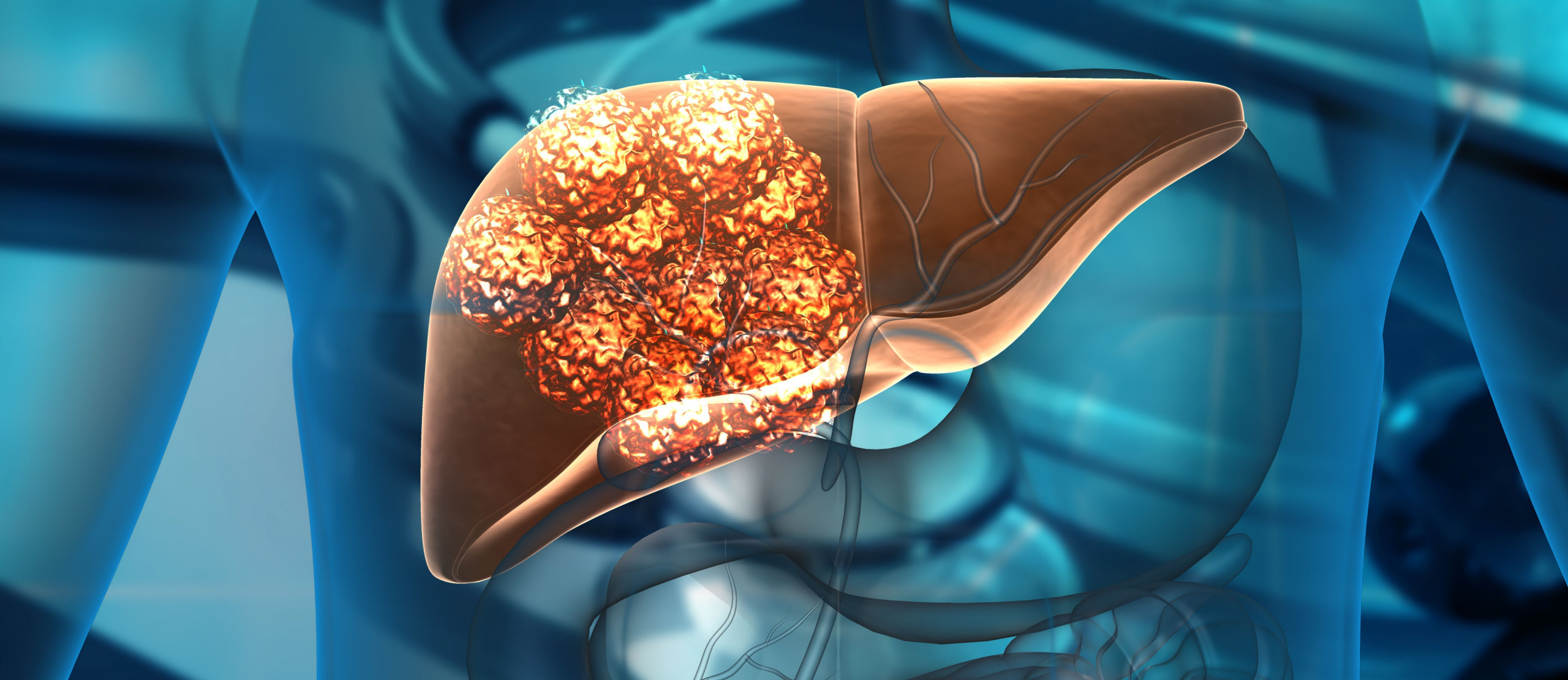




Medivir Q3 REPORT 2025

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

**MEDIVIR**

# Important notice

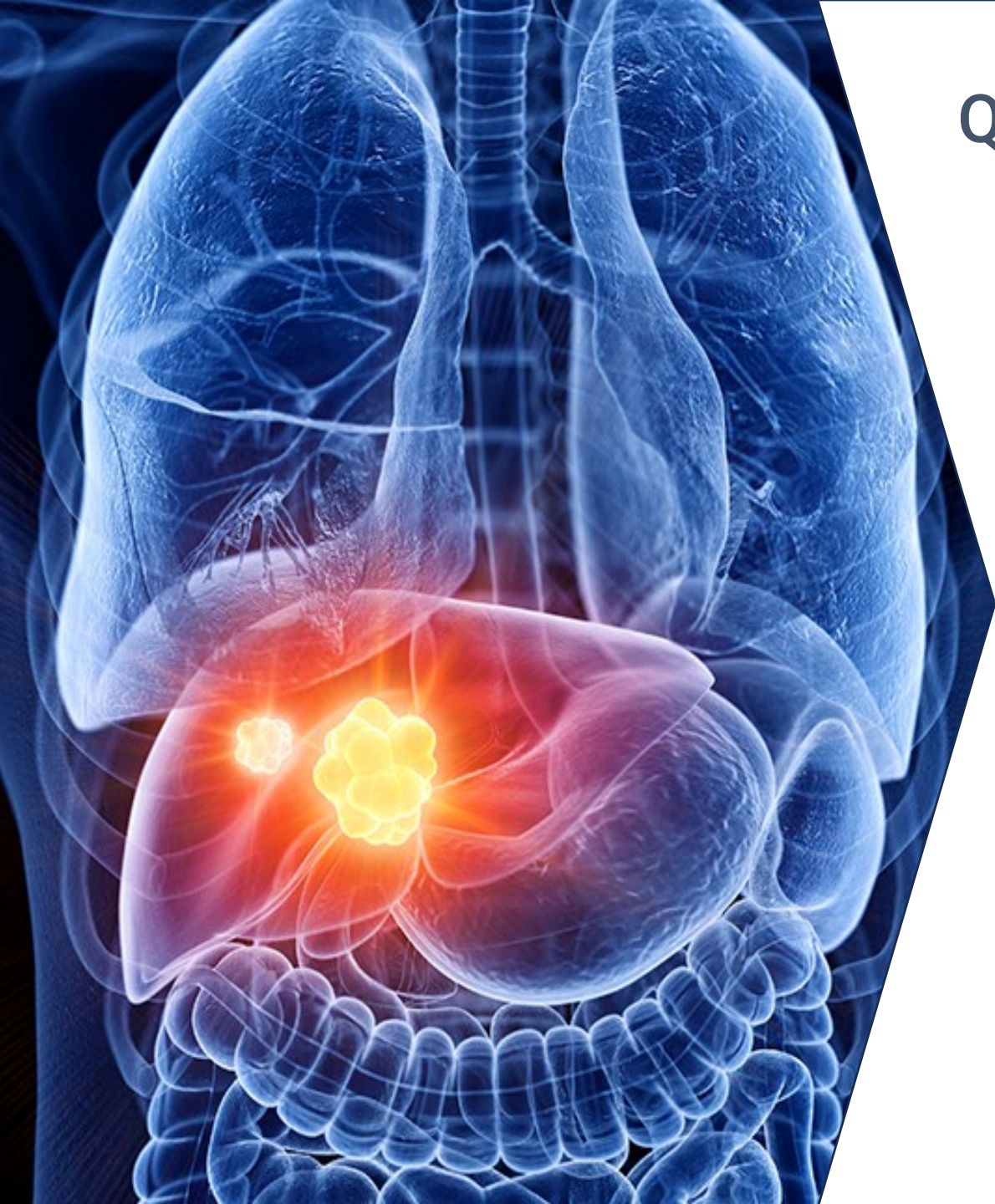
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An anatomical illustration of a human torso, focusing on the abdominal cavity. The liver is highlighted in a reddish-pink hue, and two distinct, glowing yellow-orange clusters represent liver tumors. The lungs and other internal organs are shown in a translucent blue style.

