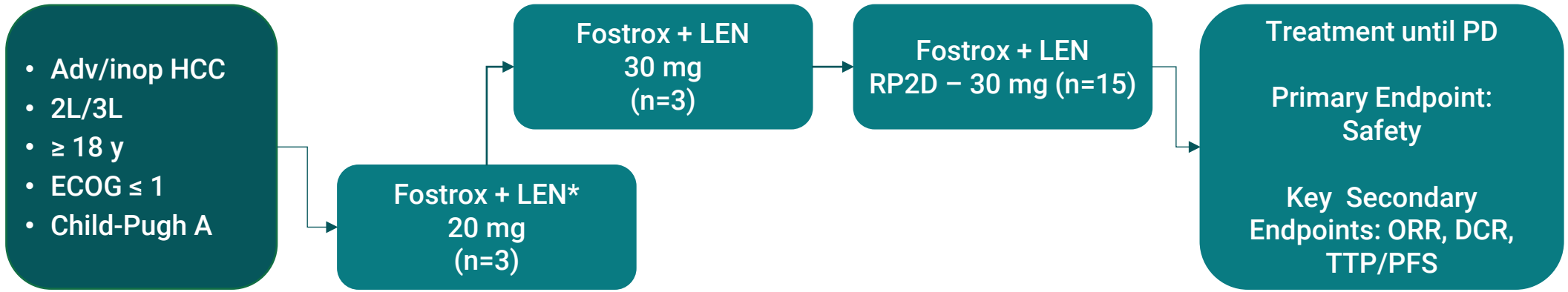
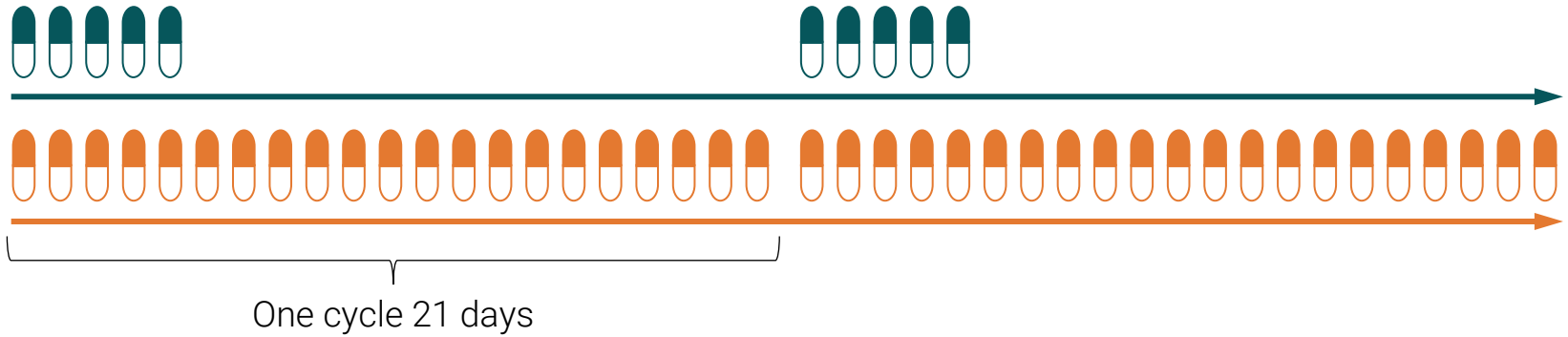
Fostrox + Lenvima phase 1b/2a study design



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

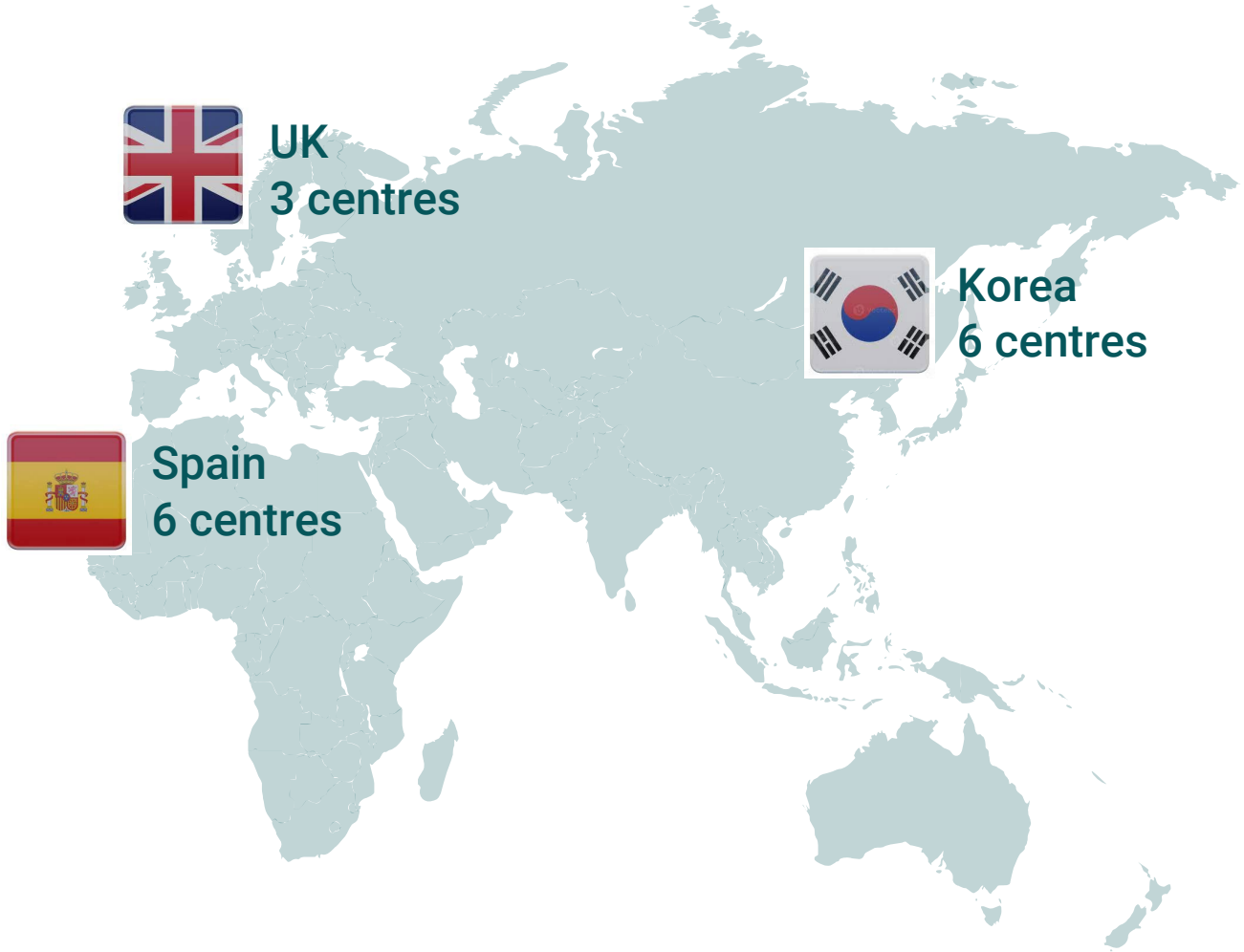
LEN: Oral QD continuous
(8 or 12 mg)



