



# MEDIVIR Q4 WEBCAST

FEBRUARY 15, 2023

MEDIVIR

# Today's presenters



**CEO**

- Jens Lindberg
- Joined Medivir 2022
- > 25 years pharma experience with focus in Oncology.
- Has led global product strategy development for late-stage compounds as well as product launch for multiple compounds.
- Experience includes interim CEO role for Sedana Medical AB.
- Medivir ownership; 25.000 shares & 490.000 warrants



**CFO**

- Magnus Christensen
- Joined Medivir 2019
- > 20 years experience in finance, including CFO at O'Learys Trademark AB.
- Previous interim CEO at Medivir
- Experience of working in listed-, private equity- and private companies.
- Medivir ownership 21.000 shares & 322.500 warrants



**CSO**

- Fredrik Öberg
- Joined Medivir 2011
- > 25 years experience in cancer research from industry and academia
- > 50 scientific articles and holds several patents.
- Adjunct professor at Medical Faculty of Uppsala University
- Medivir ownership; 69.172 shares & 257.500 warrants

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# Highlights during last quarter

# Highlights during last quarter

## Continued progress for fostrox in liver cancer

- Continued strong recruitment in fostrox study, anticipating recommended phase II dose near-term
- Pre-IND meeting with FDA completed with positive feedback on development plan
- New data, showing additive efficacy of fostrox in combination with anti-PD1 in experimental tumor models, presented at the SITC Conference in November.
- Pia Baumann recruited as new Chief Medical Officer, taking office on February 20, 2023

## Overall portfolio development

- The IGM-8444 + birinapant combination study continues to enroll patients in fourth cohort, no DLTs observed to date.
- INFEX Therapeutics announced that the MBLI program (MET-X) received FDA QIDP designation
- Tango Therapeutics announced selection of TNG348 as drug candidate for treatment of BRCA1/2 mutated cancers & intention to open IND in 2023

# Pia Baumann recruited as new Chief Medical Officer– starts on February 20, 2023



**Pia Baumann**  
CMO

- MD, Ph.D from Karolinska Institute.
- Oncologist trained at Karolinska and clinically active from 1999 to 2010.
- Since 2010 in pharmaceutical industry, predominantly in regional and global roles at various smaller biotech (Ariad, Incyte) as well as larger pharmaceutical companies (BMS, Takeda and AstraZeneca) with significant experience from:
  - Solid tumors and hematological malignancies
  - Developing global product strategies as well as designing and conducting clinical studies in close collaboration with leading clinics.
  - Engaging with regulatory authorities.



# Pipeline overview – in-house development & assets for partnering

PROJECT	PARTNER	DISEASE AREA	PRE-CLINICAL	PH 1	PH 2	PH 3	ON MARKET	FINANCIALS	POTENTIAL NEXT EVENT(S)
<b>IN-HOUSE PROGRAM</b>									
Fostroxacitabine bralpamide	In-house development	HCC (mono) HCC (combo)						100% Medivir	<ul style="list-style-type: none"> <li>Selection of dose(s)</li> <li>Dose expansion</li> </ul>
<b>PARTNERING PROGRAMS</b>									
Xerclear	GSK, SYB	Herpes						Royalties	<ul style="list-style-type: none"> <li>Registration in China</li> </ul>
Remetinostat	TBD	CTCL, BCC, SCC						TBD	<ul style="list-style-type: none"> <li>Partnering agreement</li> </ul>
MIV-711	TBD	Osteoarthritis						TBD	<ul style="list-style-type: none"> <li>Partnering agreement</li> </ul>
Birinapant	IGM Biosciences	Solid tumors						Milestones (up to \$350m) & royalties	<ul style="list-style-type: none"> <li>Selection of dose</li> <li>Expansion cohort(s)</li> </ul>
USP-1	Tango Therapeutics	Cancer						Milestones & royalties	<ul style="list-style-type: none"> <li>US IND</li> <li>Initiating phase I</li> </ul>
USP-7	Ubiquigent Limited	Cancer						Revenue share	<ul style="list-style-type: none"> <li>Partnering agreement for Ubiquigent</li> </ul>
MBLI (MET-X)	INFEX Therapeutics	Infection						Revenue share	<ul style="list-style-type: none"> <li>Initiating phase I</li> <li>Partnering agreement</li> </ul>

Projects developed by Medivir  
 Projects developed by external partner

Slide

**MEDIVIR**

# Fostroxacitabine bralpamide (fostrox)



# Traditional chemotherapy – bringing great benefits to many cancer patients but not so much in HCC

## Traditional chemotherapy used sparsely in HCC

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1. Traditional (IV administered) chemotherapy is standard of care in most cancer indications
2. However, not so in HCC, where traditional chemotherapy has not been as beneficial for patients as in other tumour types
3. The key challenge has been balancing systemic toxicities vs clinical efficacy

## Why is traditional chemo not used as much in HCC?

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1. **Narrow therapeutic window** – doses needed to enable effective concentrations in the liver also causes significant systemic toxicity
2. **Liver toxicity extra sensitive in HCC** – concomitant liver disease makes HCC patients extra sensitive to liver tox
3. **Inactivation of drugs in the liver** – Liver cells specifically express high levels of resistance mechanism designed to deactivate many of the different chemotherapy classes

