Medivir AB

Introducing smart, targeted chemotherapy for patients with advanced liver cancer (HCC)

March 7, 2024

Jens Lindberg, CEO

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Medivir – Swedish biotech (public) focused on development of innovative treatments for cancer

Company in brief

Founded	1988
Listed	Nasdaq OMX
Location	Stockholm
FTE	10
Cash position	SEK 169,5M (Q4 23)

Fostrox

Unique, proprietary clinical asset in phase 1b/2a

- Unique, liver targeted therapy inducing tumor selective cell death in primary liver cancer (HCC) patients
- Promising early & durable clinical benefit in combination with Lenvima in 2nd line HCC
- Opportunity for accelerated approval & first-to-market 2027 in target population where no other treatments are approved

Partnering programs

Potential upside without further investment

- Birinapant, out-licensed to IGM Biosciences, has completed phase 1 dose escalation with aplitabart
- TNG348 (Tango Therapeutics) initiated phase 1 in Jan 2024
- MET-X (Infex Therapeutics), intent to enter phase 1 in 2024

Pipeline overview

IN-HOUSE PROGRAM – FOSTROX

PROJECT	DISEASE AREA	PATIENT POPULATION	PRE-CLIN	PH 1	PH 2	PH 3	NEXT EVENTS
Fostrox	HCC	Monotherapy POC					▪ Fostrox + Lenvima data read-out
		Fostrox + Lenvima					▪ Fostrox + Lenvima ph 2b initiation
		Fostrox + Keytruda					

PARTNERING PROGRAMS

PROJECT	PARTNER	DISEASE AREA	PRE-CLIN	PH 1	PH 2	PH 3	MAR-KET	POTENTIAL NEXT EVENT(S)
Xerclear	GSK	Herpes						▪ Reg. in China
Remetino-stat	TBD	CTCL/BCC/ SCC						▪ Partnering
MIV-711	TBD	Osteoarthritis						▪ Partnering
Birinapant	IGM	Solid tumors						▪ Dose expansion
TNG348	Tango	Cancer						▪ Phase I start
USP-7	Ubiquigent	Cancer						▪ Partnering
MET-X	INFEX	Infection						▪ Phase I start

Completed | Ongoing | Planned

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Primary Liver Cancer (HCC)
2L – fast-to-market strategy in underserved population

	Patient population (2030)	Current Standard of Care (SoC)	Limited benefit expected with SoC
1st line treated	140k	Immunotherapy combination **Tecentriq** Anti-PD-L1 + **Avastin** VEGFi	▪ ~30% response rate[1] ▪ ~6.5 months TTP/PFS[1]
	70% go on to 2L treatment		
2nd line treated	▪ US pts ~10k ▪ Global ~100k	No approved treatments – clinical trials recommended **Fostrox** + **Lenvima** Combo of new mechanisms	▪ **~10% response rate[2]** ▪ **~3.5 months TTP/PFS[2]**

[1] Finn et al., N Engl J Med 2020; 382:1894-1905
[2] Based on previous 2nd line HCC studies with kinase inhibitors
[3] Global Data 2021, population estimate 2030

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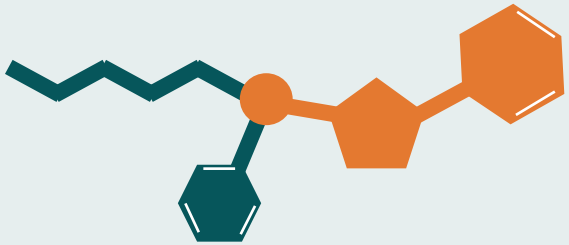
Fostrox – smart, liver targeted chemotherapy

Pro-drug tail for organ-specific targeting



Toxin to induce tumor-selective cell death

1. Oral administration
2. Targeted (>100-fold) liver exposure vs IV chemotherapy[1]
3. Selective DNA damage and cell death in tumor cells[2]

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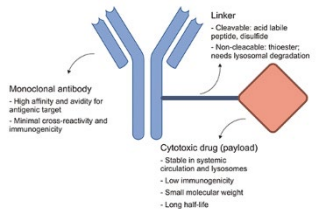
[1]Bethell et al , poster SAT-123, EASL 2017
[2]Öberg F. et al, EASL PO-221, 2022