## Q3 Highlights



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

# Today's presenters



**CEO**  
**Jens Lindberg**



**CMO**  
**Pia Baumann**



**CFO**  
**Magnus Christensen**



**CSO**  
**Fredrik Öberg**

Phase 2 study enables rapid generation of randomized, comparative data to confirm benefit of fostrox combination with Lenvima

# Latest data in HCC presented at ESMO highlights continued significant unmet medical need in second-line

- Absence of second line data in liver cancer
- High unmet medical need without any real new options
  - Potential promising options (CAR-T, ADC etc) in other tumour types is so far not applicable in HCC
- Continued high interest in fostrox post immunotherapy among investigators
- Latest data reinforces immunotherapy in 1st line HCC

2<sup>nd</sup> Line HCC

## Management of Advanced HCC: Second-line

How do we envision second-line setting?

The trials performed up to now are not fit to purpose anymore taking into account in our current reality...



WHAT YOU ORDERED



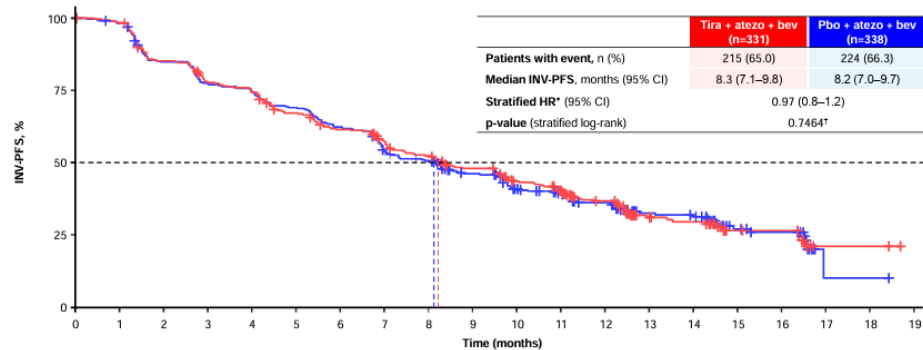
WHAT YOU GOT

ESMO congress

# ESMO 2025: Tecentriq/Avastin entrenched as 1st line SOC in HCC

- Global, randomized Phase 3 in 1st line advanced HCC (IMbrave152/SKYSCRAPER-14) with TIGIT + Tecentriq + Avastin vs Tecentriq + Avastin
- 669 pats randomized 1:1
- PFS curves superimposed – no difference in PFS

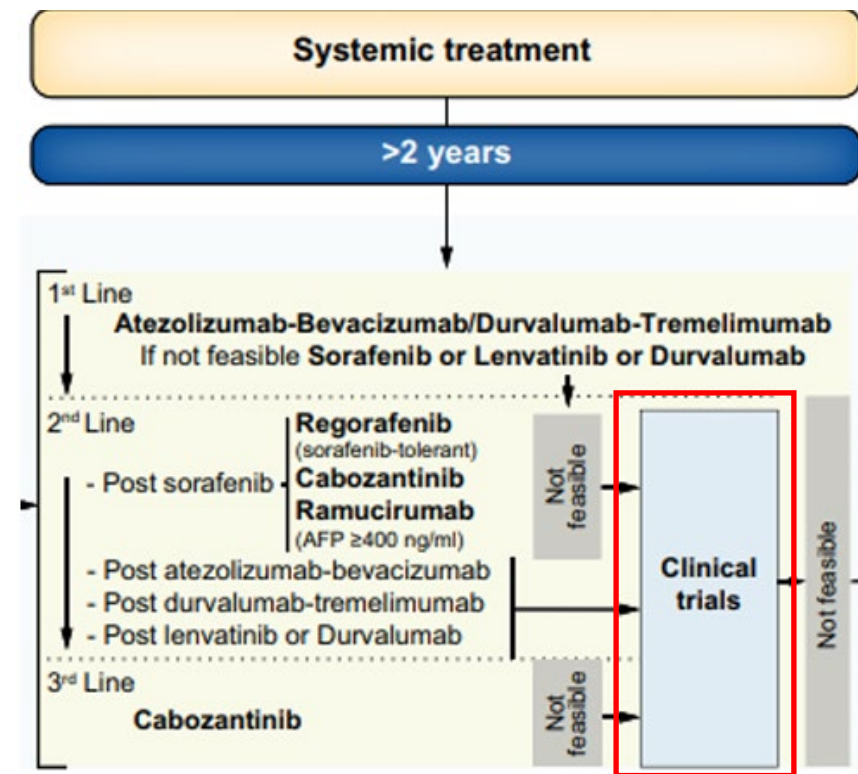
## Primary endpoint: INV-PFS per RECIST v1.1