MEDIVIR

*LEN = lenvatinib

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

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.

Reference

1. Bethell, R. et al 2017, EASL International Liver Congress, Poster SAT-123 (www.medivir.com/media/7196/liver-targeting-with-the-novel-nucleoside-prodrug-troxacitabine.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), opaque decline daily (QD), alfa feto protein (AFP), overall survival (OS)

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Patient characteristics reflecting generous inclusion criteria

Patient characteristics[1]	N = 21
Mean age (range)	62 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 (%)**	45 / 55
Region, Asia / Europ (%)	67 / 33
Prior treatment lines; 2nd line/3rd line (%)	81 /19
Prior atezolizumab/bevacizumab in 1L (%)	86
Prior local therapy (TACE, RFA etc)	70
PD on prior treatment (%)	100
Primary refractory on prior therapy (%)***	24
Starting dose fostrox, 20mg / 30mg (%)	14 / 86

*HepB-81% and HepC-19%; **AFP- NA for 1 pt; ***Active treatment ≤ 12 weeks. Data NA for 3 patients

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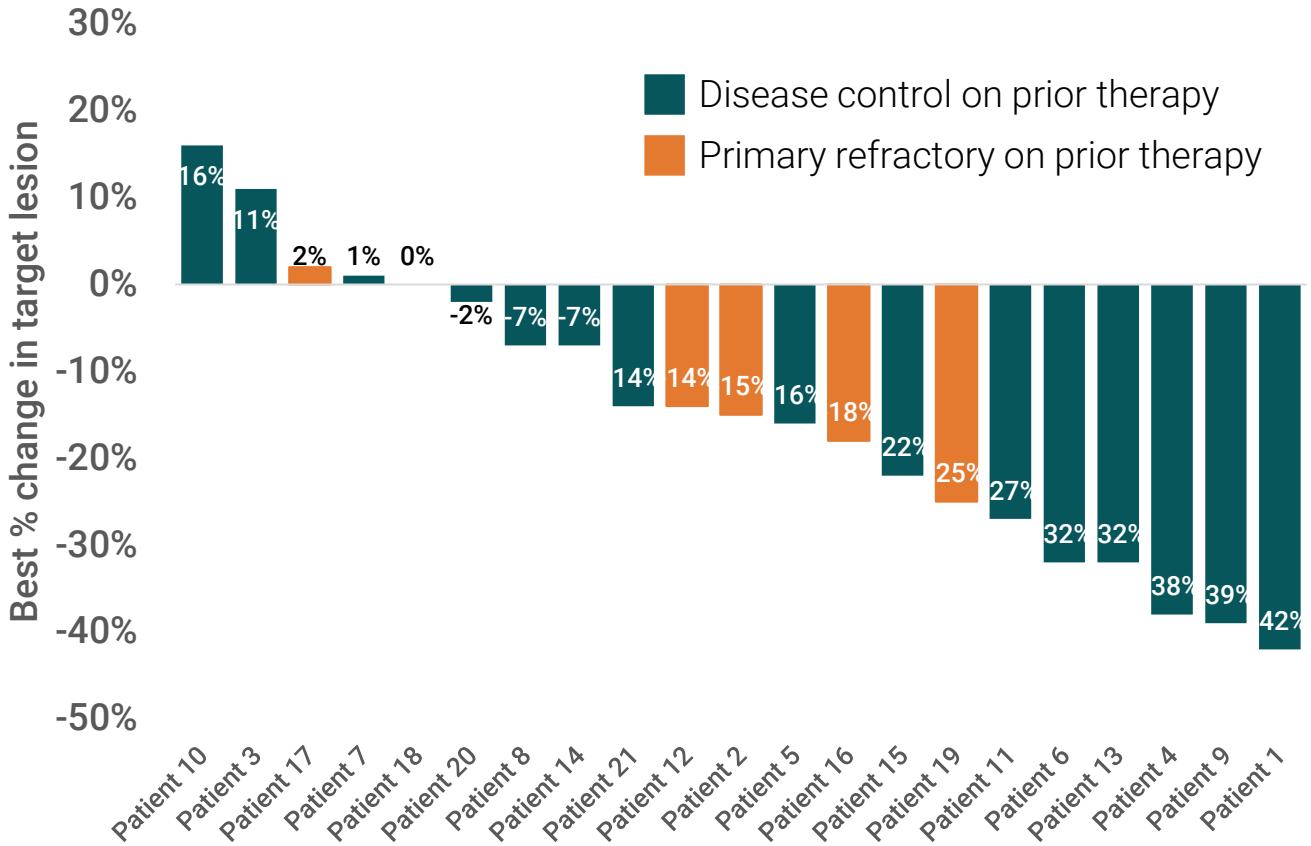
[1]Chon et al., ESMO 2024, Poster 986.