# Traditional chemotherapy – bringing great benefits to many cancer patients but not so much in HCC

## What is needed to overcome the challenges of traditional chemo?

**Liver targeted exposure** – Enable higher liver concentrations at lower doses to ensure anti-tumour efficacy but minimise systemic toxicity

**Cell killing selectivity** – Ensure cell death as much as possible only in tumour cells and not normal cells in the liver

**Avoiding resistance mechanisms** – Design molecule to avoid recognition from deactivating cellular enzymes like cytidine deaminase (CDA)

## Medivir's approach to solving for the shortcomings of traditional chemo

**Learning from pro-drug approach used successfully in HCV**

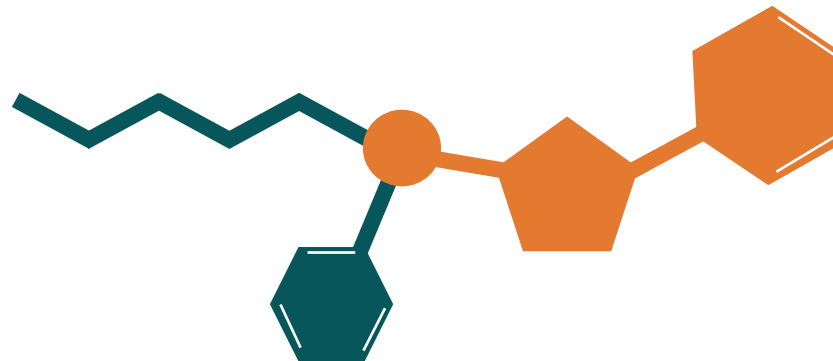
**Cytotoxic with strong link between DNA replication & DNA damaging effect**

**L-nucleoside approach to circumvent resistance mechanisms**

# Fostrox – Combination of pro-drug technology & chemotherapy to minimise systemic side effects

## Pro-drug tail

- Enables oral administration with >100-fold higher liver targeting vs traditional, iv administered chemotherapy
- Same approach as used by Sovaldi in Hepatitis C



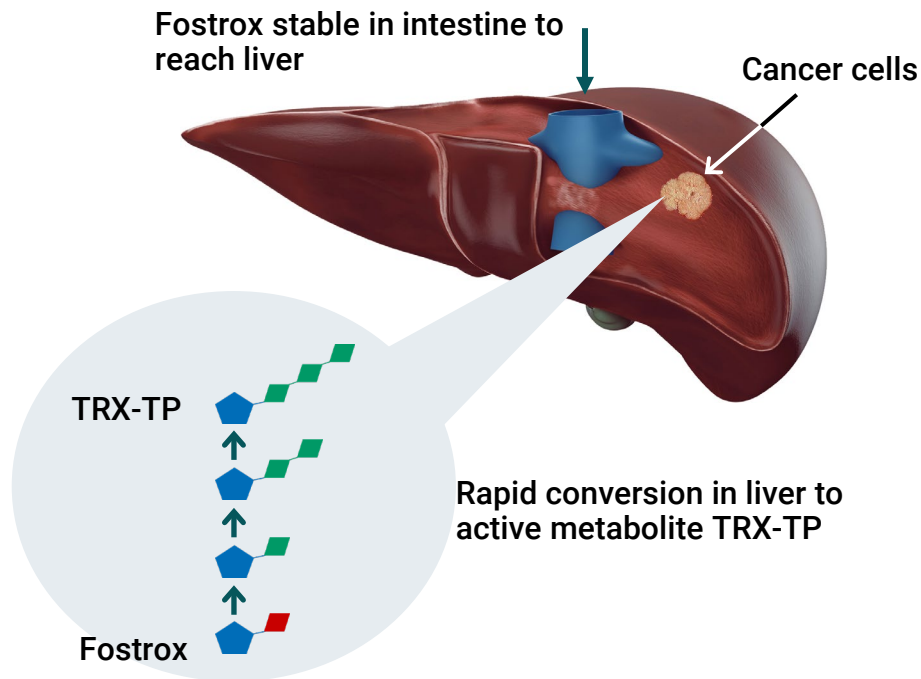
## Active substance - troxacitabine

- Chemotherapy that induces tumor selective DNA-damage & cell death
- Proven anti-tumor efficacy but with too many side effects when administered IV

# Fostrox – first-in-class, orphan drug inducing DNA damage & cell death selectively in liver tumor tissue

Differentiated mechanism of action (MoA) designed to be liver targeted & minimise systemic exposure

>100-fold higher liver targeting of fostrox than iv chemotherapy (troxacitabine) in rats