Patients at risk:

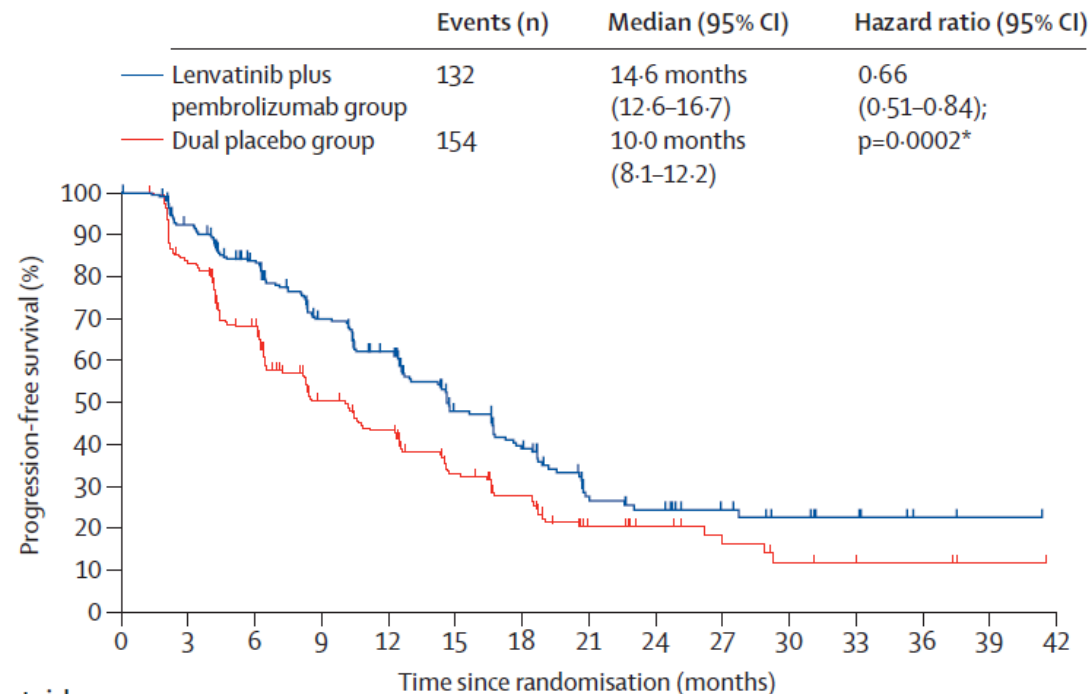
|                    |     |     |     |     |     |     |     |     |     |     |     |     |    |    |    |    |    |   |   |   |
|--------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|----|----|----|----|----|---|---|---|
| Tira + atezo + bev | 331 | 321 | 276 | 250 | 239 | 213 | 192 | 175 | 159 | 142 | 122 | 110 | 85 | 42 | 38 | 18 | 17 | 3 | 3 | 0 |
| Pbo + atezo + bev  | 338 | 326 | 279 | 254 | 246 | 227 | 205 | 174 | 162 | 136 | 112 | 98  | 87 | 54 | 51 | 26 | 22 | 1 | 1 | 0 |

NCT05904886. Data cutoff date: 8 May 2025. Minimum FU=7.5 months. Median FU=12.5 months. \*Stratification factors: geographic region (Africa and Asia, excluding Japan, vs rest of world, including Japan); HCC aetiology (viral vs non-viral); MM and/or EHS (presence vs absence); and baseline AFP (<400 vs ≥400 ng/mL). †Statistical boundary: 0.005. CI, confidence interval; FU, follow-up; HR, hazard ratio.



# Recently announced data in earlier stage HCC strengthens the positioning of fostrox + Lenvima in 2<sup>nd</sup> line advanced HCC

## ESMO 2024: Positive PFS with Keytruda + Lenvima + TACE vs TACE in intermediate stage HCC (LEAP-012)<sup>1</sup>



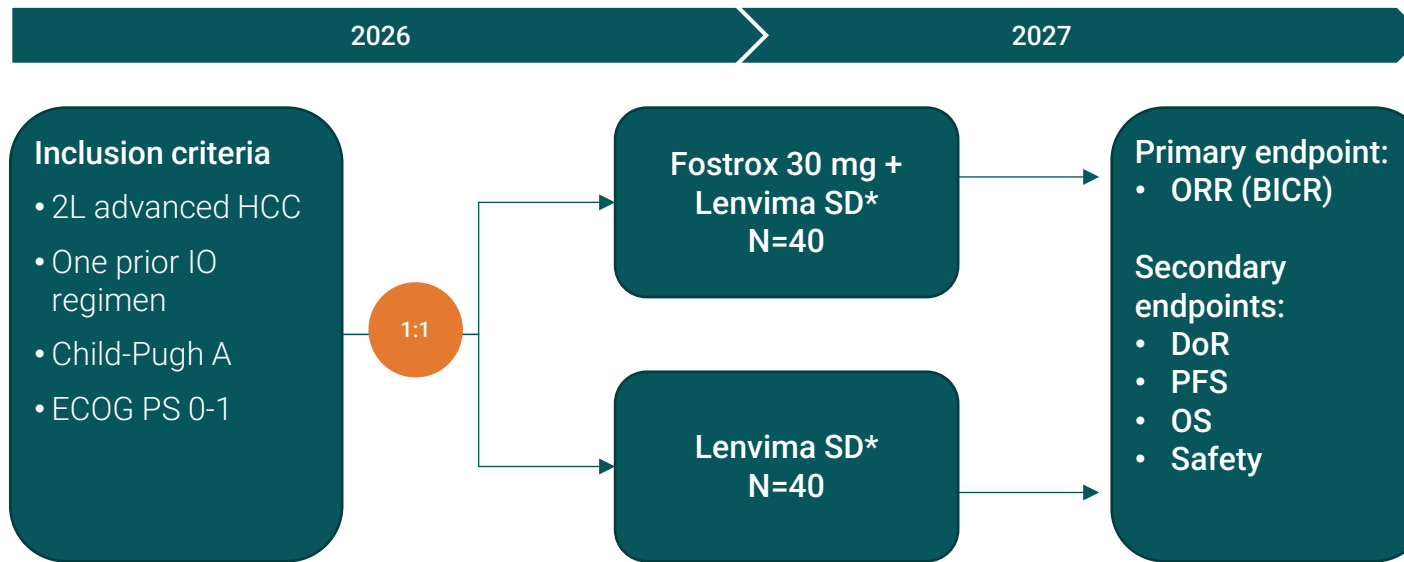
## Oct 2025: No OS benefit with addition of Keytruda + Lenvima to TACE (LEAP-012)<sup>2</sup>