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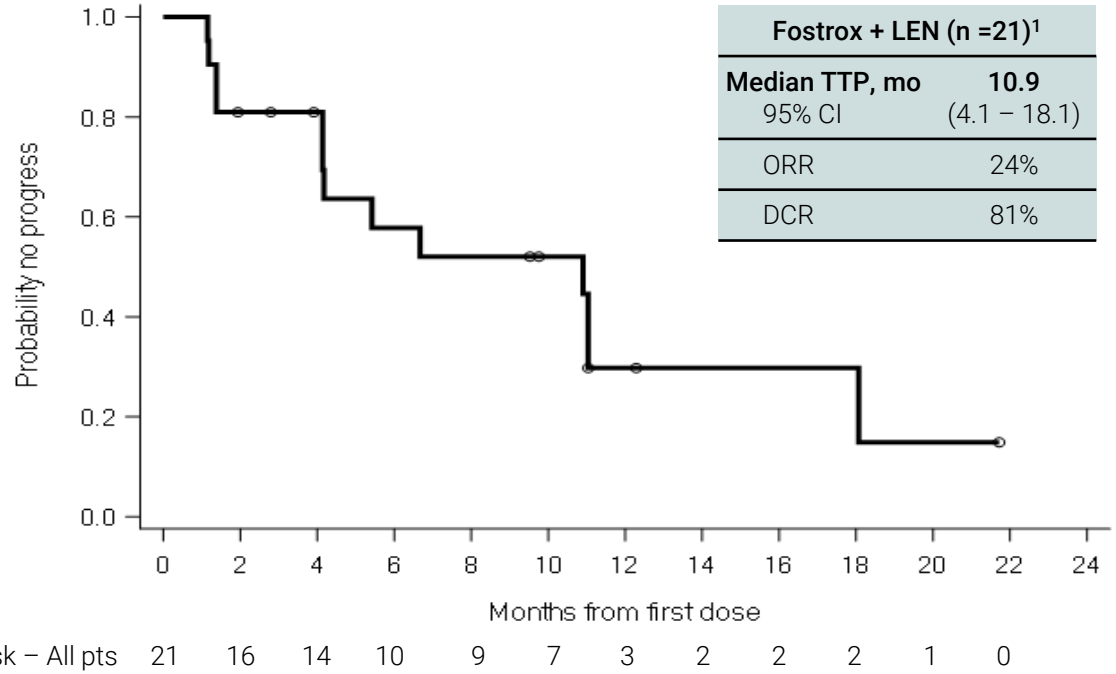
[1]Chon et al., ESMO 2024, Poster 986.

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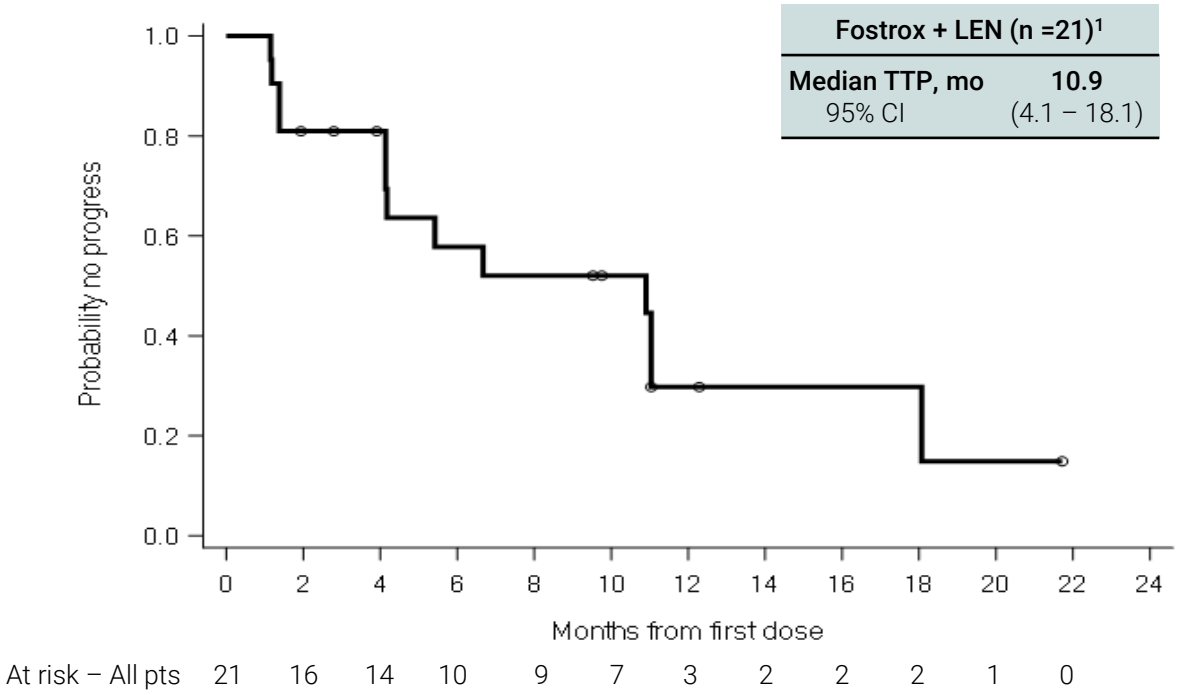
[1]Chon et al., ESMO 2024, Poster 986.

