Medivir AB

Bringing smart, targeted oral chemotherapy to primary liver cancer (HCC)

Redey Fight Cancer Day, January 24, 2024

Jens Lindberg, CEO

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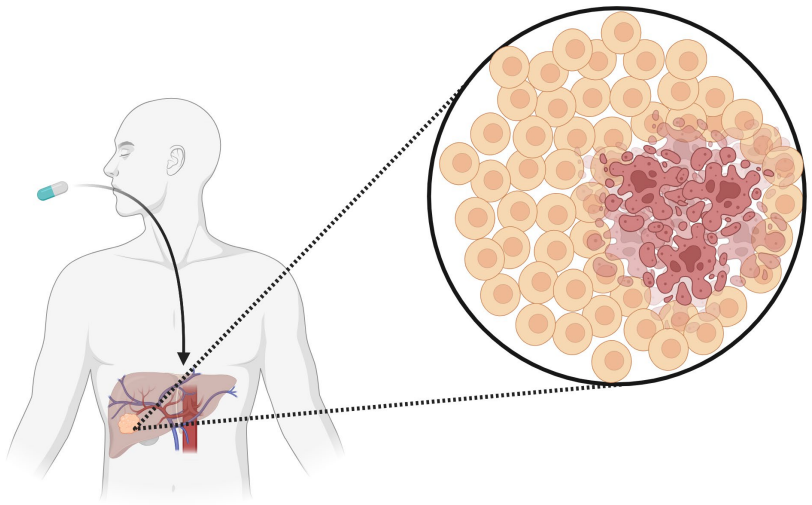
Fostrox – a smart chemotherapy with a unique, liver targeted & tumor selective treatment of HCC

Nucleotide prodrug, enabling oral administration & liver targeting



>100-fold liver targeted exposure vs traditional chemotherapy[1]

Promising signals of clinical benefit supports accelerated approval path

- **First-in-class with OD designation** in EU & US
- **Fostrox + Lenvima provides additional clinical benefit** to Lenvima alone
- Pivotal phase IIb with **Accelerated Approval intent 2027/2028**
- First-to-market opportunity in target population with **annual market value of ~$2.5bn in 2028***

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*Source: GlobalData 2021

Fostrox initial focus in 2L HCC where no treatments are approved and expected clinical benefit is low

Advanced stage HCC Treatment Algorithm

1L systemic therapy

Immunotherapy combination

- Only ~30% of patients respond to treatment[1]
- Estimated time to progression ~6.5 months[1]

↓

2L systemic therapy

No approved treatments – off-label Lenvima preferred

- **Only ~5-10% of patients respond to treatment[2]**
- **Estimated time to progression ~3.5 months[2]**
- Fostrox + Lenvima, the only novel combination in development

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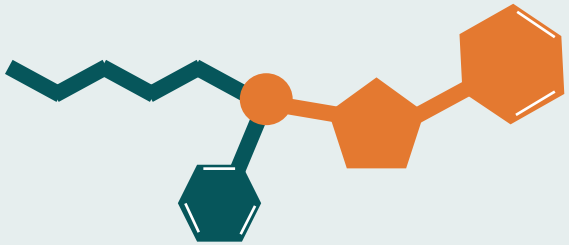
[1] Finn et al., N Engl J Med 2020; 382:1894-1905
[2] Based on previous 2nd line HCC studies with kinase inhibitors

Fostrox – liver targeted, smart chemotherapy

Proven prodrug technology



Active substance - troxacitabine

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

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[1]Bethell et al , poster SAT-123, EASL 2017