- KEYTRUDA plus LENVIMA in addition to TACE did not provide significant OS benefit, one of the study's primary endpoints
- As a result, the study will be closed
- The results from LEAP-012 further reinforces immunotherapy combinations to be used in 1<sup>st</sup> line advanced stages of HCC
- The outcome also strengthens the strategic positioning of fostrox + Lenvima in 2<sup>nd</sup> line HCC

<sup>1</sup>Llovet et al, ESMO 2024, Presidential session

<sup>2</sup>Merck & Eisai press release on October 29, 2025

# Randomized, comparative phase 2 study to strengthen evidence for fostrox + Lenvima combination in 2<sup>nd</sup> 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

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

## Second-line lenvatinib after atezolizumab-bevacizumab in advanced HCC

### Study design

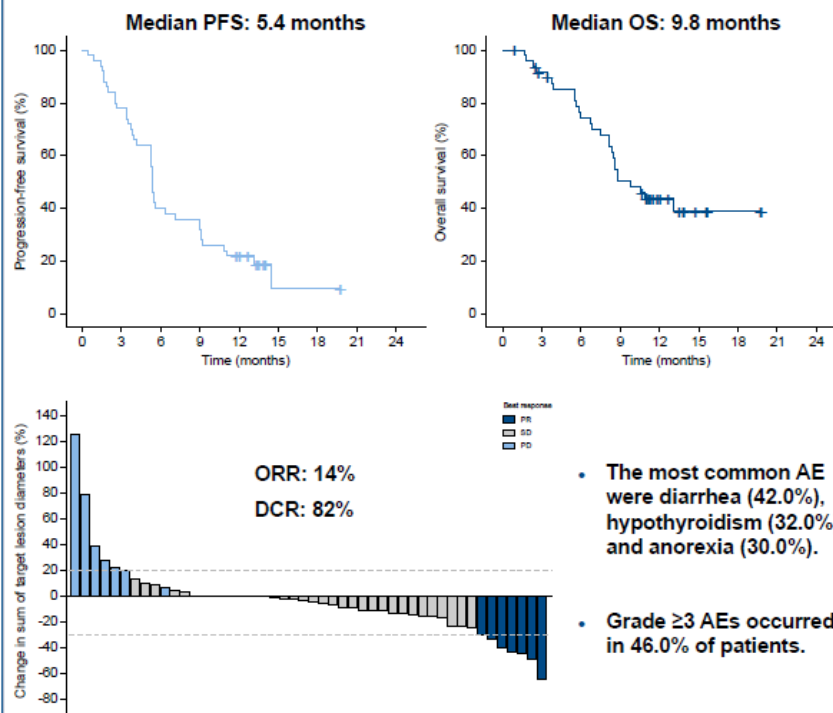
HCC progressed on 1<sup>st</sup>-line atezolizumab-bevacizumab



2<sup>nd</sup>-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



### 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.

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

| Patient characteristics                                              | N = 50<br>Lenvima monotherapy<br>13 sites in Korea <sup>1</sup> | N = 21 <sup>2</sup><br>Fostrox + Lenvima<br>15 sites in Korea, UK & Spain <sup>2</sup> |
|----------------------------------------------------------------------|-----------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 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; 2 <sup>nd</sup> line/3 <sup>rd</sup> line (%) | 100 / 0                                                         | 81 / 19                                                                                |
| Prior atezolizumab/bevacizumab in 1 <sup>st</sup> line (%)           | 100                                                             | 86                                                                                     |
| Prior TACE therapy (%)                                               | 58                                                              | 70                                                                                     |

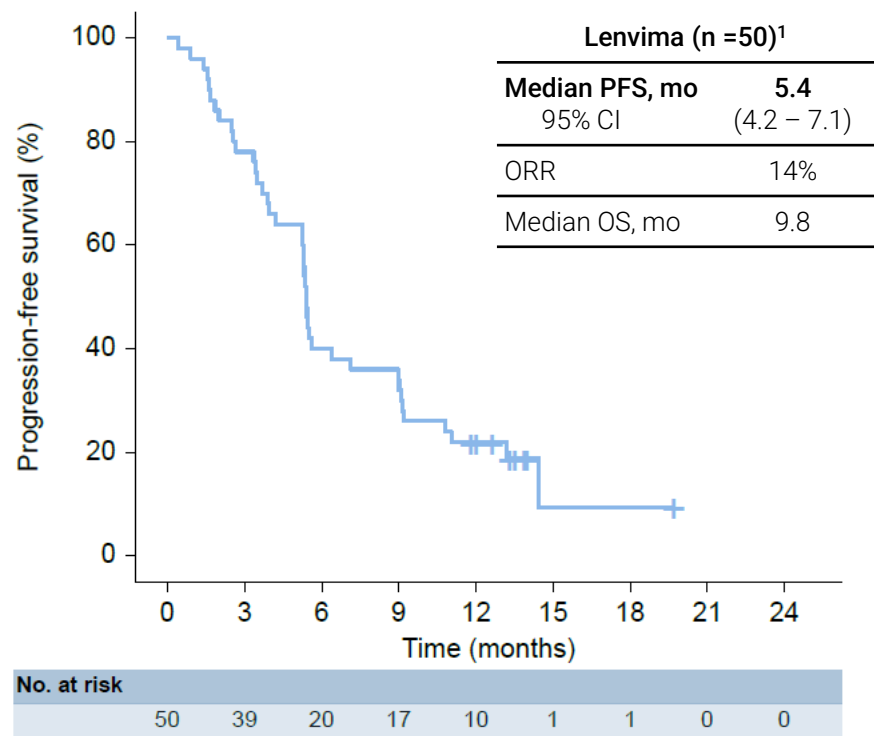
\*HepB-81% and HepC-19%; \*\*AFP- NA for 1 pt