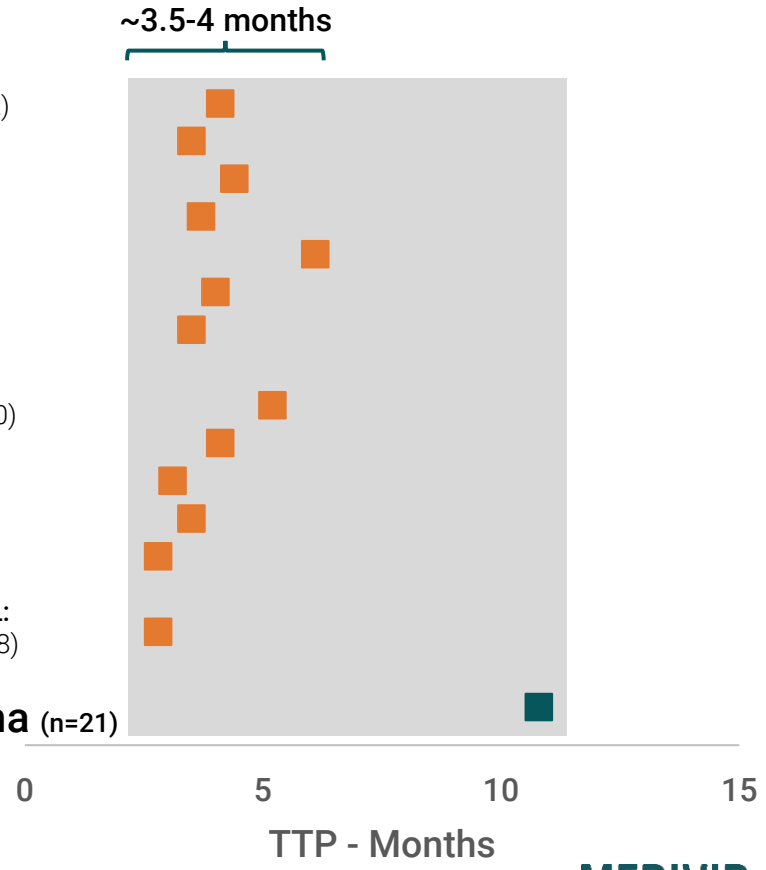
Median time to progression (TTP) 10.9 months, remarkably longer than Lenvima monotherapy and other 2L HCC treatments

Median TTP (Kaplan-Meier) with fostrox + Lenvima



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

Median TTP/PFS vs previous studies in 2L HCC



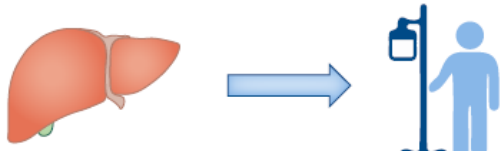
[1]Chon et al., ESMO 2024, Poster 986.

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

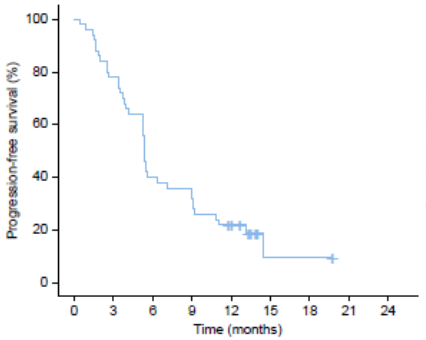


2nd-line lenvatinib

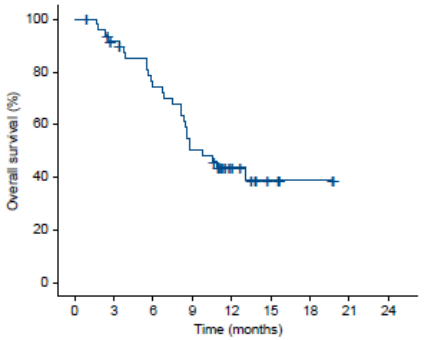
- **Investigator-initiated, multicenter, single-arm phase 2 study**
- **50 patients enrolled from 13 sites in Korea**
- **Primary end point:** PFS (>median 4.5 months)
- **Secondary endpoints:** OS, ORR, DCR, DoR, and safety.

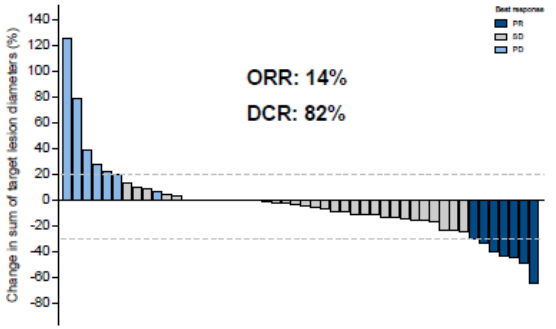
Results

Median PFS: 5.4 months



Median OS: 9.8 months





ORR: 14%

DCR: 82%

- **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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Similar patient characteristics across the Lenvima monotherapy study and the Phase 1b/2a fostrox + Lenvima study

Patient characteristics	N = 50 Lenvima monotherapy 13 sites in Korea[1]	N = 21 Fostrox + Lenvima 15 sites in Korea, UK & Spain[2]
Mean age (range)	66 (32-86)	62 yrs (42 - 82)
Gender, Female / Male (%)	18 / 82	24 / 76
Child-Pugh A (%)	100	100
BCLC stage A/B or C (%)	12 / 88	0 / 100
Viral/Non-viral (%)	72 / 28	76* / 24
AFP ≥400 ng/mL at baseline Y/N (%)**	44 / 56	48 / 52
Region, Asia / Europe (%)	100 / 0	67 / 33
Prior treatment lines; 2nd line/3rd line (%)	100 / 0	81 /19
Prior atezolizumab/bevacizumab in 1st line (%)	100	86
Prior TACE therapy (%)	58	70