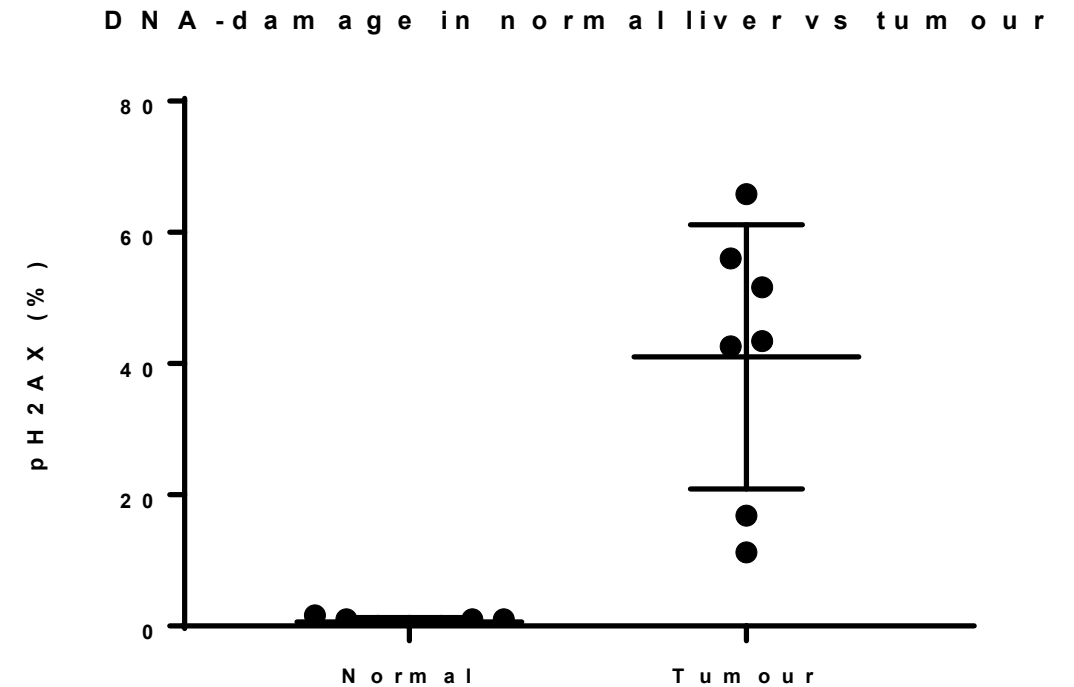
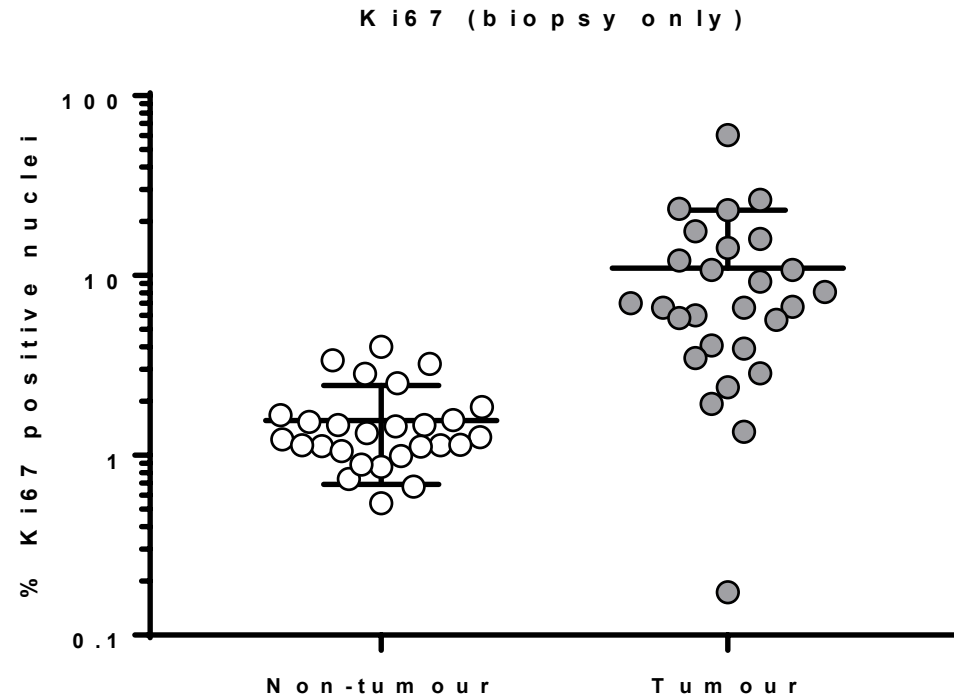


Compound	Route	Dose (μmol/kg)	AUC <sub>Liver</sub> (nmol*h/g)	AUC <sub>Plasma</sub> (μmol*h/L)	AUC ratio (Liver/Plasma)
Troxacitabine	<i>iv</i>	80	<1.2	80	<b>&lt;0.016</b>
Fostrox	<i>oral</i>	80	10	5.4	<b>1.9</b>

# Fostrox – inducing DNA damage & cell death in HCC tumour cells, sparing normal liver tissue

Significantly higher proliferation rate in liver tumour cells vs normal liver cells<sup>1</sup>, indicating vulnerability to chemotherapy

DNA-damage & cell death observed with Fostrox in tumor tissue but not in normal liver tissue<sup>2</sup>