ASCO® Gastrointestinal Cancers Symposium

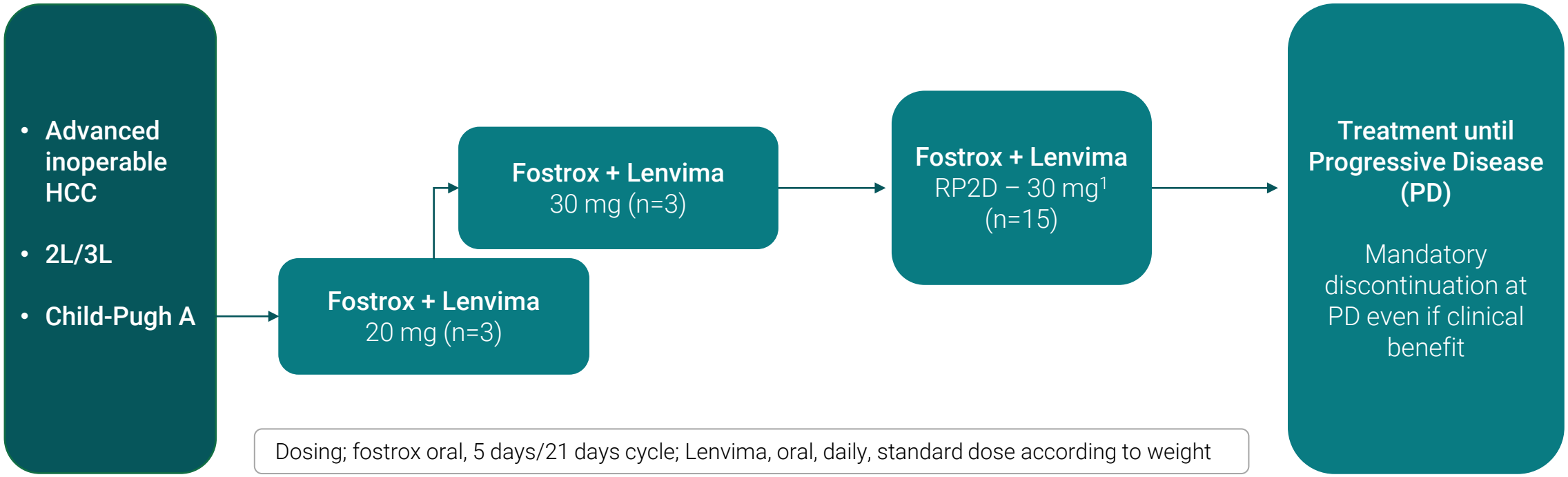
476P First safety and efficacy data from phase Ib/IIa study of fostroxacitabine bralpamide (fostrox, MIV-818) in combination with lenvatinib in patients with hepatocellular carcinoma (HCC)

Maria Reig, T.R. Jeffry Evans, Hong Jae Chon, Ho Yeong Lim, Min-Hee Ryu, Do Young Kim, Teresa Macarulla, Carlos Gomez Martín, Victor Moreno, Beate Haugk, Tom Ness, Pia Baumann, Sujata Bhoi, Malene Jensen, Karin Tunblad, Hans Wallberg, Fredrik Öberg, Jeong Heo

Dr Maria Reig, Head of the Barcelona Clinic Liver Cancer at IDIBAPs and Liver Oncology Unit at Hospital Clinic of Barcelona and CIBEREHD, Spain