<sup>1</sup>Kim et al., Journal of Hepatology, Sept 04 2025

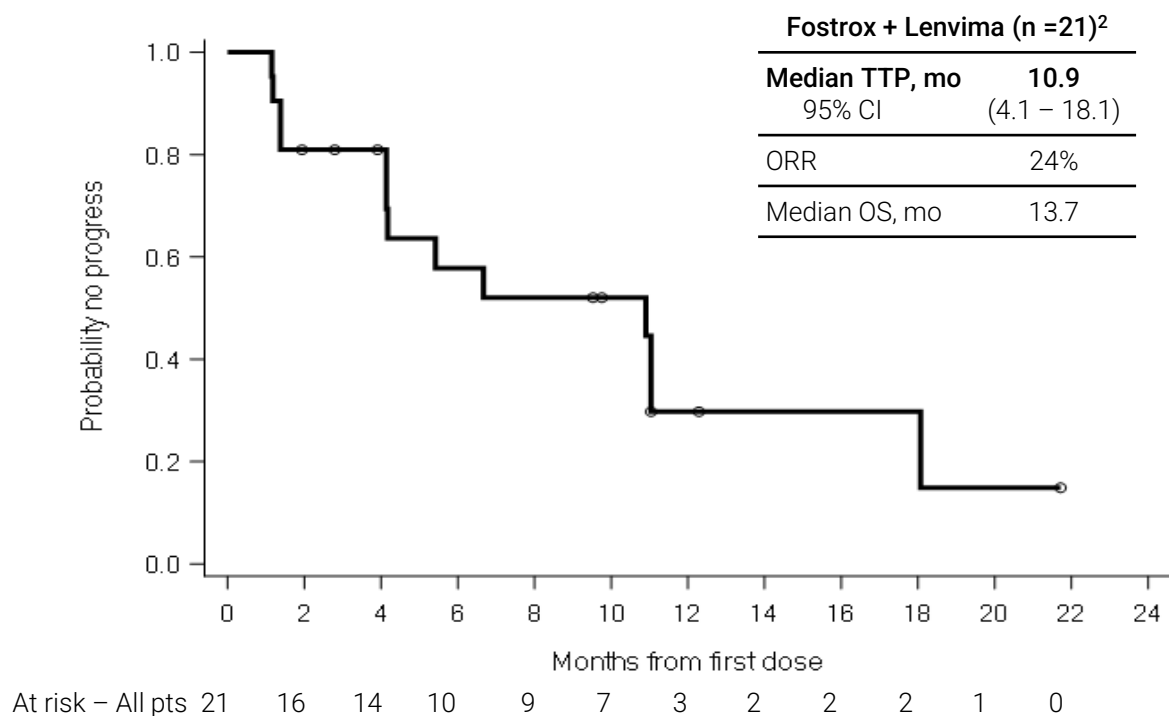
<sup>2</sup>Chon et al., ESMO 2024, Poster 986

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

Median PFS – Lenvima monotherapy<sup>1</sup>



Median TTP – Fostrox + Lenvima<sup>2</sup>



<sup>1</sup>Kim et al., Journal of Hepatology, Sept 04 2025

<sup>2</sup>Chon et al., ESMO 2024, Poster 986



Remetinostat out-license generates significant potential value upside

# Medivir enters exclusive licensing agreement with Bioassil, Inc. for remetinostat

## Medivir enters exclusive licensing agreement with Bioassil, 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 Bioassil, Inc. will receive global, exclusive development rights for remetinostat, a clinical-stage topical HDAC inhibitor. Bioassil is a Toronto-based AI-native drug developer focused on developing novel therapies for heterogeneous diseases with urgent unmet medical needs.



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



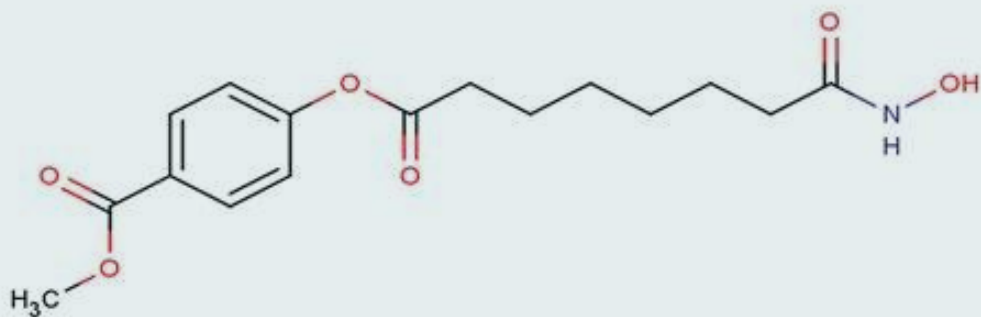
Global, exclusive, licensing agreement to develop and commercialize remetinostat



