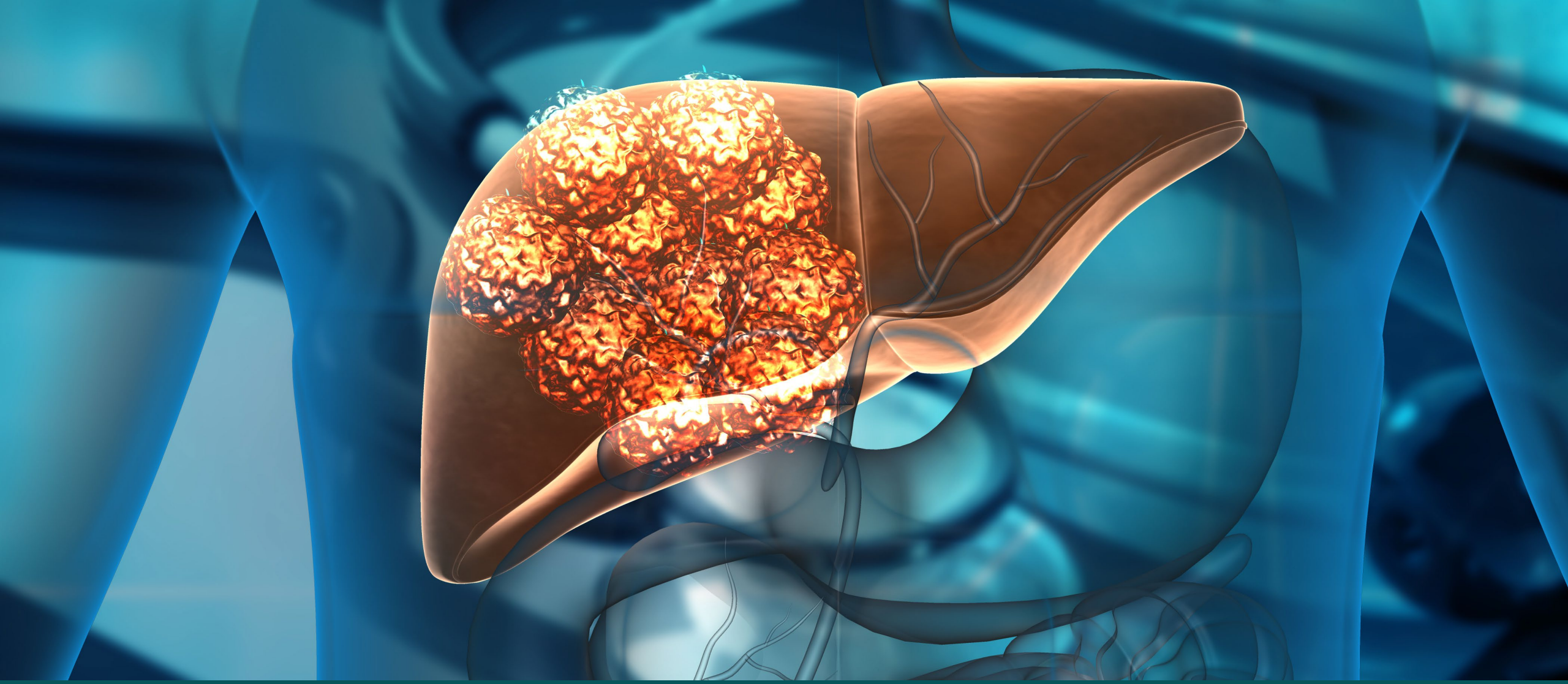

Medivir Q4 REPORT 2024
Fostrox – The first oral, liver-targeted treatment for advanced HCC