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

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



[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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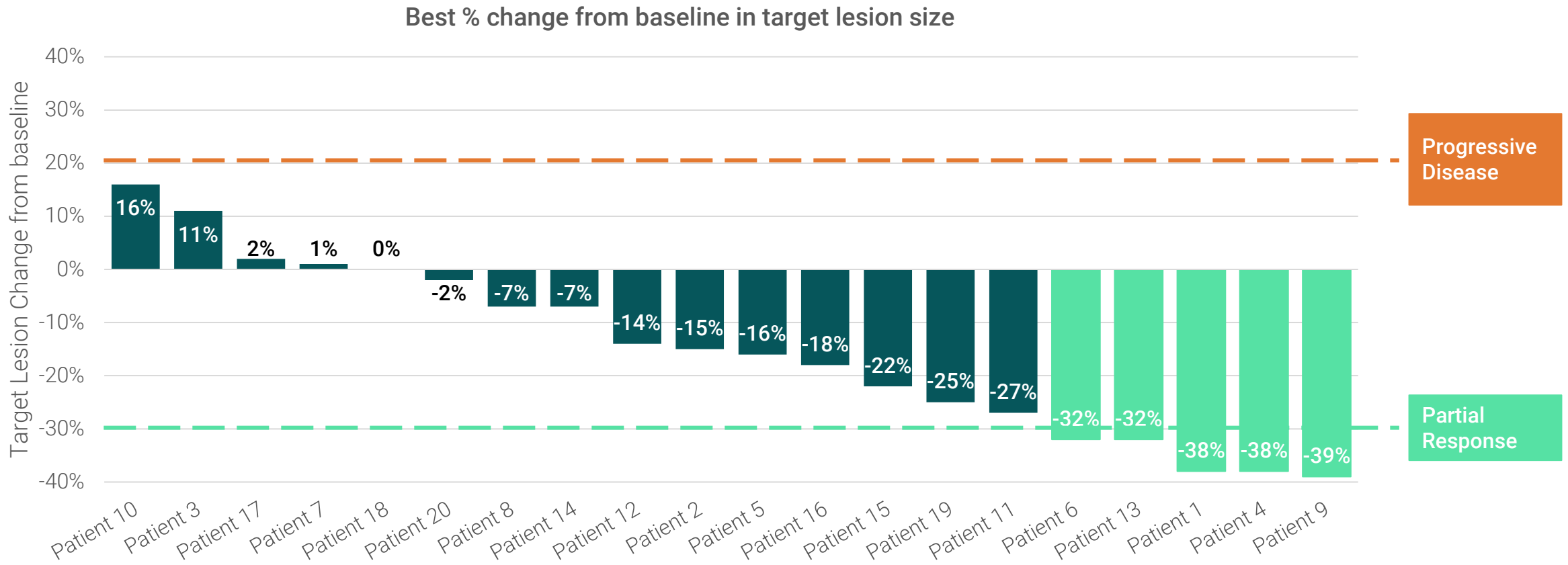
Fostrox + lenvatinib was tolerable with no new unexpected safety events

- Fostrox treatment emergent adverse events (TEAE) were typically transient and manageable haematological events
- 30% dose reduced and 5% discontinued due to fostrox adverse events
- Lenvatinib related adverse event and dose modifications (55% of the patients) were in line with expectations for monotherapy use
- No Grade 5 AE was observed

Treatment Emergent Adverse Events (TEAE) *	TEAE any grade No of pts (%)	TEAE Grade ≥ 3 No of pts (%)
Any TEAE	**20 (100)**	**14 (70)**
Thrombocytopenia	13 (65)	6 (30)
Hypothyroidism	11 (55)	
Neutropenia (no febrile)	10 (50)	8 (40)
Diarrhoea	9 (45)	
Hand-foot syndrome	9 (45)	1 (5)
Leukocyte decrease	8 (40)	2 (10)
Anaemia	7 (35)	2 (10)
Asthenia	7 (35)	3 (15)
Decreased appetite	7 (35)	
Fatigue	7 (35)	
Nausea	6 (30)	
Cough	5 (25)	
Hypertension (worsening)	5 (25)	1 (5)
Proteinuria	5 (25)	1 (5)
Pruritus	4 (20)	

*CTCAE, v5, data cut-off Sept 2023

25% Overall Response Rate (ORR)* (Investigator review RECIST 1.1)