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

# Remetinostat – a unique, first-in-class, topical HDAC inhibitor

## Topical HDAC inhibitor



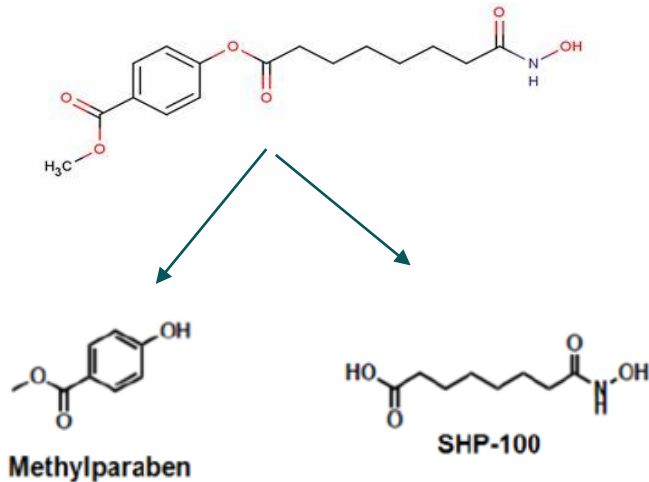
Designed to minimize systemic exposure –  
stable in skin but not in blood

- Proven clinical benefit in multiple cancers of the skin; CTCL, BCC and SCC
- Especially suitable for patients with multiple, recurring BCC skin lesions where surgery is less suitable
- Phase III ready (IND open) with potential for orphan drug designation in Gorlin Syndrome, a disease with no approved topical treatments

# Remetinostat – a unique, first-in-class, topical HDAC inhibitor

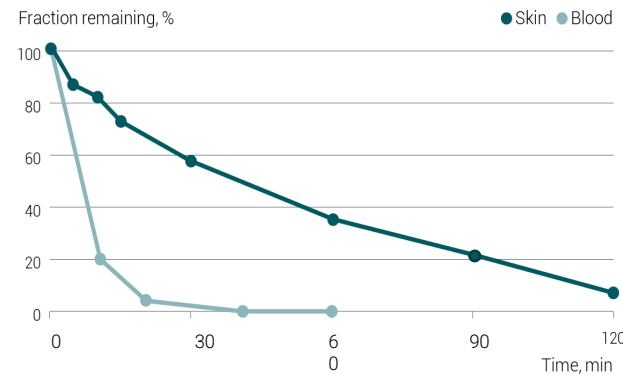
## Potent topical HDAC inhibitor

- Inhibits HDAC 1, 3 and 6, but broken down to inactive primary metabolites SHP-100 and methylparaben by serum esterases in blood



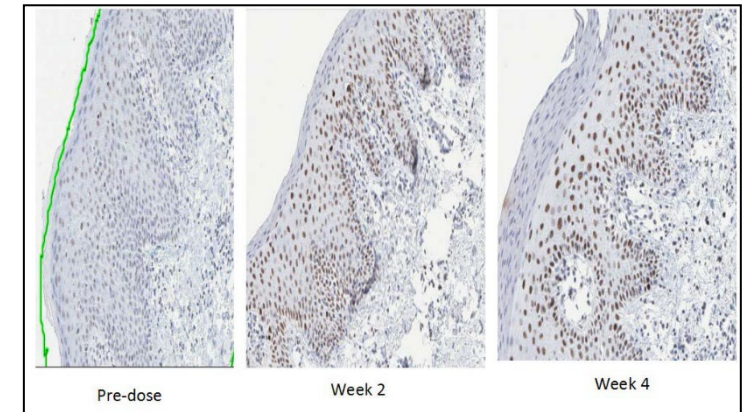
## Stable in skin but not in blood

- Designed to inhibit HDACs in skin cancers with minimal systemic exposure
- Translating to reduced risk of HDACi class-associated toxicities



## Pharmacodynamic effect in skin cancer

- Biopsy data from CTCL phase 1 study demonstrates remetinostat (1%, BID) induced hyper-acetylation



HDAC inhibition was evaluated by IHC analysis of skin biopsies from CTCL tumors using an antibody directed against acetylated lysine (brown staining)

# What we already know from remetinostat in a clinical setting

## CTCL

- Completed phase II open-label, dose-selection study (60 pts) in MF-CTCL with 40% CAILS Confirmed ORR & median duration of CAILS Confirmed Response of 7 months for chosen phase III dose<sup>1</sup>
- Tolerable AE profile with predominantly mild skin events and no signs of related systemic AEs

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## BCC

- Phase II open-label, single-arm study (30 pts) with clinically significant decrease in disease burden after six weeks of treatment, 58% reaching complete pathological resolution<sup>2</sup>
- No serious or systemic AEs reported, safety results in line with previous trials for CTCL