*HepB-81% and HepC-19%; **AFP- NA for 1 pt

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

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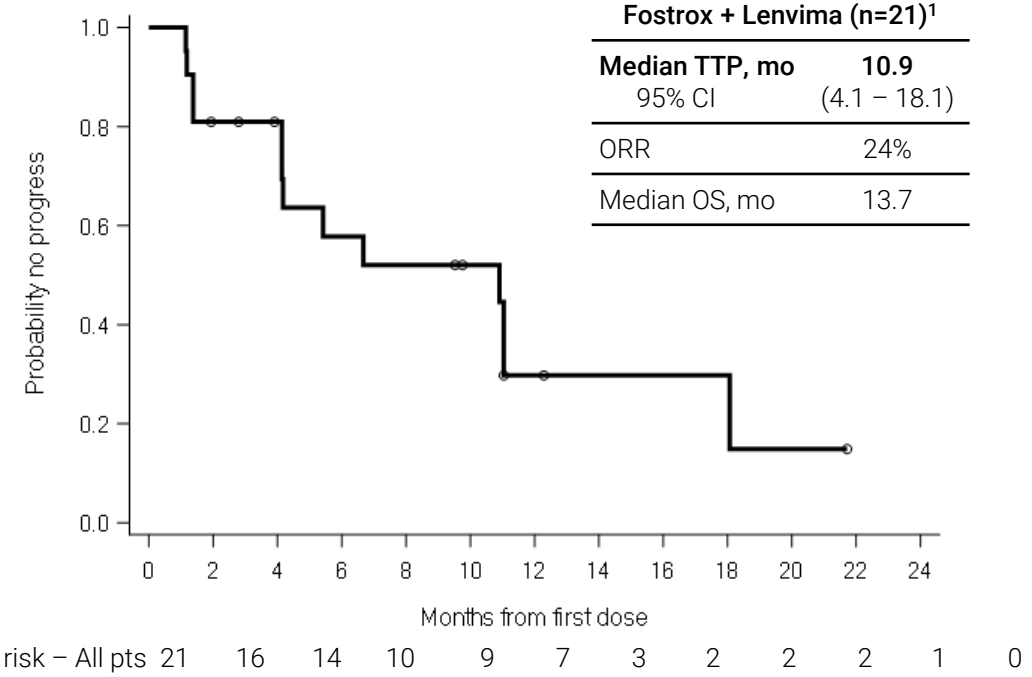
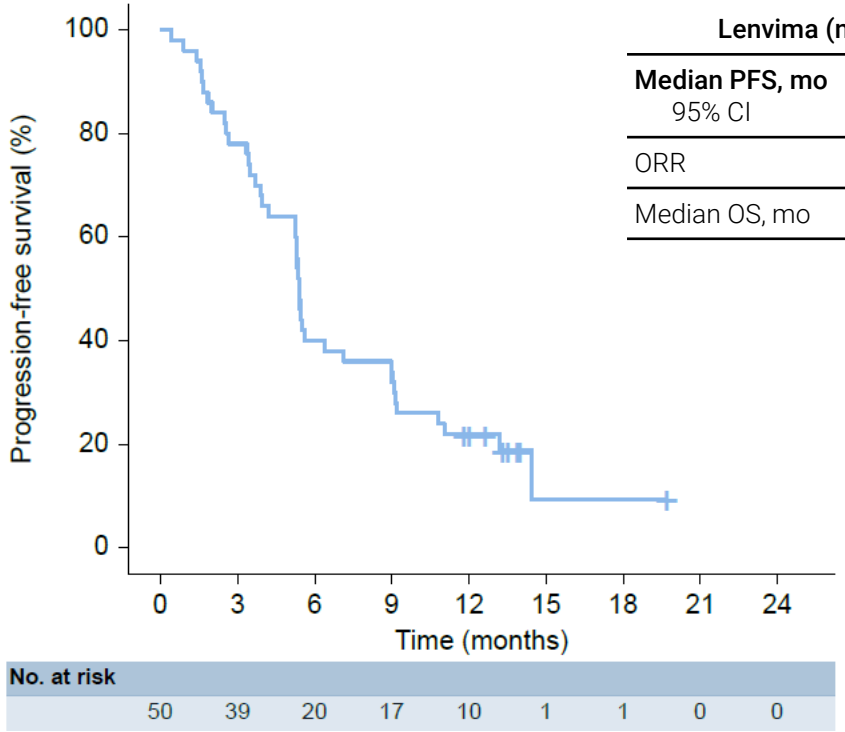
Fostrox + Lenvima phase 1b/2a data showed substantially better outcome data compared to the Lenvima montherapy study

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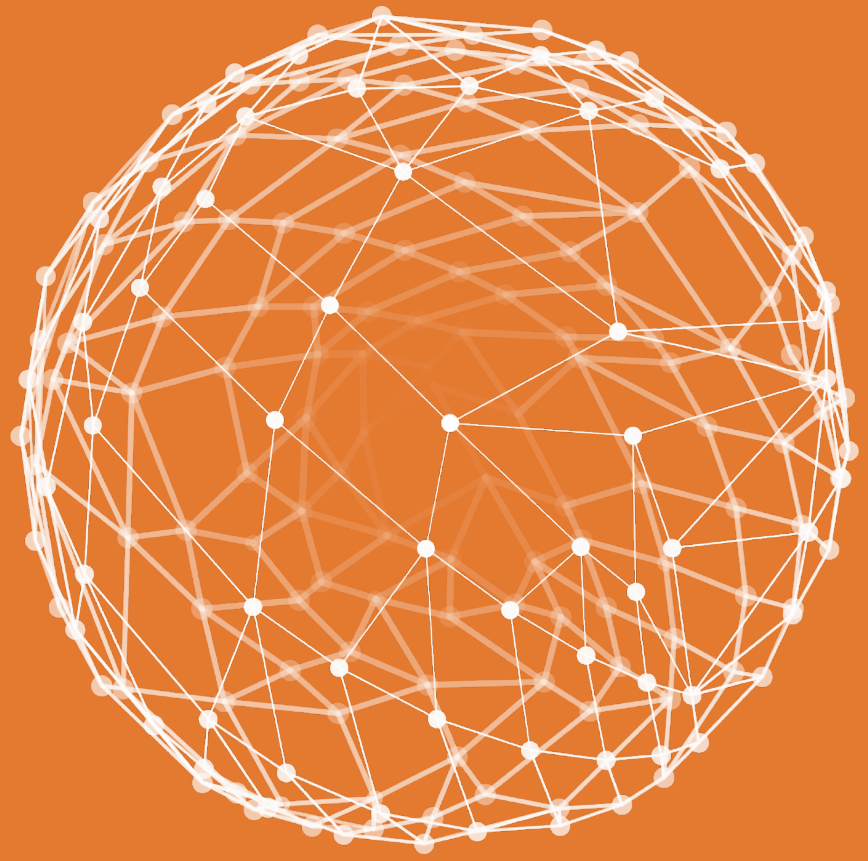
[1]Chon et al., ESMO 2024, Poster 986
[2]Kim et al., Journal of Hepatology, Sept 04 2025