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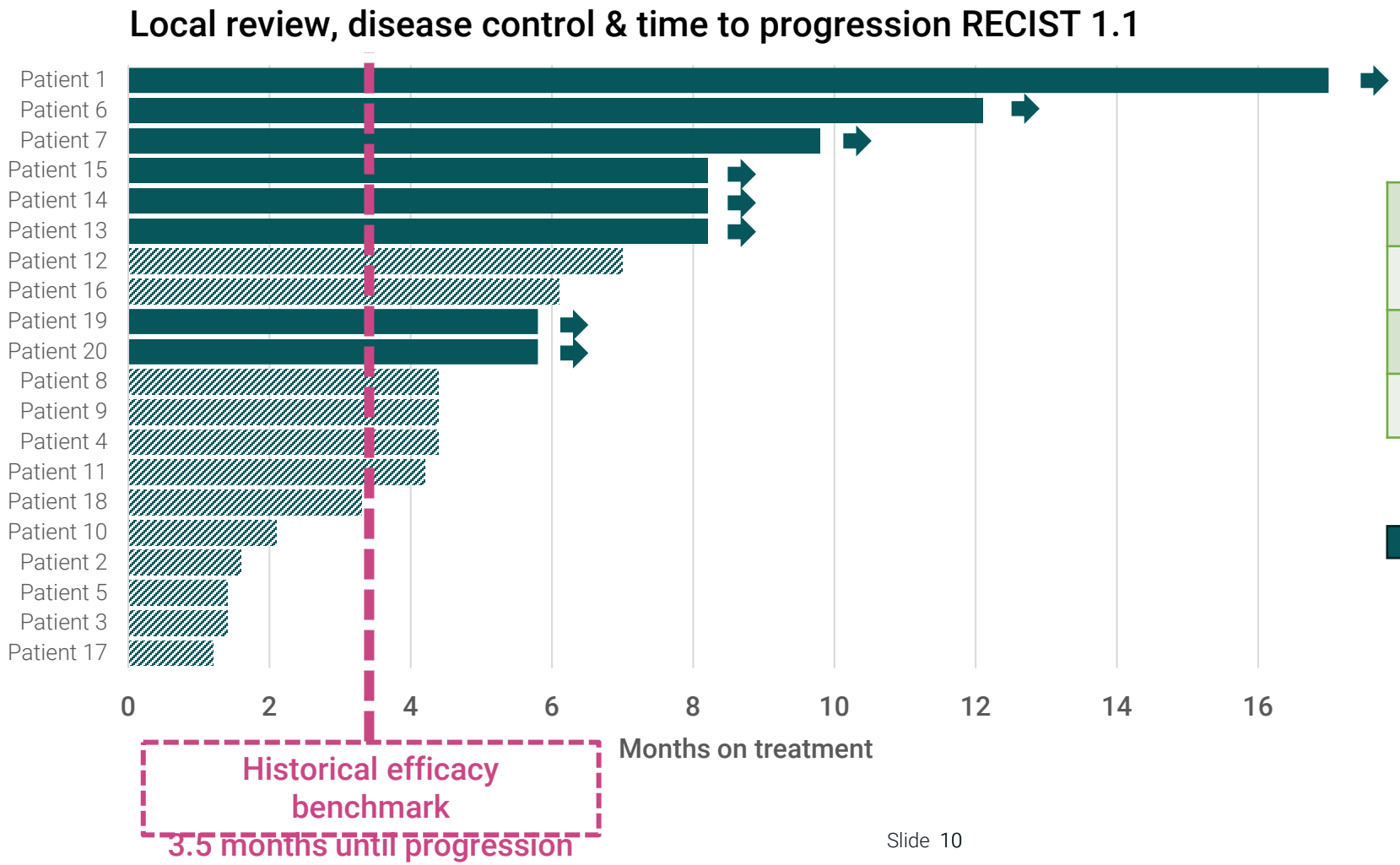
Promising clinical benefit and ability to stay on treatment long-term



DCR 6 w	80%
DCR 12 w	79%
DCR 18 w	61%
Median TTP*	**5.1 months**

Patients still on treatment

*Data cut-off Jan 2, 2024, 20 patients included >12 w follow-up

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Fostrox + Lenvima compares favourably with benchmarks

RECIST 1.1	Previous 2nd line studies[1]	2nd line Lenvima[2] (n=12)	Fostrox + Lenvima[3] (n=20)
ORR	~10%	8-17%	**25%**
DCR	~60%	58%*	**79%**
Median PFS/TTP	~3.5 months	2.8-4.1 months	**5.1 months**

*DCR at 12 weeks

[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]Preliminary results from Investigator review (20 patients, data cut-off January 2, 2024)