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## SCC

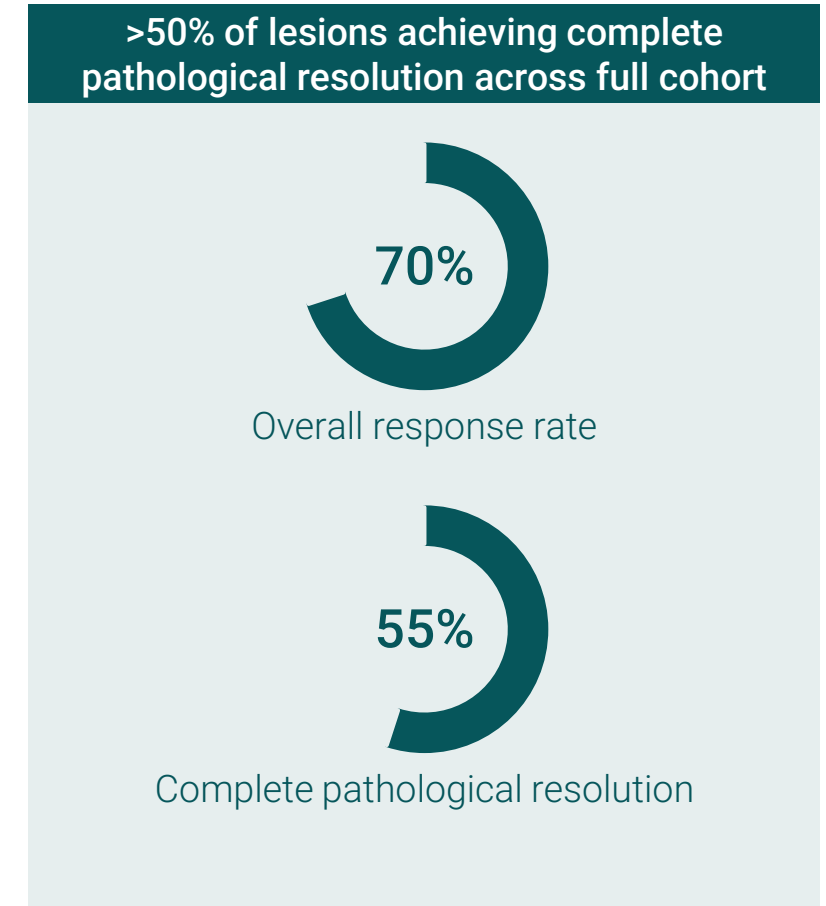
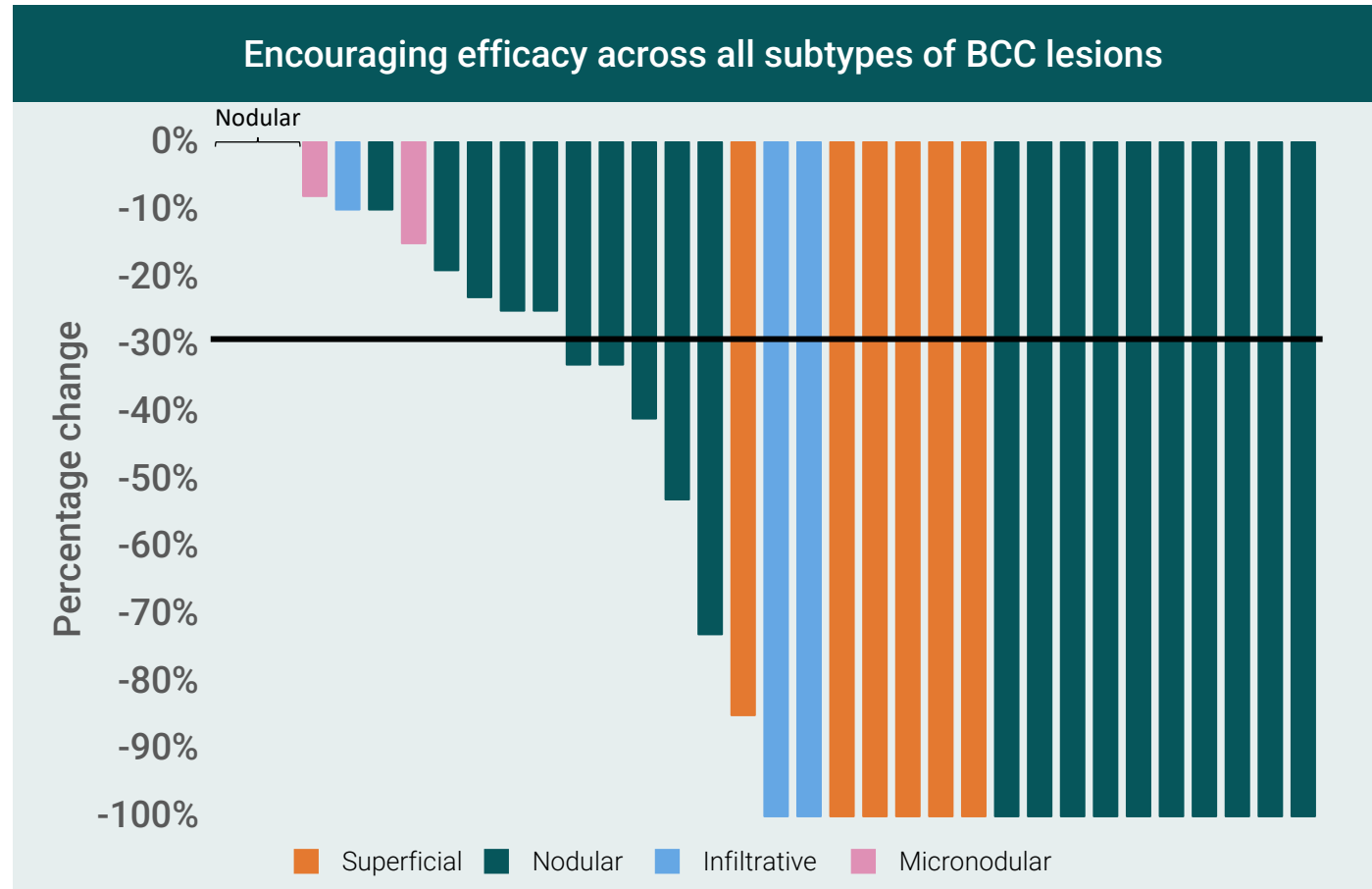
- Study terminated due to COVID outbreak but proof-of-principle demonstrated with 100% complete clinical and pathological resolution in 5 evaluable tumors<sup>3</sup>
- No serious adverse events observed

<sup>1</sup>M. Duvic et al International Investigative Dermatology (IID) meeting presentation 2018. doi.org/10.1016/j.jid.2018.03.615

<sup>2</sup>J. Kilgour et al, Clinical Cancer Research published online 6 August 2021. doi: 10.1158/1078-0432.CCR-21-0560

<sup>3</sup>J. Kilgour et al, JAMA Dermatology published online 17 November, 2021. doi:10.1001/jamadermatol.2021.4549