2 different approaches to smart, targeted chemotherapy

Selectively delivering chemotherapy to cancer cells while minimizing damage to healthy cells

Antigen-specific targeting

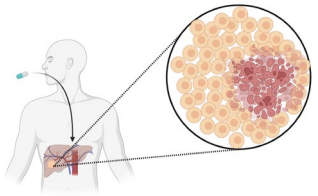
ADC



- For cancers with high expression of target antigen selectively on tumor cells
- Breast (HER2)

Organ-specific targeting

Fostrox



- For heterogenous cancers without specific target antigen on select tumor cells
- Liver

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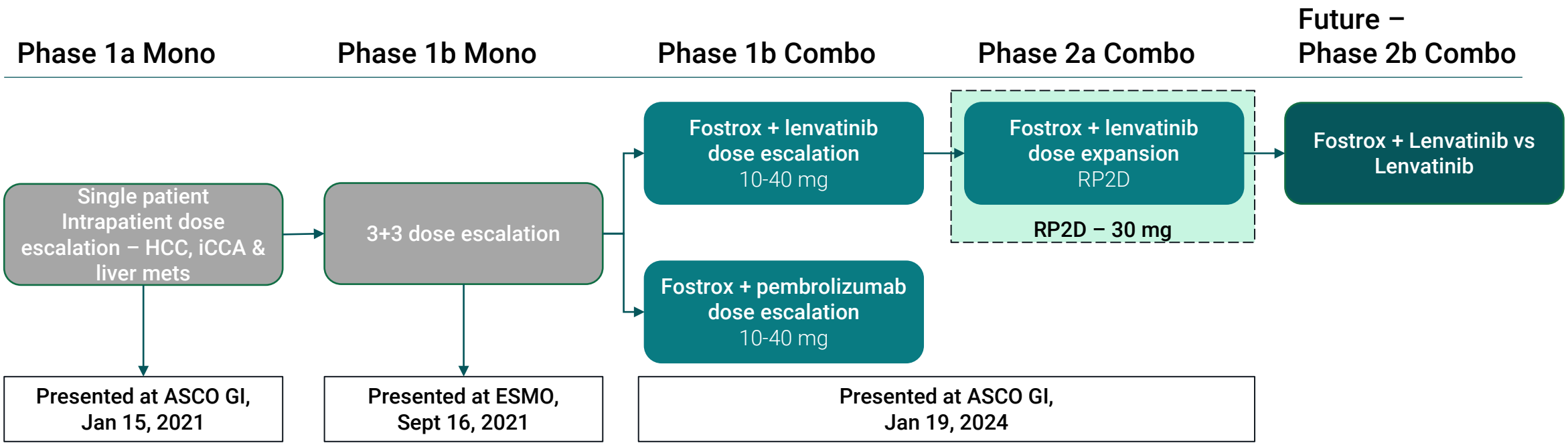
Fostrox clinical program; currently in phase 2a combination with Lenvima



Patient Population:

- 2L & 3L advanced inoperable HCC, Child-Pugh A,
- Progressed on or intolerant of 1L or 2L SOC therapy for HCC

15 sites in UK, Spain & Korea

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Fostrox

a novel combination partner in HCC with promising clinical benefit & safety profile in high unmet need population