Fostrox + Lenvima shows encouraging tolerability enabling patients to remain on treatment long-term



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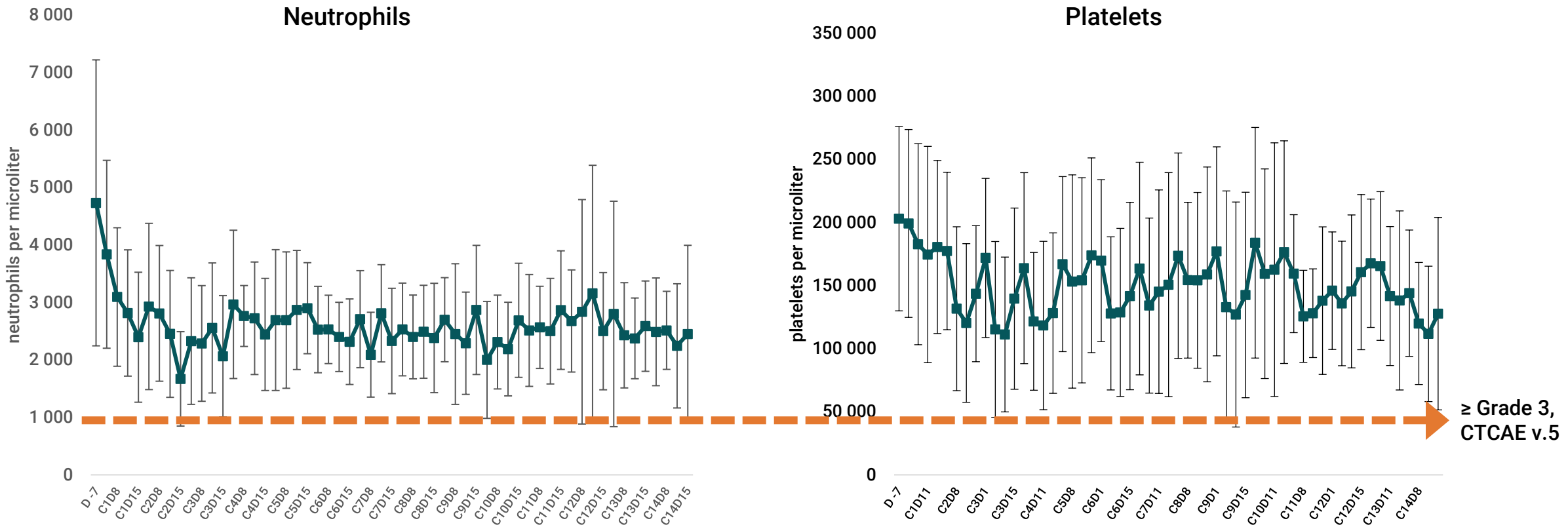
Absolute neutrophile and platelet counts were stable over the course of treatment, enabling long-term use[1]

Longitudinal neutrophil & platelet counts, at all time points measured over first 10 months of treatment



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

Liver targeting properties supports encouraging tolerability profile, enabling patients to remain on treatment long-term

Adverse Events*	Treatment emergent AEs any grade No of pts (%)	Treatment emergent AEs Grade ≥ 3 No of pts (%)	Fostrox Treatment-related Grade ≥ 3 No of pts (%)	LEN Treatment-related Grade ≥ 3 No of pts (%)
Any AE	**21 (100)**	**17 (81)**	**11 (52)**	**14 (67)**
Hematologic AE				
Thrombocytopenia	13 (62)	6 (29)	5 (24)	6 (29)
Neutropenia (no febrile)	10 (48)	8 (38)	8 (38)	6 (29)
Anaemia	7 (33)	3 (14)	3 (14)	3 (14)
Leukocyte decrease	5 (24)	1 (5)	1 (5)	1 (5)
Other AE				
Hypothyroidism	12 (57)			
Diarrhoea	10 (48)	1 (5)		1 (5)
Hand-foot syndrome	10 (48)	1 (5)		1 (5)
Fatigue	9 (43)			
Asthenia	8 (38)	3 (14)	1 (5)	2 (10)
Decreased appetite	8 (38)			
Proteinuria	7 (33)	1 (5)		1 (5)
Hypertension	6 (29)	2 (10)		2 (10)
Cough	5 (24)			
Pruritus	5 (24)			

- No unexpected adverse events
- Hematological AEs were transient and manageable in nature
- Grade ≥ 3 events in 11 patients (52%) with only 7 events resulting in dose delay or discontinuation
- No patients with febrile neutropenia or low platelet count with bleeding
- No fostrox related deaths or SAEs