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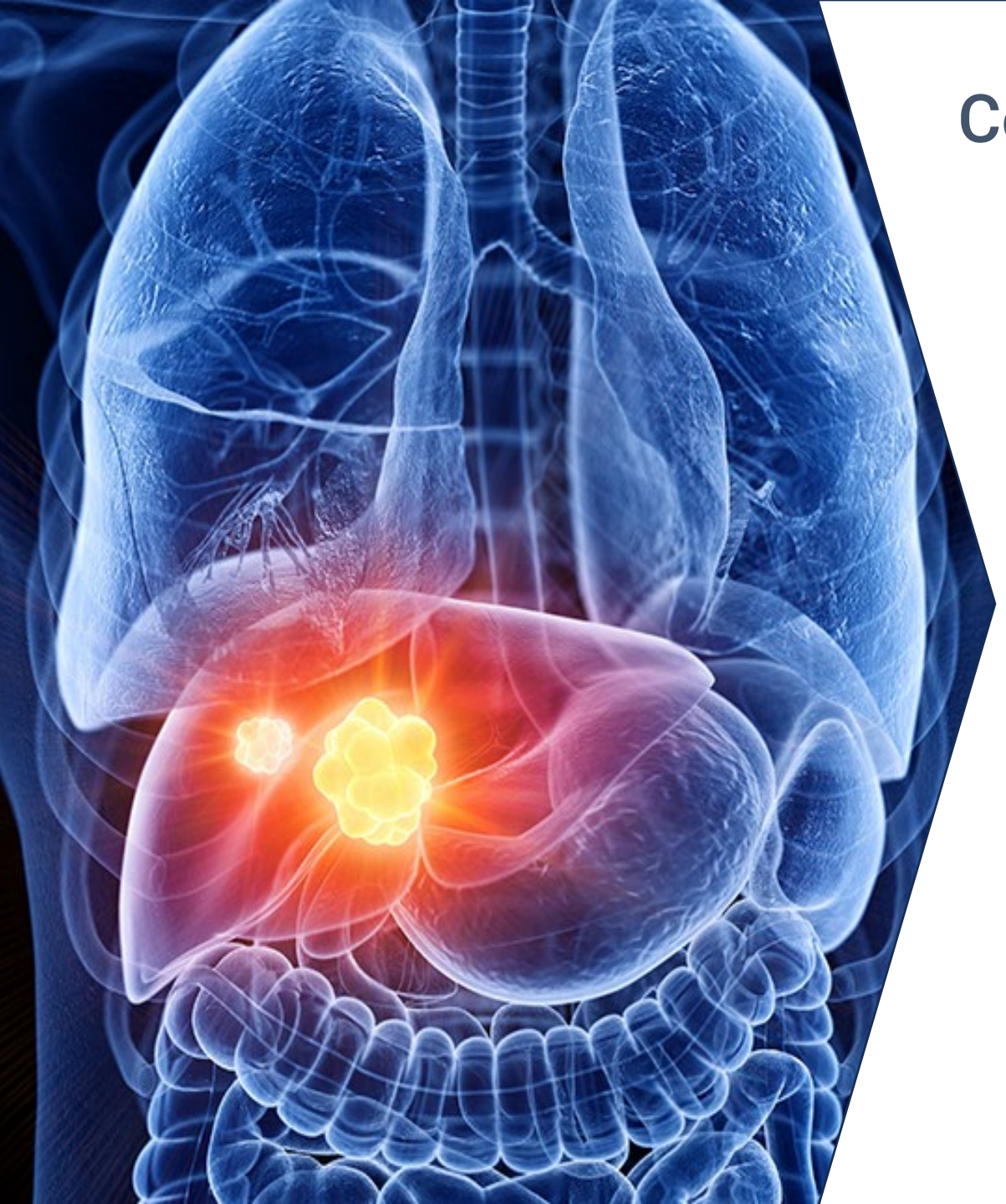

Continued momentum in Q4

- Phase 1b/2a study closed & final data to be presented at EASL Liver Cancer Summit, February 20
- IND approval for phase 2b study FOcuS-2
- Ramping up collaboration with Eisai & progressing plans outside USA

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Today’s presenters

CEO
Jens Lindberg

CMO
Pia Baumann

CFO
Magnus Christensen

CSO
Fredrik Öberg

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Continued phase 2b study initiation in progress with prospective ESMO Asia data confirming fostrox + Lenvima® clinical benefit

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IND approval obtained for randomized FOcuS-2 study of fostrox + Lenvima vs Lenvima

Medivir obtains IND approval for fostrox - the first oral, liver-targeted treatment for advanced liver cancer

2024-12-16

- *FDA clearance of Investigational New Drug (IND) application to evaluate fostrox (fostroxacitabine bralpamide) in combination with Lenvima® vs Lenvima alone in a randomized phase 2b study in second-line advanced liver cancer (hepatocellular carcinoma, HCC).*
- *Phase 1b/2a data has demonstrated that the combination of fostrox + Lenvima has shown a manageable safety profile and encouraging anti-tumor activity in second-line population, including a median time to progression (TTP) of 10.9 months* [1].
- *Medivir plans to recruit patients in at least 8 countries across USA, Europe and Asia, aiming for study read-out in 2027.*

- Study design with dose run in to select optimal dose, aligned with FDA Project Optimus
- ORR selected as primary endpoint, a surrogate endpoint accepted for accelerated approvals in HCC
- Statistically powered to show a clinically meaningful difference between fostrox + Lenvima vs Lenvima alone