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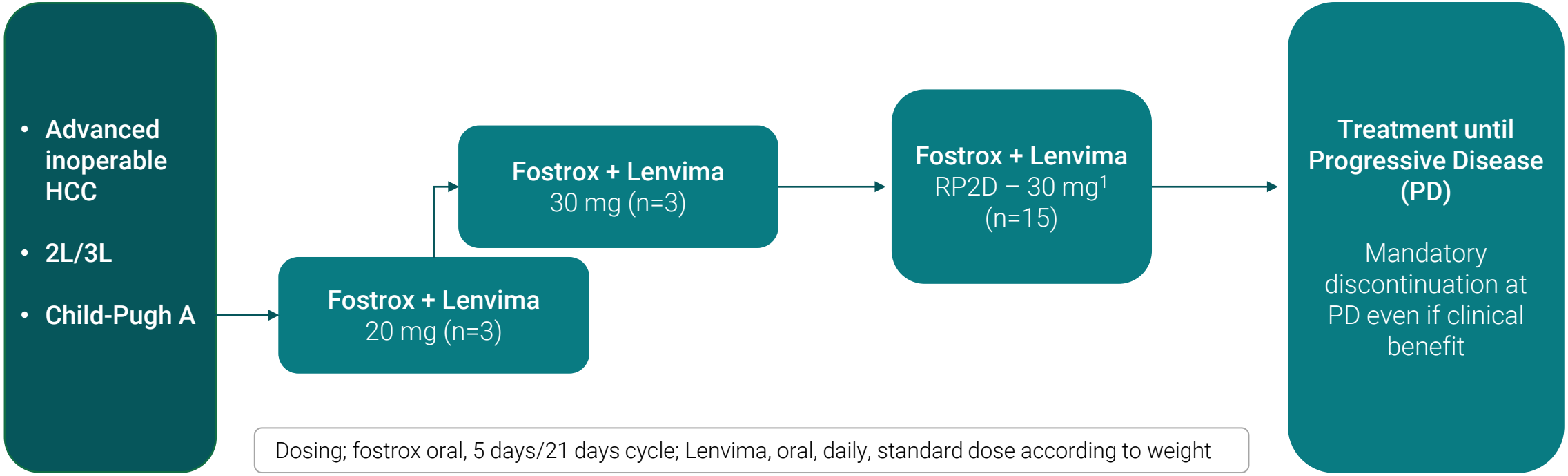
Phase 1b/2a study fully recruited with >40% of patients still on treatment

Fostrox + Lenvima phase 1b/2a dose expansion study – 21 patients dosed



[1]Maximal tolerated dose not reached with no DLTs reported. 30 mg selected with a focus on optimal dose ensuring balance between efficacy and tolerability

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Generous inclusion criteria

- Third line patients (19%) included
- High share of extrahepatic metastasis (67%)
- Macrovascular invasion all grades allowed
- All patients had tumor progression on prior treatment

Patient Characteristics	N = 21
Mean age (range)	62 y (42 - 82)
Gender, Female / Male (%)	24 / 76
ECOG Performance Status 0/1 (%)	71 / 29
Viral/Non-viral (%)	76 / 24
Extra hepatic lesion Y/N (%)	67 / 33
Prior treatment lines; 2L/3L (%)	81 /19
Prior Tecentriq/Avastin 1L (%)	86