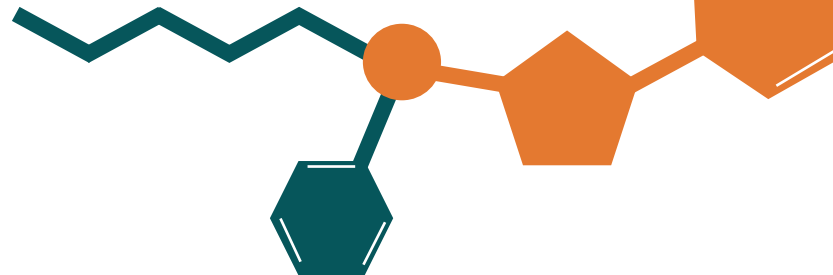
<sup>1</sup>Albertella, M. et al EASL Summit P01-05, 2017

<sup>2</sup>Öberg F. et al, EASL PO-221, 2022

# Fostrox – troxacitabine chosen as the active substance due to its ability to avoid resistance mechanisms

## Pro-drug tail

- Enables oral administration with >100-fold higher liver targeting vs traditional, iv administered chemotherapy
- Same approach as used by Sovaldi in Hepatitis C

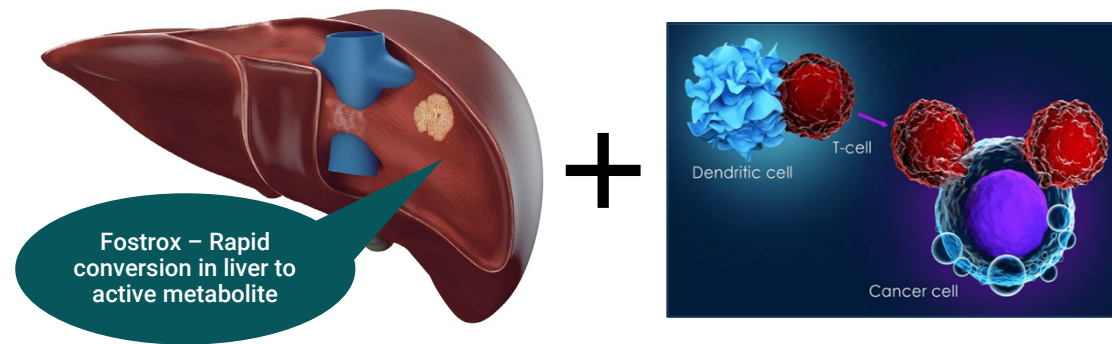


## Active substance - troxacitabine

- L-nucleoside (instead of natural D-nucleosides)
- L-nucleosides are not recognized by many cellular enzymes, thereby avoiding resistance mechanisms & toxicity

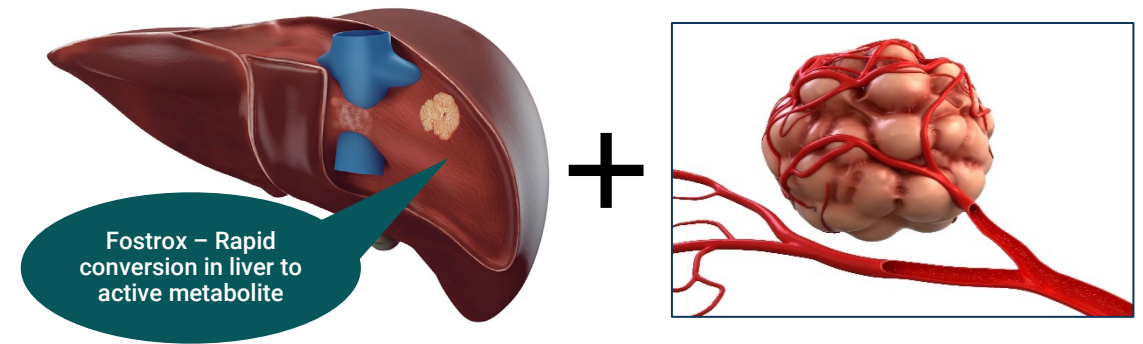
# Fostrox – A unique, differentiated MoA in HCC inhibiting DNA replication; strong potential for combinations

Fostrox + stimulation of immune system (PD-1)



“Fostrox induces DNA damage and tumor cell death, potentially leading to **increased tumor antigen presentation and increased immune response**”

Fostrox + blocking blood supply to tumor (TKI)

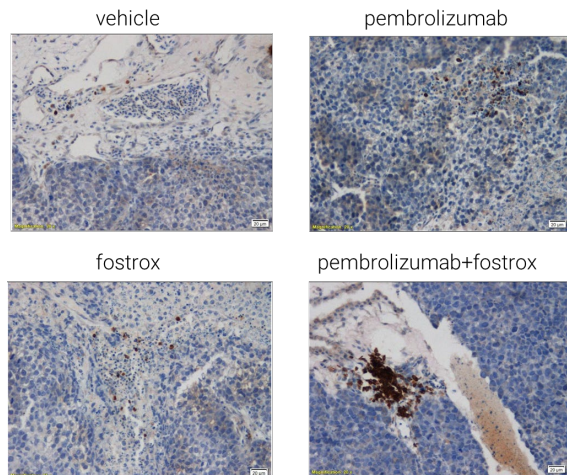


“TKI’s induce lack of oxygen in tumors leading to increased PGK1\* expression and most importantly **higher levels of fostrox active metabolite**”