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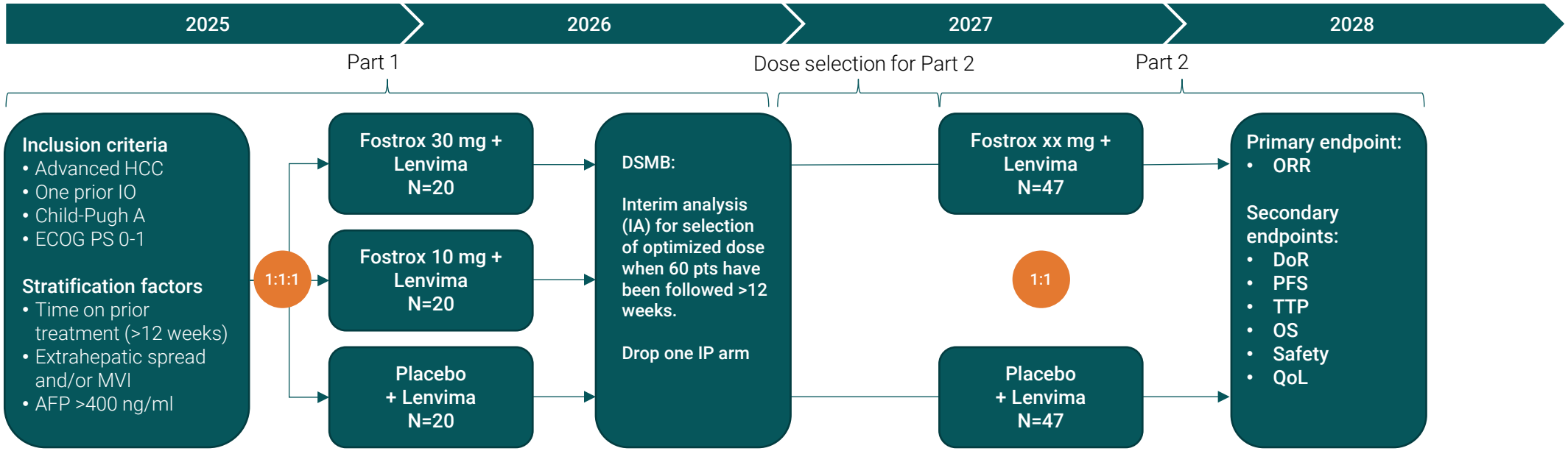
FOcuS-2 IND approved; design optimized for potential breakthrough therapy designation & accelerated approval filing



Statistics

- **Total sample size = 154**
- Interim analysis: dose selection by independent board (DSMB)
- Final analysis: Statistical power >80% to detect clinically meaningful difference in ORR

Time estimate and sites:

- Assumed enrolment: 12 months in each part (1+2)
- Primary endpoint FU: 6 months
- 40 sites in 8 countries in the US, Europe and Asia

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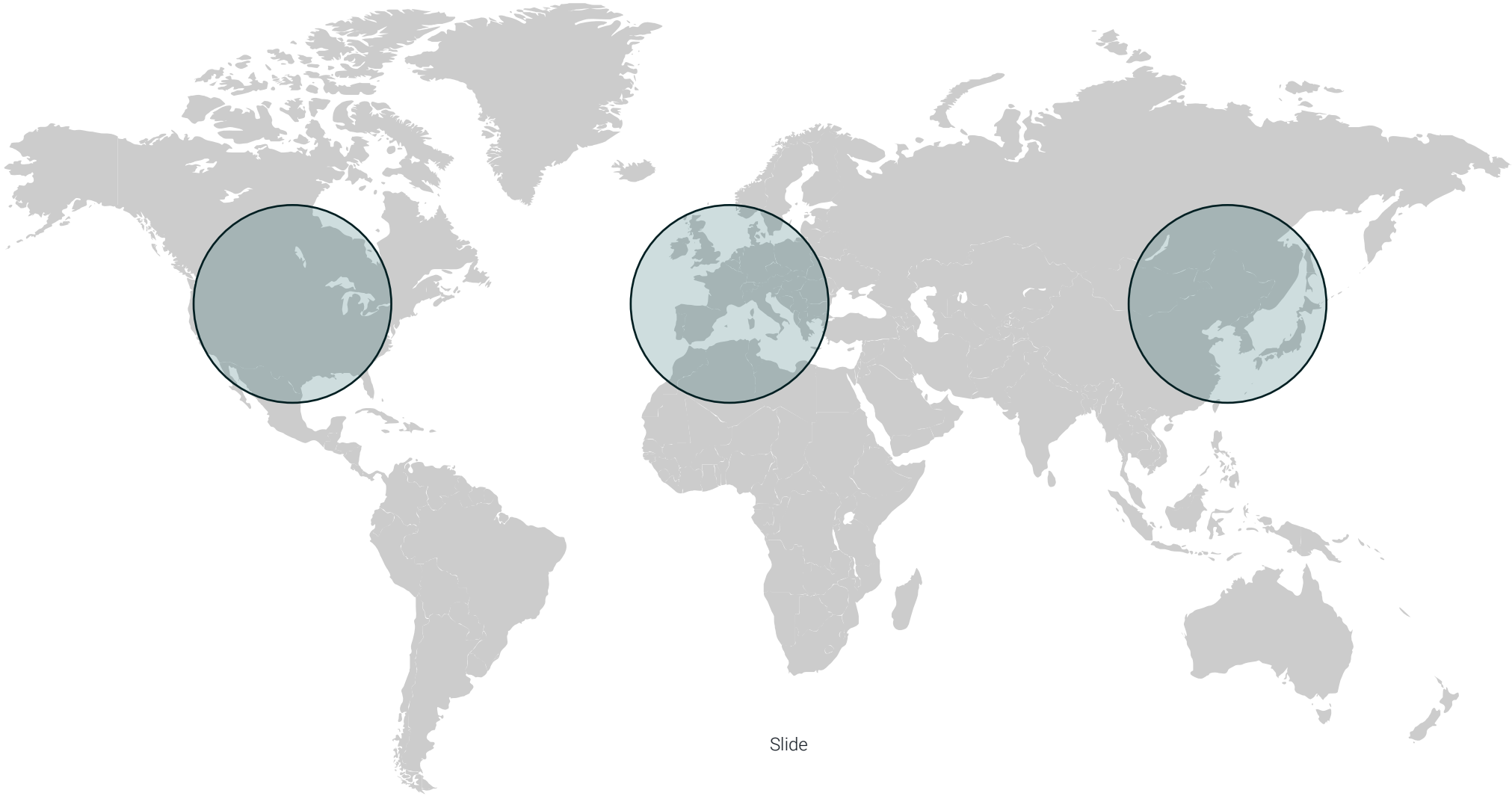
Focus-2: Global, randomised phase 2b at 40 sites in 8 countries across 3 regions to maximise speed and clinical relevance