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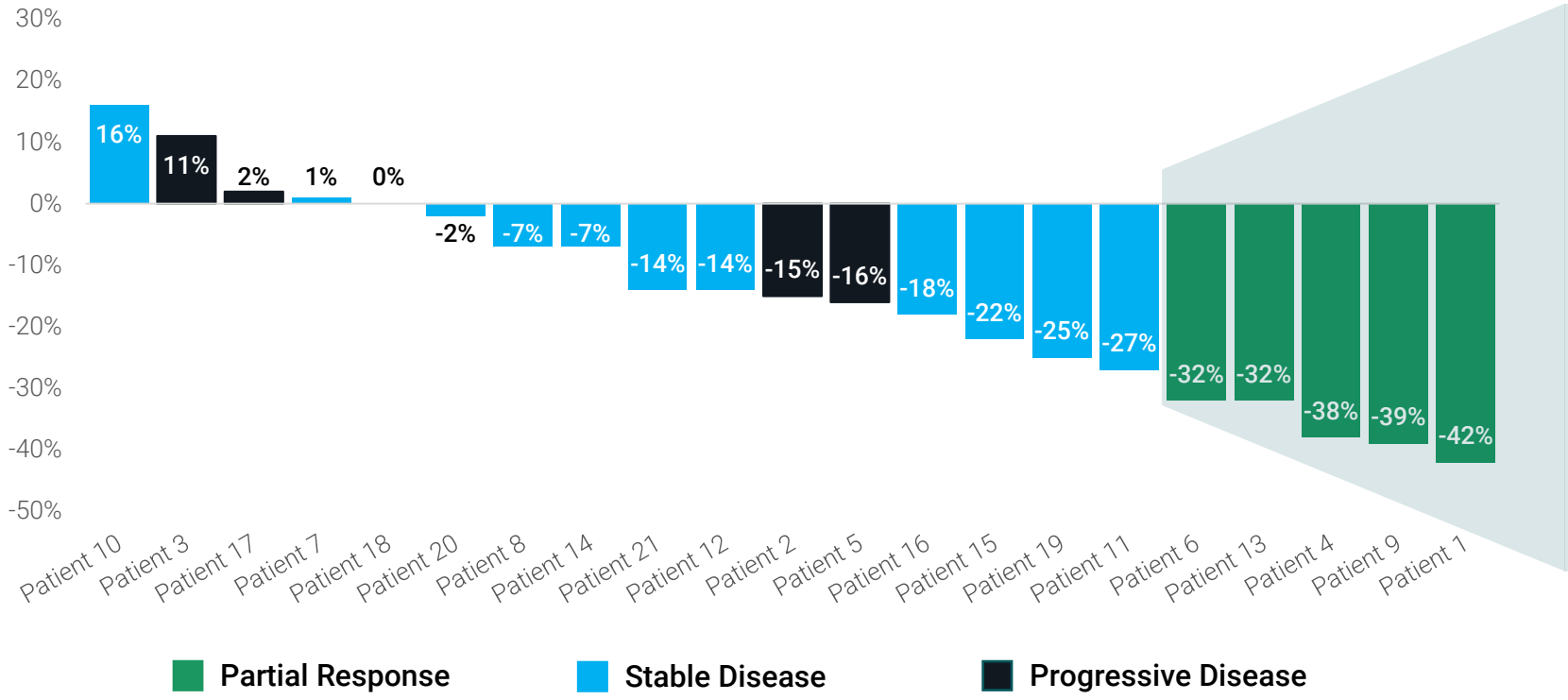
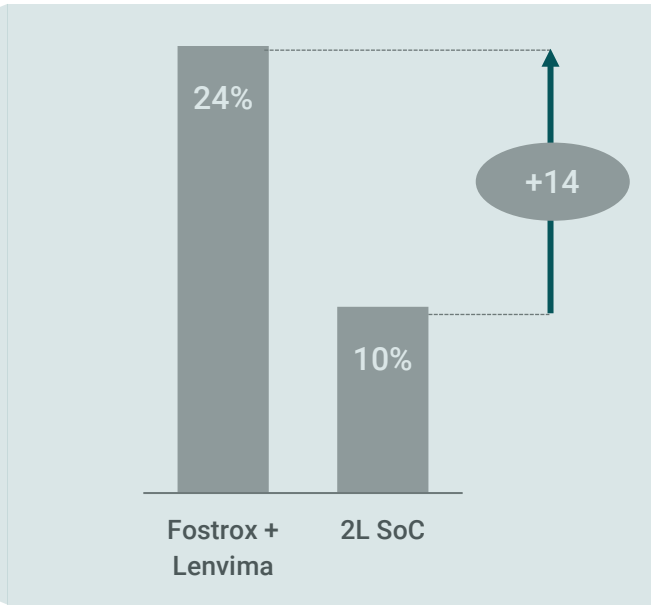
Objective response (ORR) reported in 24% of the patients[3], comparing favorably with 2L HCC SoC benchmark[1,2]

Best percentage change in target lesion size, local review RECIST 1.1



2L ORR benchmark (%)



[1]Data from previous 2L phase 3 HCC studies with Stivarga, Cyramza & Cabometyx
[2]Kobayashi et al., Clinical Cancer Research, Oct 5, 2023 online
[3]Local review (All 21 patients data cut-off February 14, 2024)