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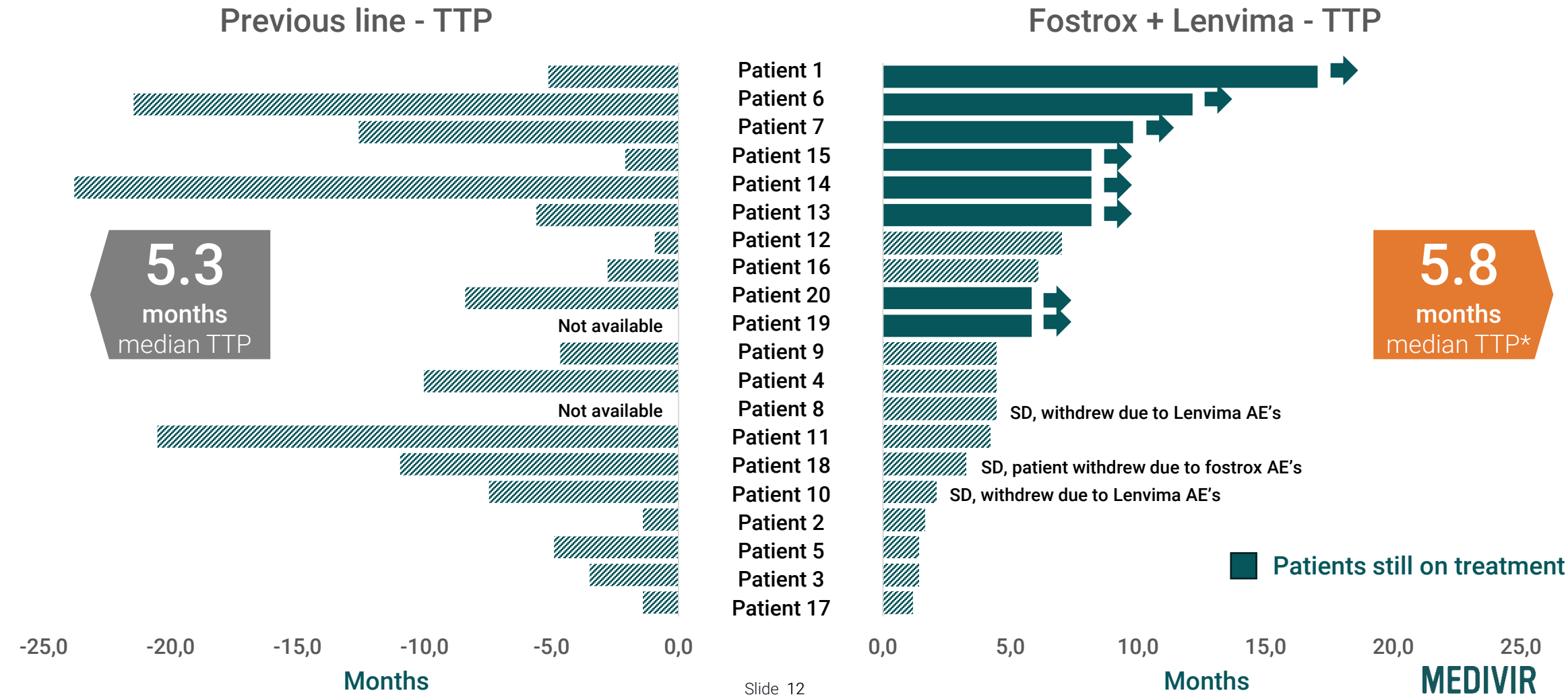
Long duration of benefit seen in patients with limited effect on prior treatment, updated median TTP 5.8 months*



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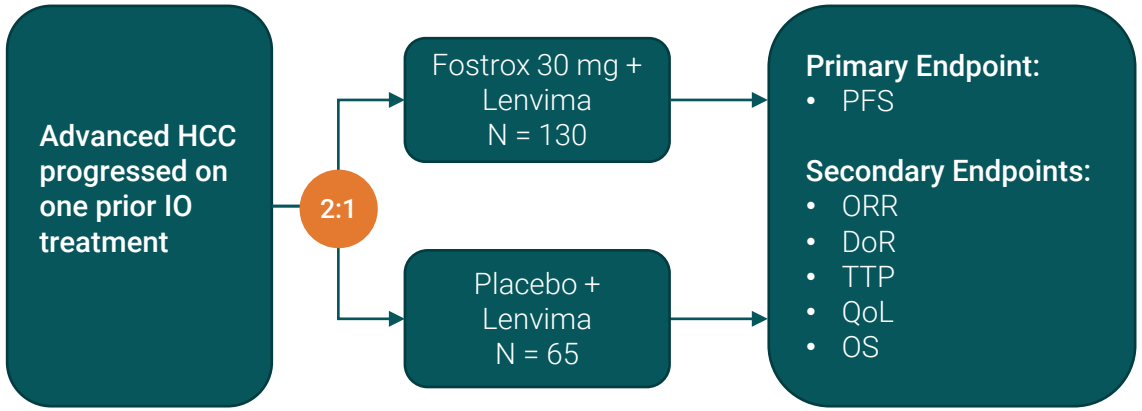
*TTP – Time to Progression, data cut-off January 22, 2024, >40% of patients still on treatment