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Focus-2: Post IND approval – progress in study start-up activities

Key preparation activities for FOCUS-2

- Site selection finalisation & initiation of contracts
- Country regulatory and ethic committee submissions
- Study set-up collaboration with Eisai, including Lenvima supply
- Supply of study drugs ready at sites
- All systems set up for data capture

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ESMO Asia 2024 – First prospective 2nd line study in advanced HCC evaluating Lenvima monotherapy post Tecentriq + Avastin

SINGAPORE 2024 ESMO ASIA

Multicenter phase 2 trial of lenvatinib in patients with advanced hepatocellular carcinoma after progression on first-line atezolizumab plus bevacizumab (KCSG HB23-04)

Changhoon Yoo, Hyung-Don Kim, Hong Jae Chon, Sun Jin Sym, Moonho Kim, Jung Hun Kang, Baek-Yeol Ryoo, Choong-kun Lee, Joohyun Hong, Hyewon Ryu, Woo Kyun Bae, Hyeyeong Kim, Hyunho Kim, Jin Won Kim, Tae-Yong Kim

KCSG HB23-04 Study design

Investigator-initiated multicenter single-arm phase 2 trial (NCT06138769)

- Unresectable HCC
- Progression following prior first-line Atezo-Bev (after at least C2)
- No other systemic Tx
- At least one measurable lesion per RECIST v1.1
- Child-Pugh Class A
- ECOG PS 0-1
- Adequate organ function

N=50 from 13 Korean sites

→ **Lenvatinib (12 mg or 8 mg)** → **Treatment until loss of clinical benefit or unacceptable toxicity** → **Survival follow-up**

Response assessment every 8 weeks

Efficacy objectives
- **Primary:** PFS*
- **Secondary:** OS, ORR,* DCR*

Safety objective
- Adverse events graded by CTCAE v5.0

*INV-assessed per RECIST v1.1

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Similar patient characteristics across studies