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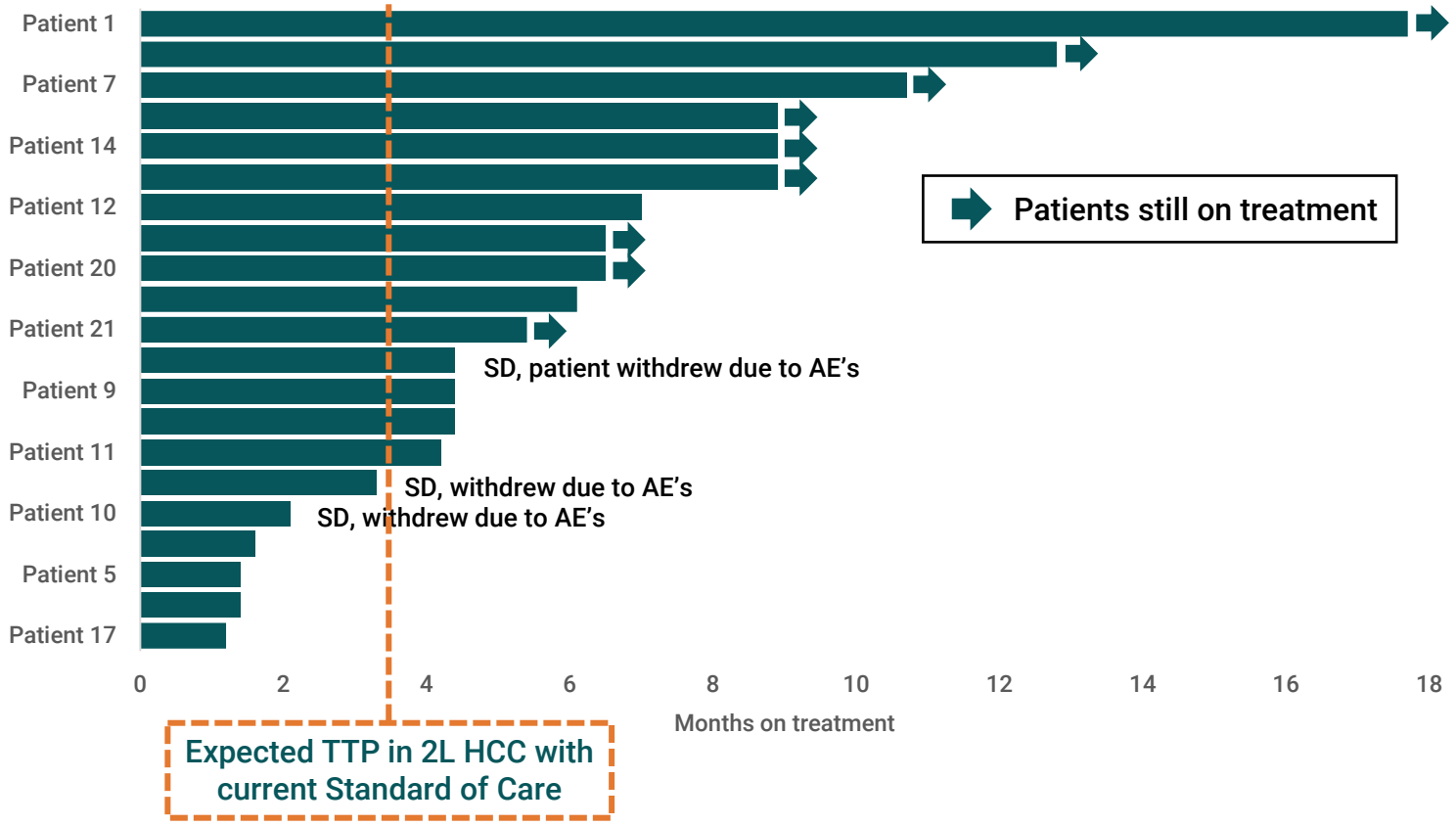
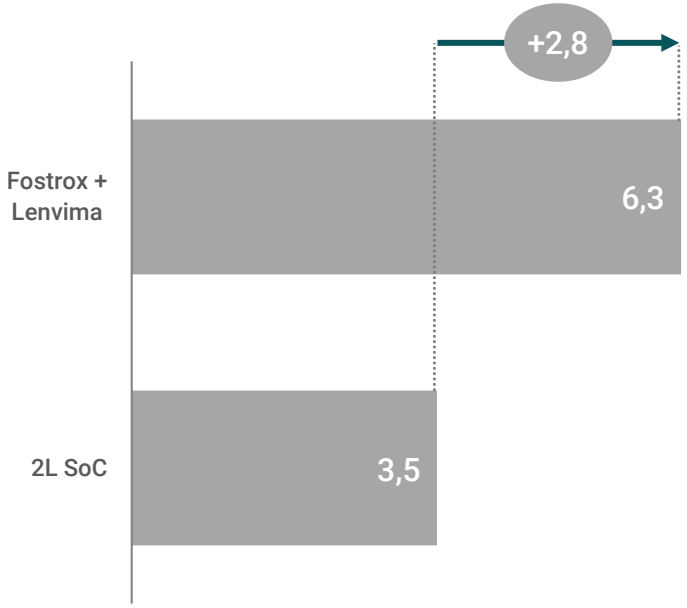
Promising median time to progression (TTP) of 6.3 months[3], >40% of patients still on treatment