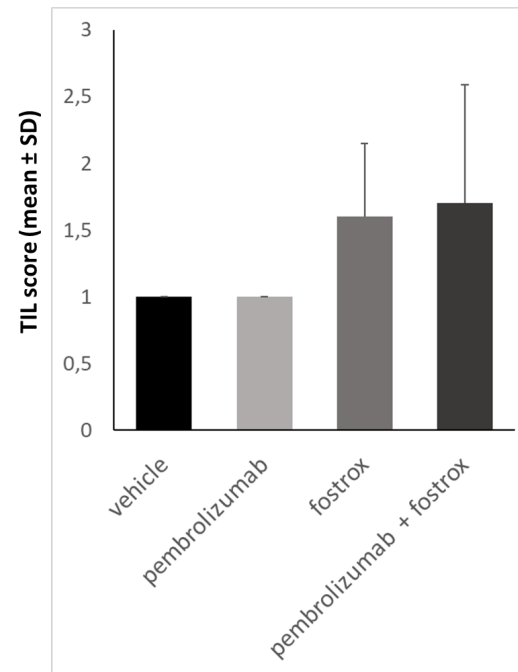
\*Phosphoglycerate kinase 1 – hypoxia inducible gene

# Fostrox treatment increases tumour infiltrating lymphocytes and enhances checkpoint inhibitor activity

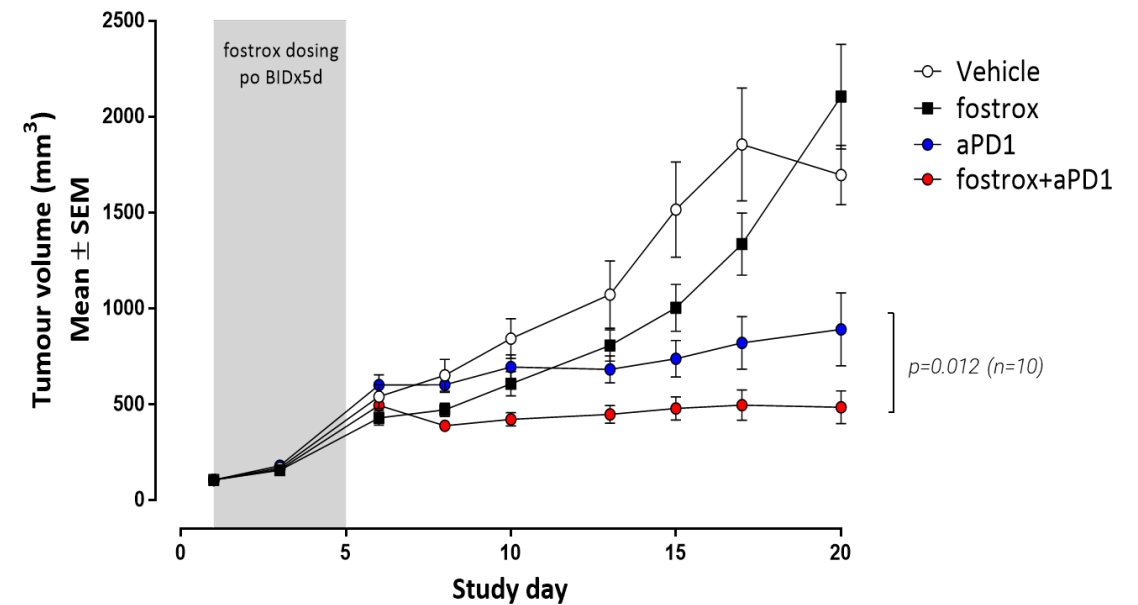
Increased tumour infiltrating lymphocytes (TILs) with fostrox treatment<sup>1</sup>