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



**MEDIVIR**

# Financial highlights Q3

# Financial summary Q3, 2025

## Consolidated Income Statement, summary (SEK m)

|                                          | Q3           |              | Q1 - Q3      |               | Full year     |
|------------------------------------------|--------------|--------------|--------------|---------------|---------------|
|                                          | 2025         | 2024         | 2025         | 2024          | 2024          |
| Net turnover                             | 0.9          | 0.9          | 3.0          | 2.5           | 3.5           |
| Other operating income                   | 0.0          | 0.3          | 0.5          | 0.5           | 1.0           |
| <b>Total income</b>                      | <b>1.0</b>   | <b>1.2</b>   | <b>3.6</b>   | <b>3.1</b>    | <b>4.5</b>    |
| Other external expenses                  | -8.1         | -29.6        | -31.2        | -80.6         | -101.3        |
| Personnel costs                          | -5.8         | -6.3         | -19.9        | -20.4         | -27.2         |
| Depreciations and write-downs            | -0.7         | -0.7         | -2.0         | -2.0          | -2.7          |
| Other operating expenses                 | 0.0          | -0.3         | -0.5         | -0.4          | -0.6          |
| <b>Operating profit/loss</b>             | <b>-13.6</b> | <b>-35.7</b> | <b>-50.1</b> | <b>-100.4</b> | <b>-127.3</b> |
| Net financial items                      | -1.0         | 1.1          | -1.1         | 3.8           | 4.0           |
| <b>Profit/loss after financial items</b> | <b>-14.6</b> | <b>-34.6</b> | <b>-51.2</b> | <b>-96.7</b>  | <b>-123.3</b> |
| Tax                                      | -            | -            | -            | -             | -             |
| <b>Net profit/loss for the period</b>    | <b>-14.6</b> | <b>-34.6</b> | <b>-51.2</b> | <b>-96.7</b>  | <b>-123.3</b> |

- Net turnover for Q3 was SEK 0.9 million
- Operating loss for Q3 was SEK -13.6 million
- Cash flow from operating activities for Q3 was SEK -14.1 million
- Cash balance end of Q3 was SEK 23.5 million

The background is a deep purple with a bokeh effect of out-of-focus light circles. A dense cluster of thin, white, fiber-optic-like lines radiates from the center, creating a starburst effect.

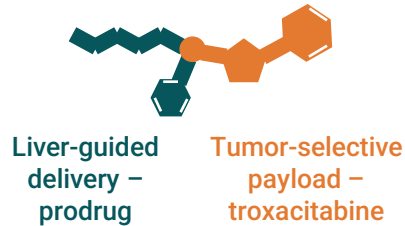
Q/A

# Fostrox (fostroxacitabine bralpamide)

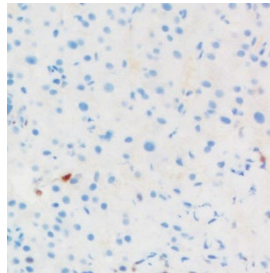
## The first oral, liver-targeted treatment tailored for HCC

Oral, liver-activated small molecule inducing DNA damage in tumor cells, sparing healthy liver cells<sup>3</sup>

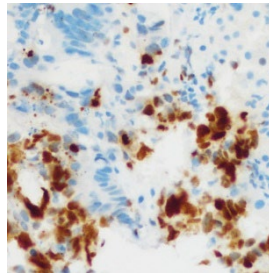
Unique, liver-targeted approach in HCC



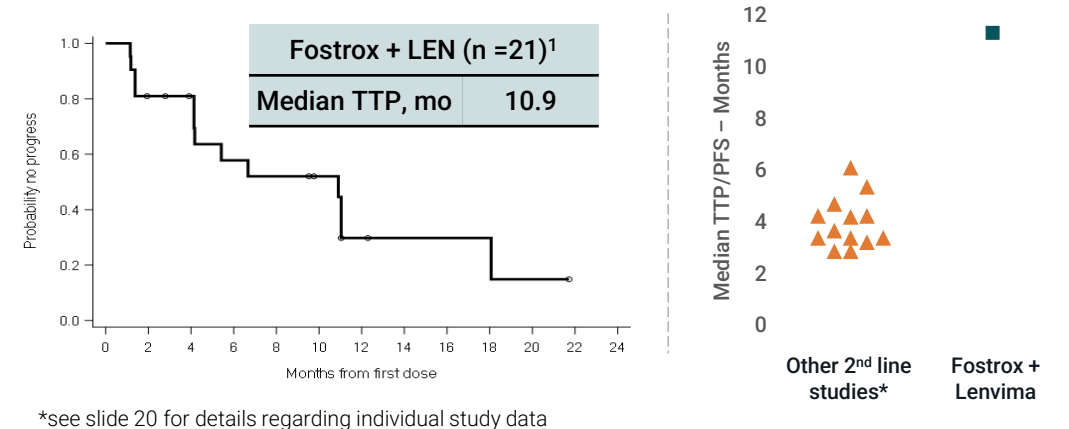
No DNA damage in healthy liver tissue



DNA damage in tumor tissue



10.9 months time to progression, substantially better than SoC<sup>1,2</sup>



Absence of effective treatment options in 2<sup>nd</sup> line enables first-to-market opportunity for fostrox + Lenvima



- No 2<sup>nd</sup> line treatments approved in advanced HCC
- Phase 2 designed to rapidly confirm comparative benefit of fostrox in combination with Lenvima

Market opportunity in 2<sup>nd</sup> line HCC >\$2.5bn, with significant upside potential

>\$2.5bn

2<sup>nd</sup> line HCC market by 2030, fastest growing cause of cancer death in US<sup>4</sup>



Significant upside in liver metastasis from other solid tumors

<sup>1</sup>Chon et al., ESMO, 2024, Poster 986

<sup>2</sup>Based on data from previous 2L phase 3 HCC studies with Stivarga, Cyramza & Cabometyx and investigator initiated prospective & retrospective 2L studies with Lenvatinib

<sup>3</sup>Evans et al ASCO GI, 2021

<sup>4</sup>Ma et al., Cancer, June 15, 2019; 2089-2098

The background is a deep purple with a bokeh effect of out-of-focus light circles. Numerous thin, white, curved lines radiate from the center towards the right side of the frame, creating a sense of motion or a starburst effect.

# Thank You!