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

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

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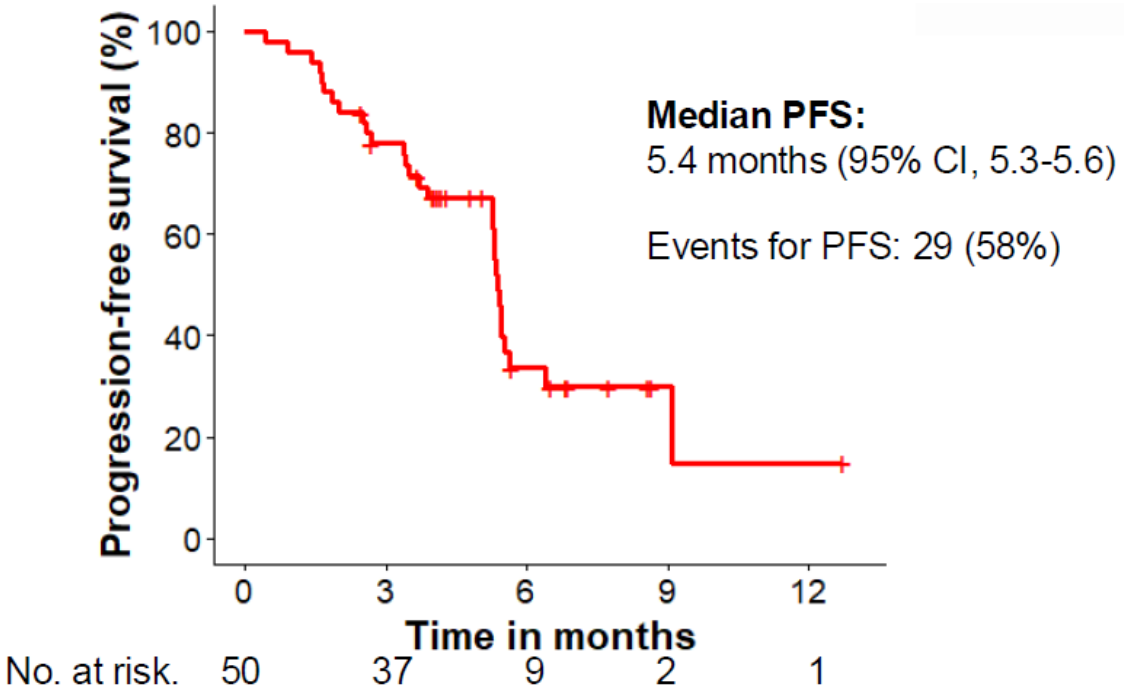
[1]Chon et al., ESMO 2024, Poster 986.
[2]Yoo et al., ESMO Asia 2024

ESMO Asia 2024 – 2nd line prospective Lenvima monotherapy data post Tecentriq + Avastin, confirms previous outcome data

Median PFS (investigator assessed RECIST 1.1)



- Median PFS confirming previously reported outcome data for Lenvima as monotherapy in advanced HCC post an IO combination
- OS 8.6 months - in line with previous reported data in 2nd line

[1]Yoo et al., ESMO Asia 2024,

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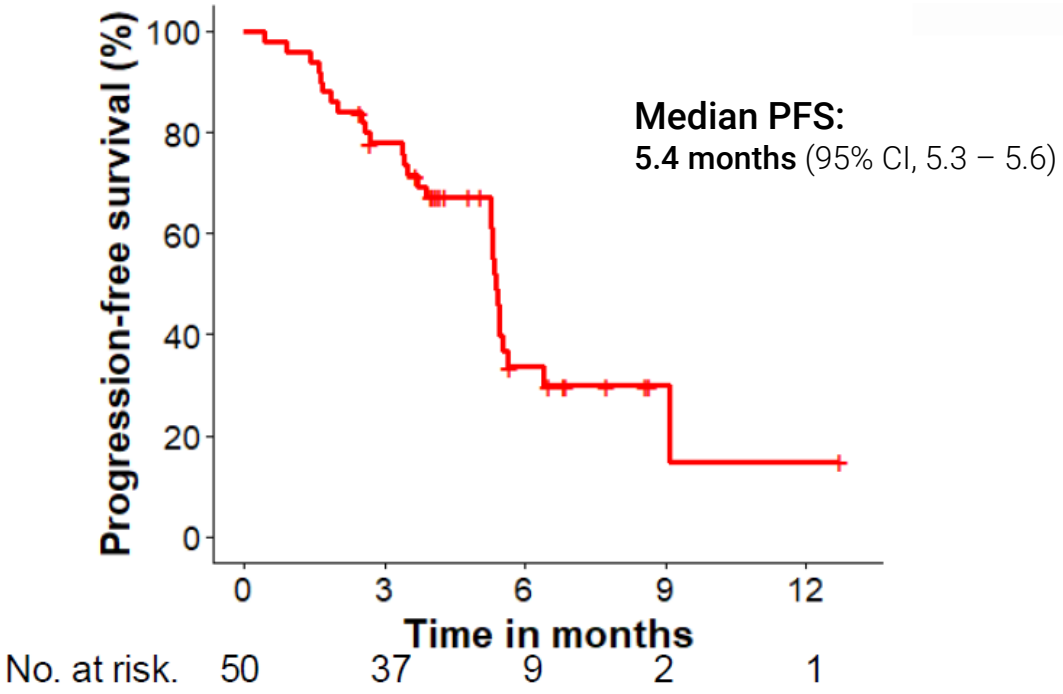
Fostrox + Lenvima phase 1b/2a data showed substantially longer PFS/TTP compared to prospective study of Lenvima alone