IHC of CD8 positive T-cells (brown) in a preclinical tumour model



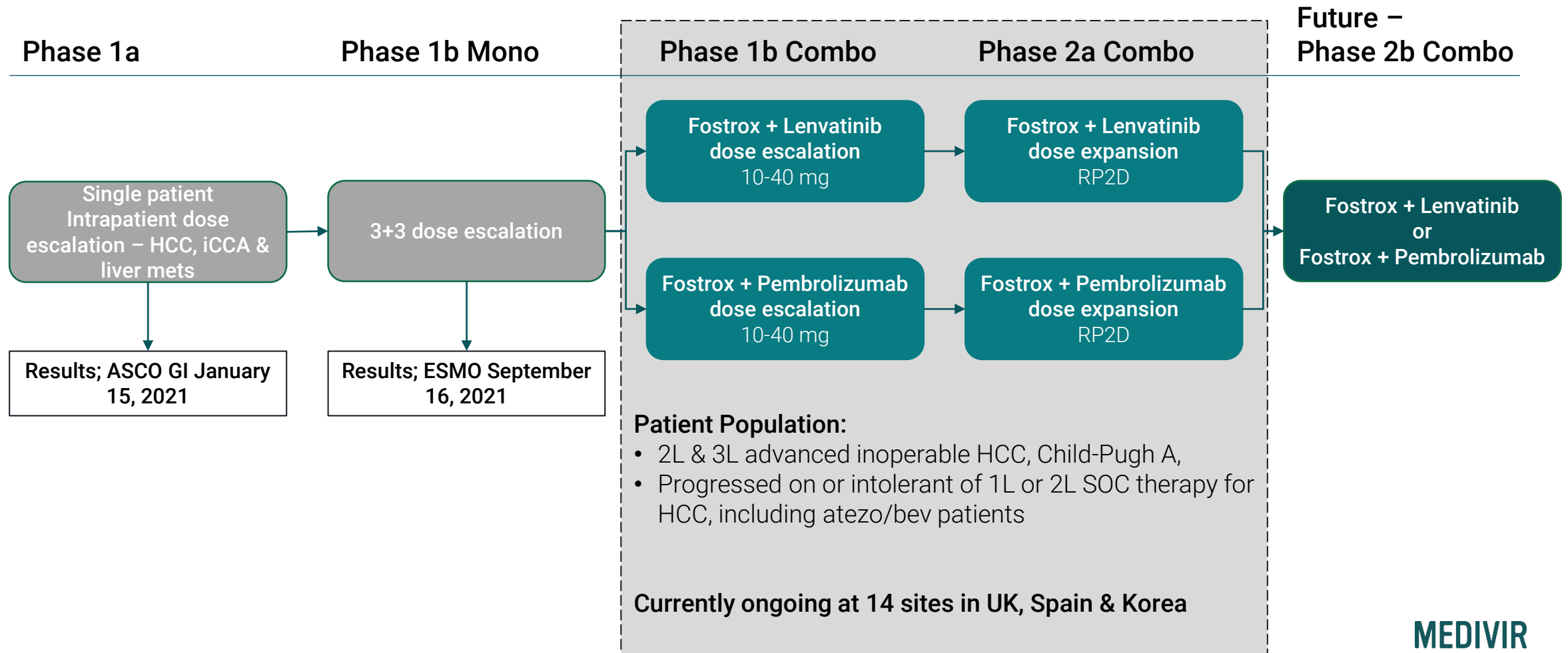
Fostrox + anti-PD-1 combination data presented at SITC conference 2022 supporting additive efficacy<sup>1</sup>



<sup>1</sup> The syngeneic HCC mouse model H22 was treated with anti-PD-1 (Biocell CD279, 3mg/kg ip BIW for 3 weeks), fostrox (30 mg/kg po BID for 5 days) or the combination. A significant enhancement of tumor growth inhibition was observed for the combination ( $p=0.012$ ,  $n=10$ ) (Poster 455 at SITC 37th annual meeting, Boston 10 November 2022)

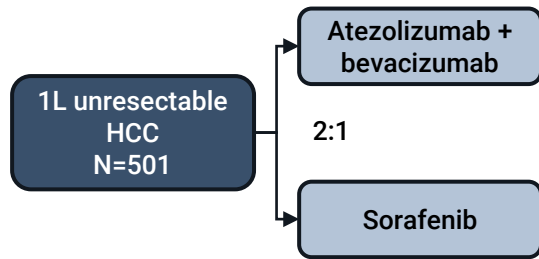


# Ongoing phase 1b/2a combination study in 2nd line HCC exploring combinations with both anti-PD-1 & TKI



# Recent study read-outs from various 1L PD-1 + TKI studies showing very similar results across combinations

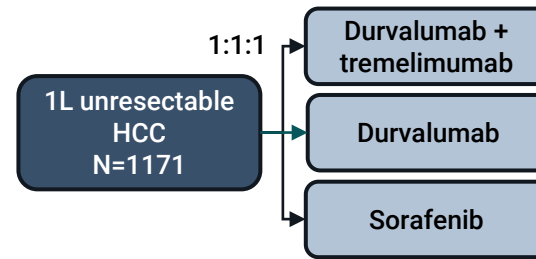
## IMBrave150



### Study results

- **ORR – 27.3%** vs 11.9%
- PFS – 6.8 months vs 4.3 months
- **OS – 19.2 months** vs 13.4 months

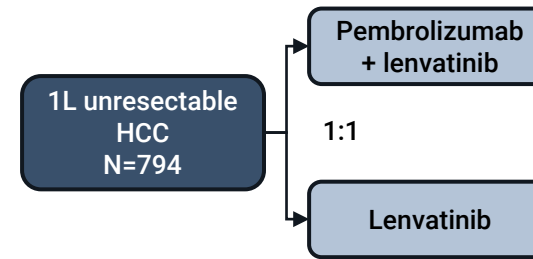
## HIMALAYA



### Study results (Durva+Treme vs Sorafenib)

- **ORR – 20.1%** vs 5.1%
- PFS – 5.4 months vs 5.6 months
- **OS – 16.4 months** vs 13.8 months

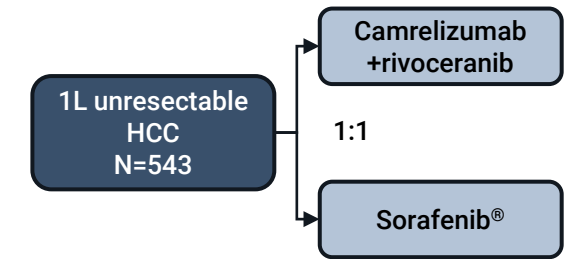
## LEAP-002



### Study results

- **ORR – 26.1%** vs 17.5%
- PFS – 8.2 months vs 8.1 months
- **OS – 21.2 months** vs 19.0 months