Pivotal phase 2b; global HCC expert input at ASCO supports proposed study design ahead of FDA interactions

Phase 2b: randomized, double-blind study design



HCC experts feedback on study design

- ✓ No 2L data at progression on 1L IO; strong support for a randomized phase 2b study design
- ✓ Lenvima preferred 2L option, rational combination partner with fostrox
- ✓ Lenvima 2L monotherapy efficacy estimate; PFS/TTP ~4 months and ORR ~10%
- ✓ 2 months PFS benefit is clinically relevant
- ✓ Approriate study endpoints, to be confirmed in FDA interactions

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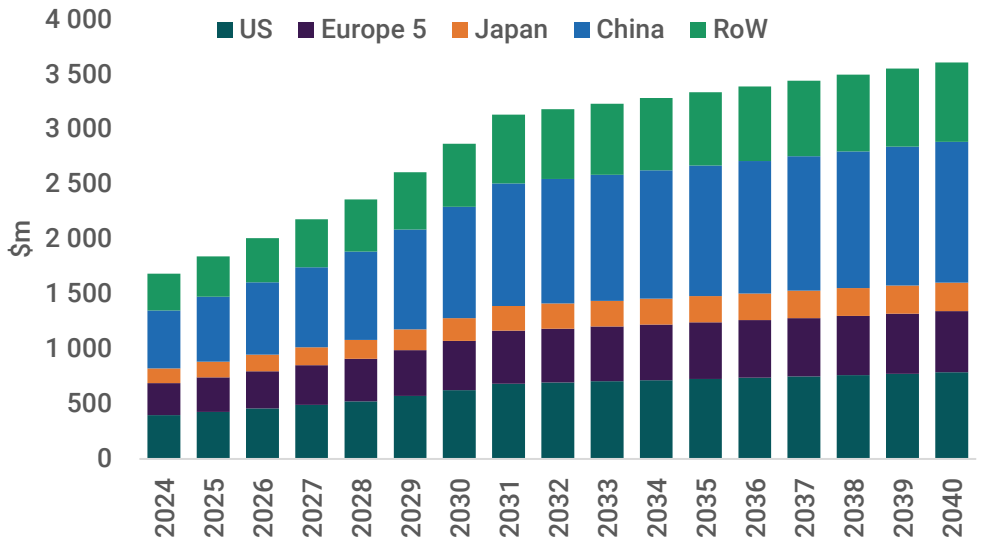
ASCO GI interactions reinforces first-to-market opportunity for fostrox in 2nd line HCC market worth ~$2.5bn by 2028

Significant market growth* driven primarily by NASH/NAFLD induced HCC



As medical treatments improve, 2nd line treatment duration will increase significantly*

2L treated patients 2028	▪ US: ~7.500 | EU5: ~11.000 | JP: 5.000 | CN: ~38.000
2L treatment duration	▪ 2L patients assumed to be **treated for 7 months** on average
Anticipated 2L competition 2028	▪ Base case – **no approved treatments post current 1L SoC** to compete with Fostrox + Lenvima
Cost of therapy per month	▪ US - $10.000 | EU - $5.000 | JP - $5.000 | CN - $3.000

*Source: GlobalData 2021 & internal analysis

Strategic evolution – Earlier treatment lines in HCC provides additional market opportunity of >$5bn

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Fostrox – a smart chemotherapy with a unique, liver targeted & tumor selective treatment of HCC, potential for accelerated approval 27/28

- Fostrox + Lenvima clinical benefit improves as study matures and shows consistently improved efficacy compared with Lenvima alone
- Acceleration of fostrox development to initiate registrational phase 2b in 2nd line HCC with Accelerated Approval intent 2027/2028
- 2nd line HCC post Tecentriq® + Avastin® lacks approved treatments & is a market valued at ~$2.5bn annually

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Thank You!

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