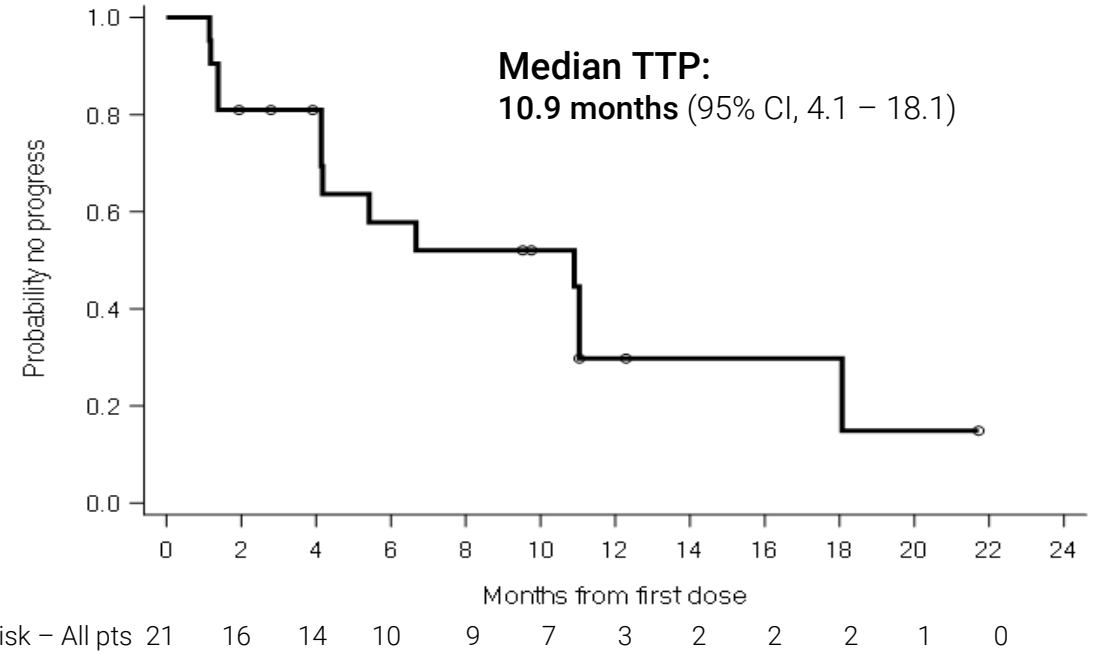
Median PFS – Lenvima monotherapy[2]



Median PFS:
5.4 months (95% CI, 5.3 – 5.6)

Scans performed with 8 weeks interval

Median TTP – Fostrox + Lenvima[1]



Median TTP:
10.9 months (95% CI, 4.1 – 18.1)

Scans performed with 6 weeks interval

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

Final phase 1b/2a data to be presented at EASL Liver Cancer Summit on Thursday February 20th

Poster P02-13: 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 Martín[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]

- Final efficacy data including Overall Survival
- Correlation clinical efficacy & biomarkers
- Final update on safety and tolerability

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Lack of effective treatment options in 2nd line HCC with absence of 2nd line data at ASCO GI and EASL