## Camrelizumab + rivoceranib



### Study results

- **ORR – 25.4%** vs 5.9%
- PFS – 5.6 months vs 3.7 months
- **OS – 22.1 months** vs 15.2 months

- 1 Similarities across studies cement combination of atezo/bev as standard of care in 1L
- 2 TKI monotherapy with lenvatinib becomes standard option in 2L, highlighting relevance of fostrox + lenvatinib arm
- 3 Different or additional modes of action needed to further enhance clinical benefit in 1L

# Fostrox – A unique, first-in-class potential treatment for primary liver cancer



**Significant unmet need & commercial potential**



**Unique MoA that selectively targets cancer in the liver and bypasses resistance mechanisms**



**Strong potential for attractive combinations**

# Clinical portfolio and partnerships

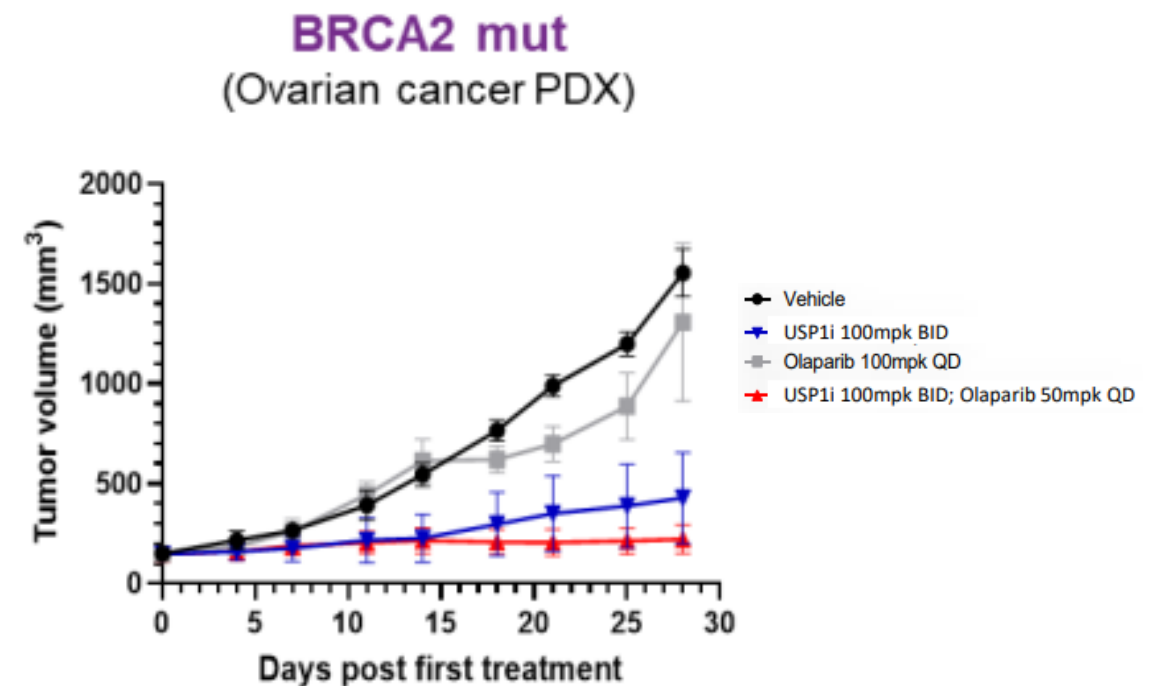


# USP1 (TNG348) – CD selected & IND filing planned for 2023

Preclinical licensing agreement, novel target moving towards the clinic in 2023

- Pre-clinical program outlicensed to Tango Therapeutics Q1 2020; TNG348 nominated as CD, well tolerated in non-GLP preclinical safety studies
- Distinct mechanism of action from PARP inhibitors with synergy in both PARPi-sensitive and resistance models
- Significant patient opportunity with BRCA1/2 mutations occurring in ~15% ovarian, 10% breast, 10% prostate, 5% endometrial and 5% pancreatic cancers
- Potential development and commercial milestone payments and low single digit royalties on future products