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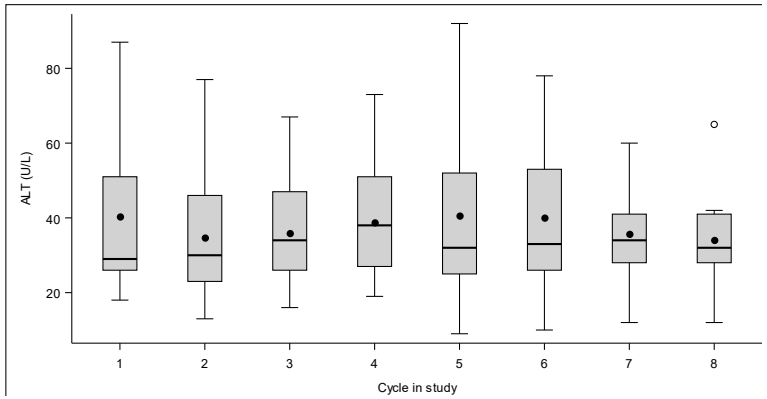
[1]Chon et al., ESMO 2024, Poster 986.

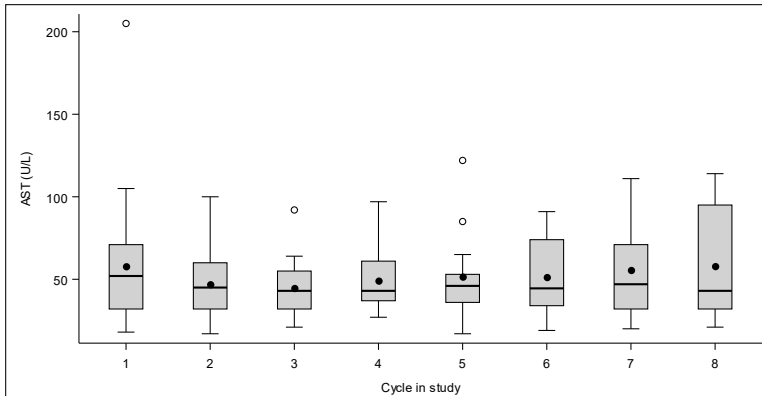
Stable liver function during treatment with fostrox + Lenvima – no deterioration in liver enzymes or change in ALBI score

ALT change over duration of treatment



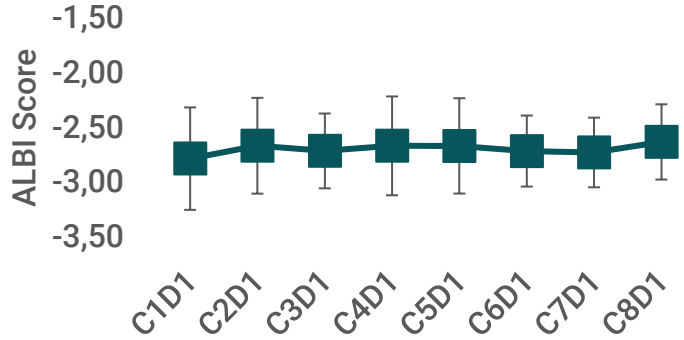
Patients At risk								
	21	21	16	15	14	14	11	10

AST change over duration of treatment



Patients At risk								
	21	21	16	15	14	14	11	10

ALBI score change over duration of treatment



Patients At risk								
	21	21	16	15	14	14	11	10

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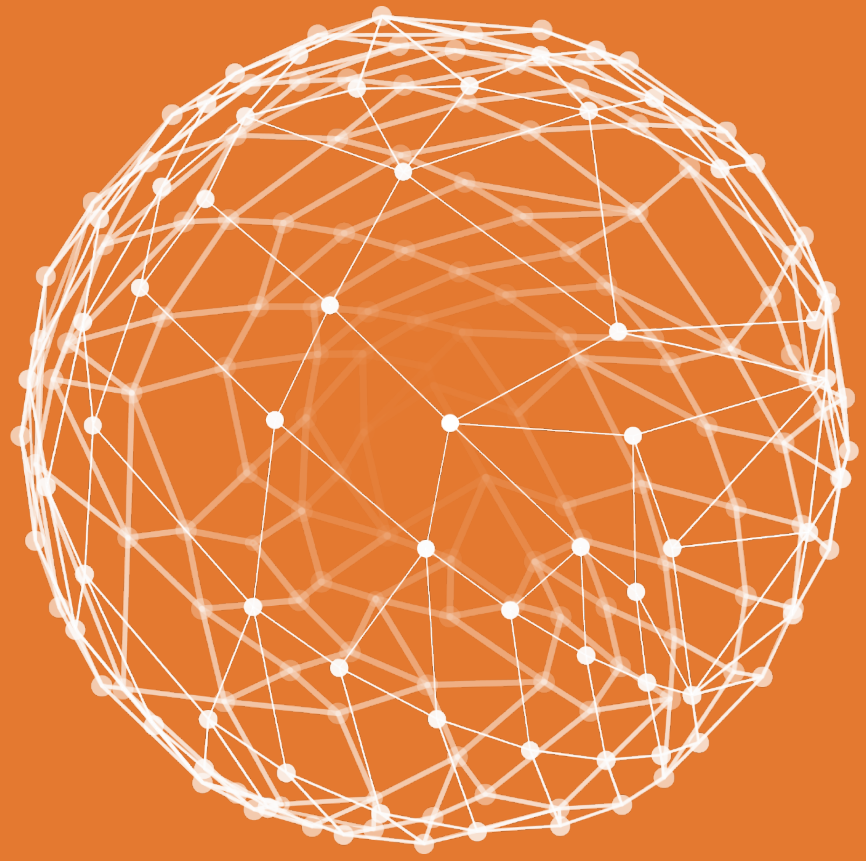
[1]Chon et al., ESMO GI 2024, Poster 176.