Treatment algorithm – major need for new 2nd line options

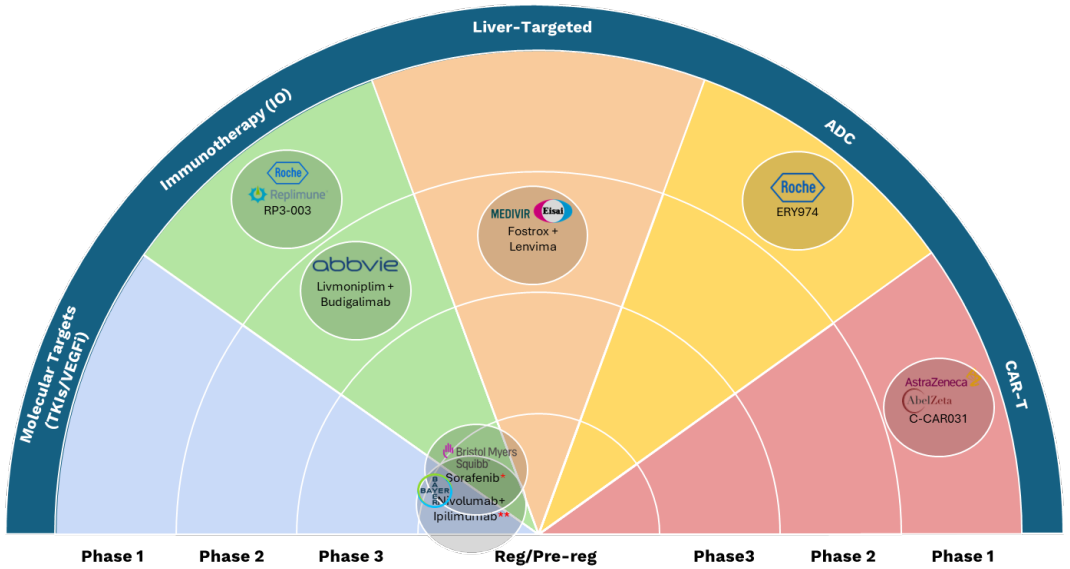
1st line treatment

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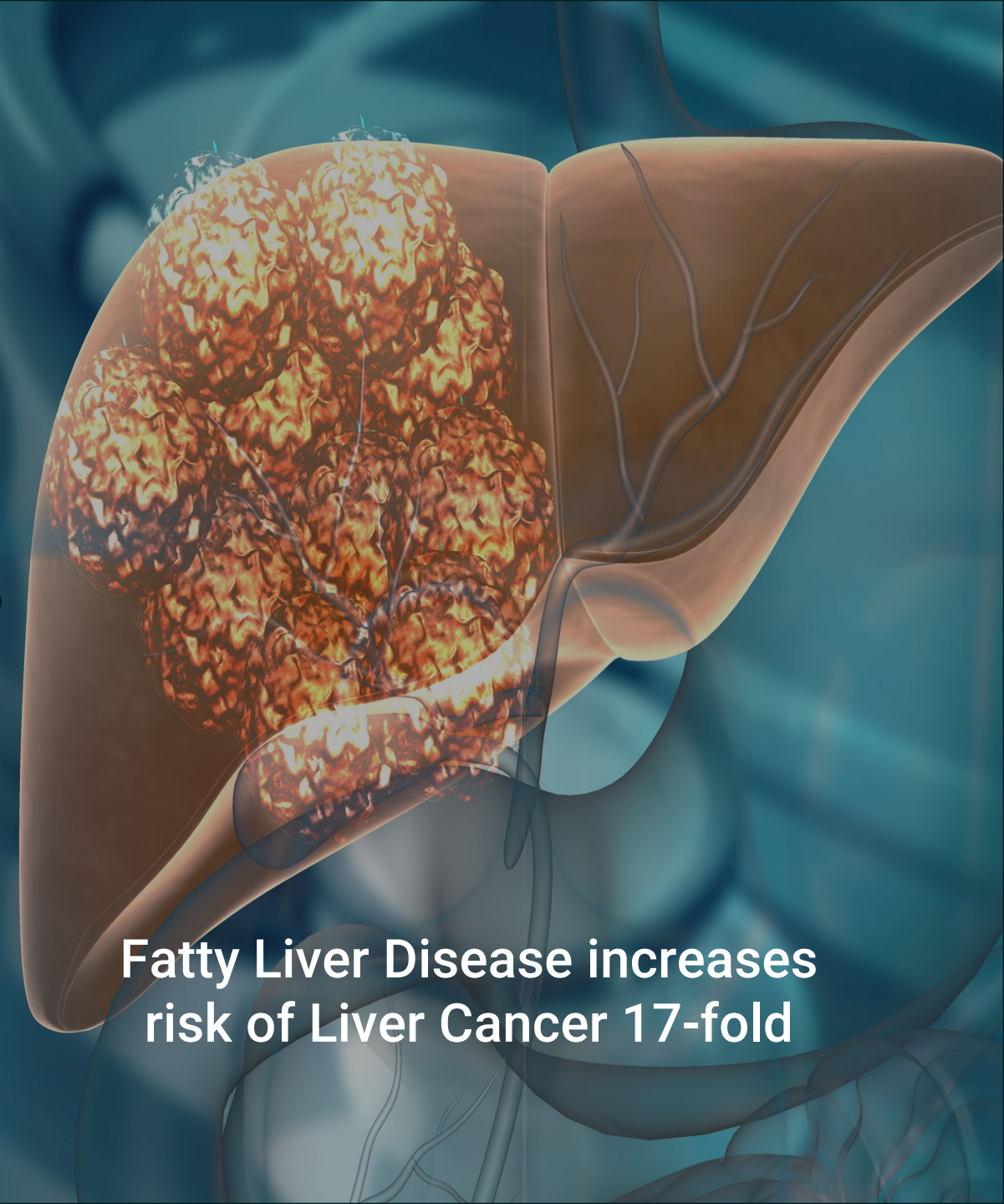
*Sorafenib was the first approved 1st-line treatment for HCC. Although approved for 2nd-line use, guidelines recommend against it due to a lack of evidence showing efficacy after immunotherapy combinations.
**Nivolumab + Ipilimumab were approved for patients post-sorafenib but are now moving into 1st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