Local review, time to progression RECIST 1.1



2L median TTP/PFS benchmark (months)[1,2]



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Fostrox + Lenvima showed a good safety and tolerability profile enabling patients to stay on treatment long-term

- No new, unexpected safety events
- Fostrox related side effects were mainly haematological and temporary with 70% of patients staying on the full dose
- Lenvima tolerability not affected by fostrox
- Lenvima dose modification/ discontinuation in line with monotherapy

	Lenvima monotherapy[1]	Fostrox + Lenvima[2]
Fostrox dose modification	-	29%
Fostrox discontinuation	-	5%
Lenvima dose modification	62%	57%
Lenvima discontinuation	20%	10%

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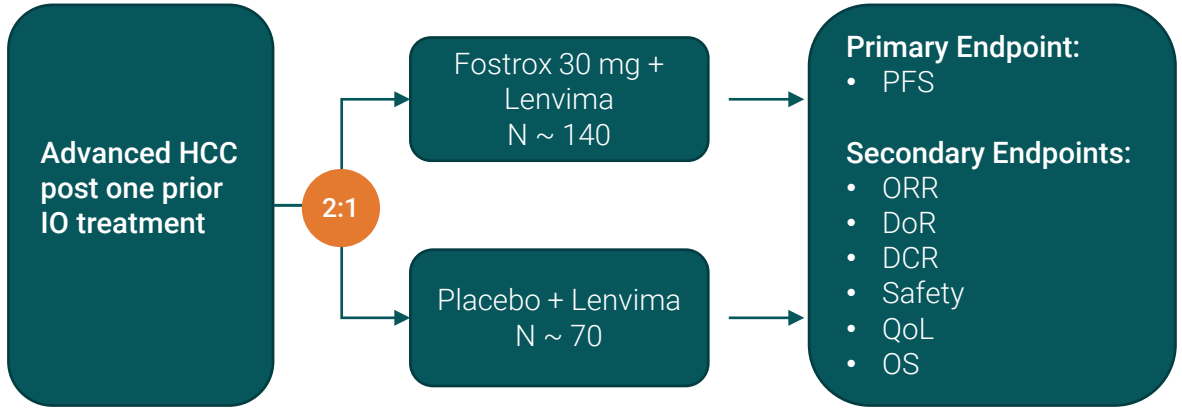
[1]REFLECT study in 1L advanced HCC, lenvatinib vs sorafenib
[2]Data cut-off February 14, 2024, >40% of patients still on treatment

Next step pivotal phase 2b; randomized design with PFS as primary endpoint to enable accelerated approval 27/28

Phase 2b: planned, randomized, double-blind study design



- Enrolment 18 months
- Planning for 7 initial countries (SK, UK, ES, DE, PL, JP, US)

Key factors supporting accelerated approval process

- ✓ Strong KOL support for proposed 2L phase 2b study
- ✓ Serious, orphan disease with high unmet medical need
- ✓ Appropriate patient safety database
- ✓ Study design to be confirmed in FDA interactions

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Making good progress in preparing for pivotal phase 2b

Phase 2b: acceleration activities underway to enable initiation 24/25

- Q4 23 – Capital raise to enable acceleration of activities to prepare for phase 2b
- Q4 23 – Formulation & process development for commercial manufacture
- Q1 24 – Scientific Advisory Council & extensive KOL engagement ahead of FDA interactions
- H1 24 – FDA Type C engagement to confirm study design and file for IND & fast track designation
- H1 24 – CRO selection & initiate study feasibility

Key steps moving towards 2025

1. Confirm study design with FDA for accelerated approval study
2. Establish development & commercialization partnership with focus on Asia
3. Finance phase 2b

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Fostrox – Potential to transform 2nd line HCC

Fostrox is a smart, organ-specific chemotherapy that selectively kills liver cancer cells, while sparing healthy cells

Fostrox + Lenvima outperforming Standard of Care benchmark in 2L HCC; data keeps improving as >40% of patients are still on treatment

Fast-to-market opportunity with lead indication in highly underserved population with a total potential of $2.5bn

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Thank You!

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