FLEX-HXX: Phase 2 study enables rapid generation of randomized, comparative data to confirm benefit of fostrox combination with Lenvima in 2nd line HCC



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FLEX-HCC
Fostrox + Lenvatinib Combination for Advanced HCC

Primary Investigator

Dr. Hong Jae Chon

**CHA Bundang Hospital,
Seoul, Korea**

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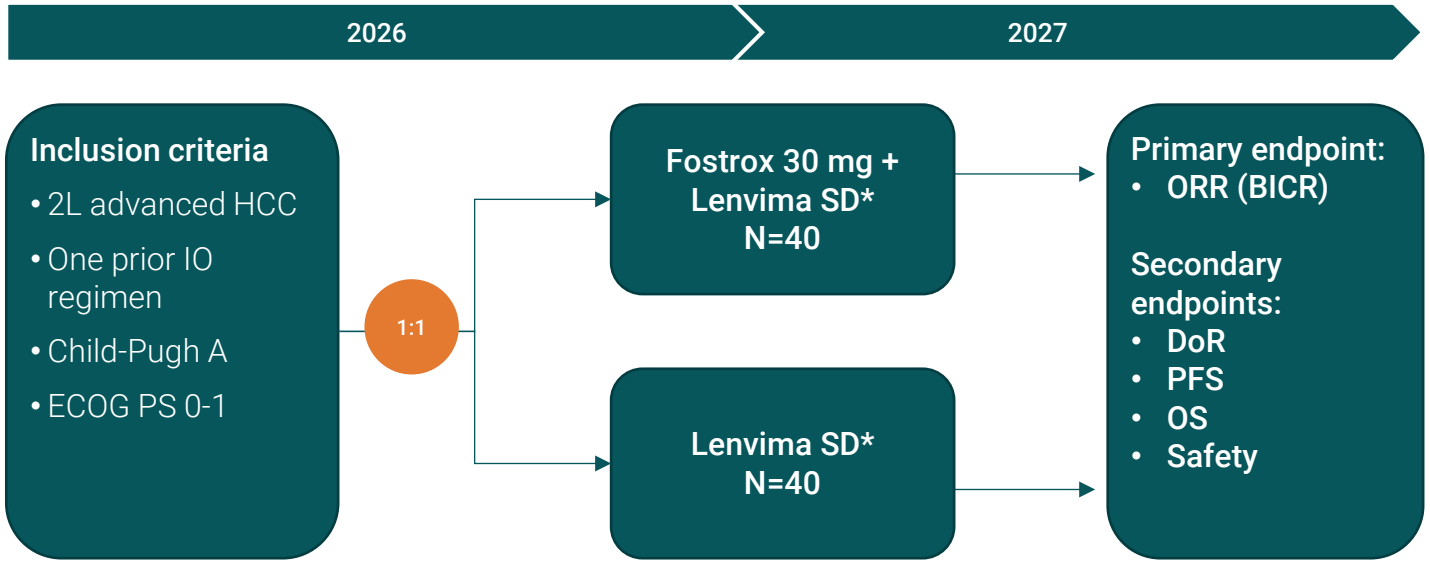
FLEX-HCC: Randomized, comparative phase 2 study to confirm benefit for fostrox + Lenvima combination in 2nd line HCC



*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

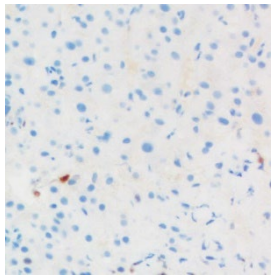
Oral, liver-activated small molecule inducing DNA damage in tumor cells, sparing healthy liver cells[3]

Unique, liver-targeted approach in HCC

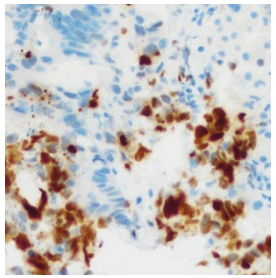
Liver-guided delivery – prodrug

Tumor-selective payload – troxacitabine

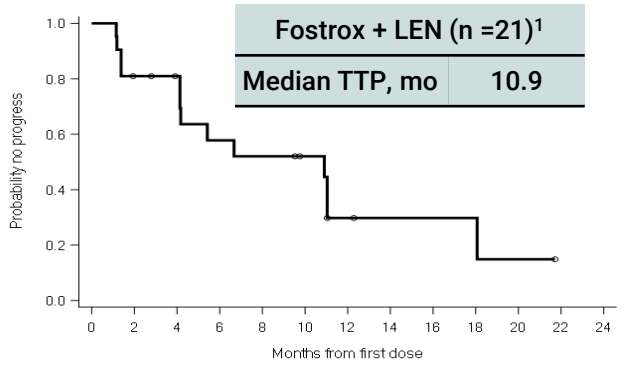
No DNA damage in healthy liver tissue

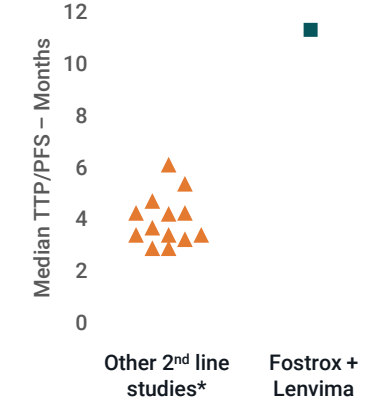


DNA damage in tumor tissue



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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Board with extensive drug development experience

Chairman of the Board
Dr. Uli Hacksell

- Member since 2018, Chairman since 2021
- Over 30 years pharma & biotech experience, including 10 years' experience as CEO of publicly owned companies.

Board member
Dr. Angelica Loskog

- Ph D, Clin. Immunology
- CEO Lokon Pharma & scientific advisor at venture cap Nexttobe
- More than 25 year's academic drug development experience within immune oncology

Board member
Dr. Anna Törner

- Ph D Statistics, MScs Pharmacy
- Broad experience from drug development, especially regulatory affairs
- Founder consulting company SDS Life Science within drug development and statistics.

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Thank You!