Single agent activity and strong PARPi synergy in breast and ovarian models



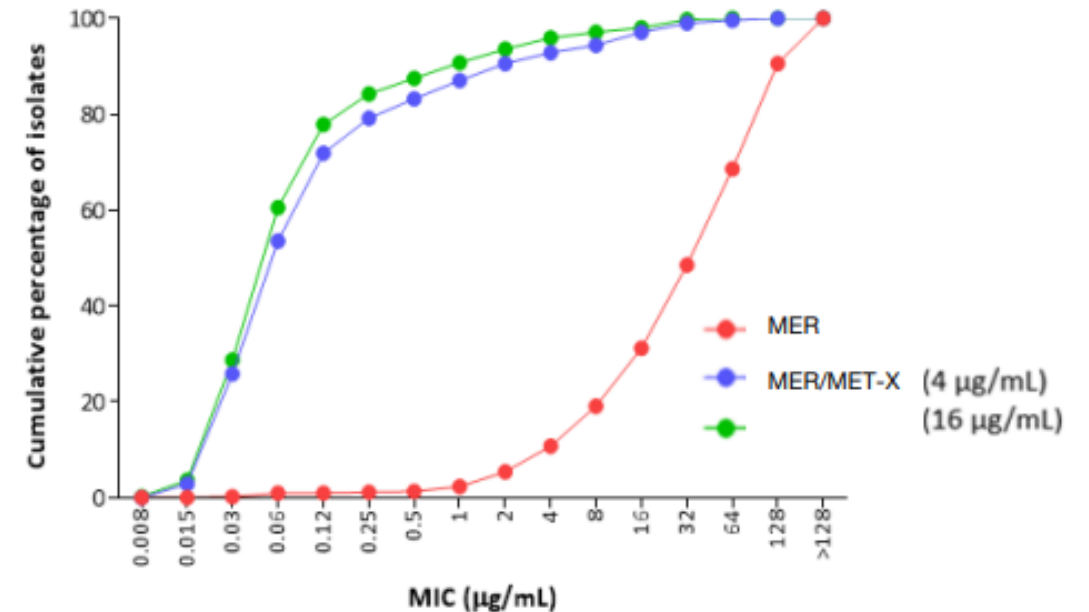


# MET-X (MBLI) – FDA QIDP Designation received

## Potential best-in-class Metallo- $\beta$ -Lactamase Inhibitor

- MET-X is a potent broad-spectrum MBL inhibitor in combination with  $\beta$ -lactams to restore their activity, targeting one of the most serious global threats from AMR. (Anti Microbial Resistance)
- Moving towards clinic in 2023, recently received FDA QIDP designation in January
- Revenue share agreement on all commercialisation revenue.
- Recent developments in financing solutions for novel antibiotics generating increased commercial opportunity; UK “Netflix” model by NICE, PASTEUR Act in US & G7 call-to-action.

## MET-X restores activity of Meropenem\*



\*Restoration of meropenem activity in critical threat Gram-negative pathogens (519 clinical isolates of MBL-positive Enterobacteriales). Clinical isolate panel containing NDM (n=385), IMP (n=44) and VIM (n=90) producers

# Financial highlights Q4

# Financial summary Q4, 2022

## Consolidated Income Statement, summary

(SEK m)

	Q4		Q1 - Q4	
	2022	2021	2022	2021
Net turnover	2.3	13.9	4.4	25.5
Other operating income	0.2	1.3	1.8	10.2
<b>Total income</b>	<b>2.5</b>	<b>15.3</b>	<b>6.2</b>	<b>35.7</b>
Other external expenses	-15.7	-32.0	-69.1	-73.3
Personnel costs	-4.8	-6.1	-20.7	-21.4
Depreciations and write-downs	-0.7	-0.6	-2.6	-2.6
Other operating expenses	0.1	-0.6	-1.2	-0.6
<b>Operating profit/loss</b>	<b>-18.6</b>	<b>-24.1</b>	<b>-87.4</b>	<b>-62.1</b>
Net financial items	0.5	-0.3	-1.4	-0.5
<b>Profit/loss after financial items</b>	<b>-18.1</b>	<b>-24.3</b>	<b>-88.8</b>	<b>-62.6</b>
Tax	-	0.0	-	-0.5
<b>Net profit/loss for the period</b>	<b>-18.1</b>	<b>-24.3</b>	<b>-88.8</b>	<b>-63.1</b>

- Net turnover for Q4 was SEK 2.3 million
- Operating loss for Q4 was SEK -18.6 million
- Cash flow from operating activities for Q4 was SEK -24.7 million
- Cash balance end of Q4 was SEK 117 million



# Continued momentum across portfolio delivering on key strategic priorities; more to come

## 2022 progress across product portfolio

## Potential future key events

### Accelerating fostrox

- Continued strong recruitment in fostrox study, anticipating recommended phase II dose near-term
- Pre-IND meeting with FDA completed with positive feedback on development plan
- New data, showing additive efficacy of fostrox in combination with anti-PD1 in experimental tumor models, presented at the SITC Conference in November.
- Pia Baumann recruited as new Chief Medical Officer, taking office on February 20, 2023

- First safety data from phase 1b combo study in Caucasian & Asian patients
- Initiation of phase 2a dose expansion study with one or two combination arms
- First efficacy data from combination arm(s)
- IND filing
- Asia development plan

### Maximise value of assets for partnering & out-licensing

- The IGM-8444 + birinapant combination study continues to enroll patients in fourth cohort, no DLTs observed to date.
- INFEX Therapeutics announced that the MBLI program (MET-X) received FDA QIDP designation
- Tango Therapeutics announced selection of TNG348 as drug candidate for treatment of BRCA1/2 mutated cancers

- Birinapant + IGM8444 first data & decision which tumors to continue development in
- IND-filing for USP-1/TNG348 by Tango Therapeutics
- Phase I initiation for MET-X by Infex Therapeutics
- Value added partnering opportunities for remaining assets

Q/A

# Upcoming activities

- Erik Penser Bank Healthcare Day, February 23
- AACR Conference, April 14-19
- Annual General Meeting, May 4
- Erik Penser Bank Company Day, May 25
- ABGSC Life Science Summit, May 30-31
- Redeye Growth Day, June 1



**Thank You!**