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



Fatty Liver Disease increases
risk of Liver Cancer 17-fold

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

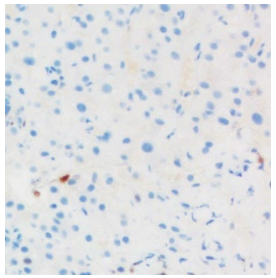
Oral, liver-activated small molecule inducing DNA damage in tumor cells, sparing healthy liver cells[3]

Unique, liver-targeted approach in HCC

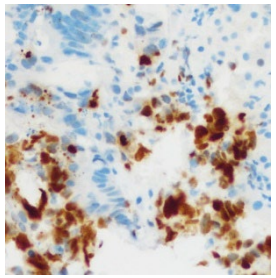
Liver-guided delivery – prodrug

Tumor-selective payload – troxacitabine

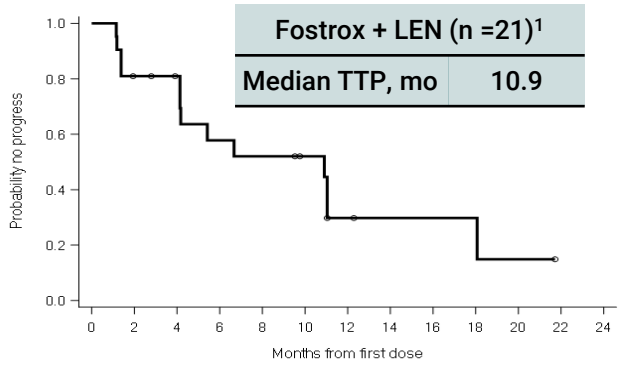
No DNA damage in healthy liver tissue

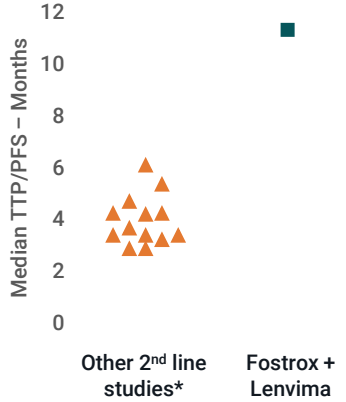


DNA damage in tumor tissue



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
- 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 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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Financial highlights Q4

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Financial summary Q4, 2024

Consolidated Income Statement, summary (SEK m)	Q4		Q1 - Q4	
	2024	2023	2024	2023
Net turnover	1.0	4.4	3.5	7.6
Other operating income	0.4	0.2	1.0	1.4
Total income	**1.4**	**4.7**	**4.5**	**9.0**
Other external expenses	-20.6	-16.5	-101.3	-68.9
Personnel costs	-6.8	-7.9	-27.2	-27.4
Depreciations and write-downs	-0.7	-0.7	-2.7	-2.7
Other operating expenses	-0.2	-0.4	-0.6	-1.4
Operating profit/loss	**-26.9**	**-20.8**	**-127.3**	**-91.4**
Net financial items	0.2	0.5	4.0	2.1
Profit/loss after financial items	**-26.7**	**-20.3**	**-123.3**	**-89.3**
Tax	-	-	-	-
Net profit/loss for the period	**-26.7**	**-20.3**	**-123.3**	**-89.3**

- Net turnover for Q4 was SEK 1.0 million
- Operating loss for Q4 was SEK -26.9 million
- Cash flow from operating activities for Q4 was SEK -29.4 million
- Cash balance end of Q4 was SEK 62.5 million

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Q/A

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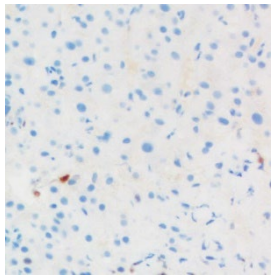

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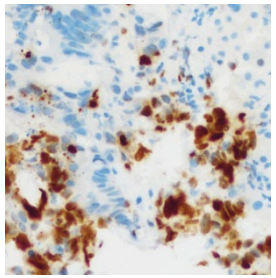

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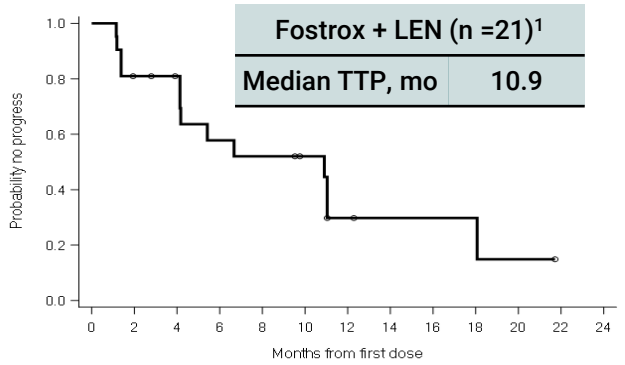

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