



# STOCKHOLM CORPORATE FINANCE LIFE SCIENCE SEMINARIUM

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MEDIVIR AB

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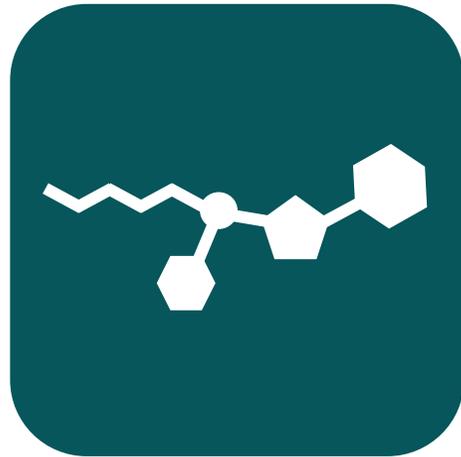
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# Medivir - A Swedish biotech focused on development of innovative treatments for cancer



**Focused strategy with clear priority for first-in-class, orphan drug in liver cancer**



**Active partnering strategy for additional value creation across product portfolio**

# Highlights during last quarter

## Continued progress for fostrox in liver cancer

- Continued strong recruitment in fostrox study, anticipating recommended phase II dose near-term. **Recommended phase II dose now established at 30 mg for fostrox + lenvatinib**
- 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 – new Chief Medical Officer as of February 20

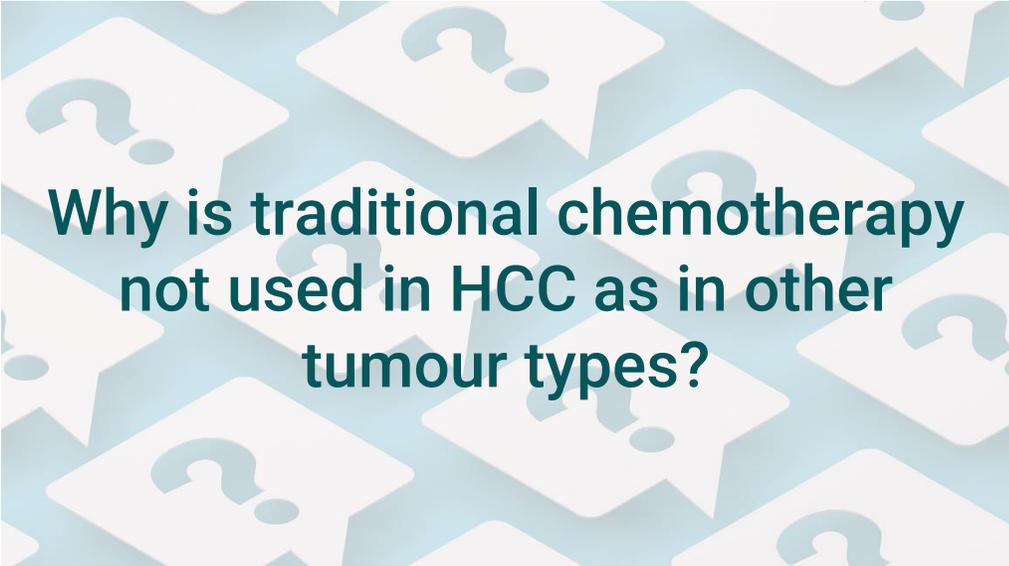


**Pia Baumann**  
CMO

- 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.

# Fostroxacitabine bralpamide (fostrox)

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



Why is traditional chemotherapy not used in HCC as in other tumour types?

- 1 Narrow therapeutic window
- 2 Liver toxicity extra sensitive in HCC
- 3 Inactivation of drugs in the liver

# Fostrox – 3 key elements to overcoming shortcomings of traditional chemotherapy



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

1

Same pro-drug approach used successfully in HCV to ensure **liver targeted exposure**

2

**Cell killing selectivity**; cytotoxic with strong link between DNA replication & DNA damage

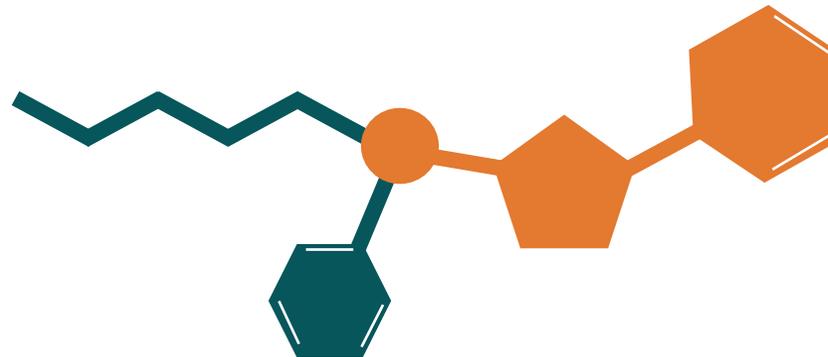
3

L-nucleoside approach to **avoid 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



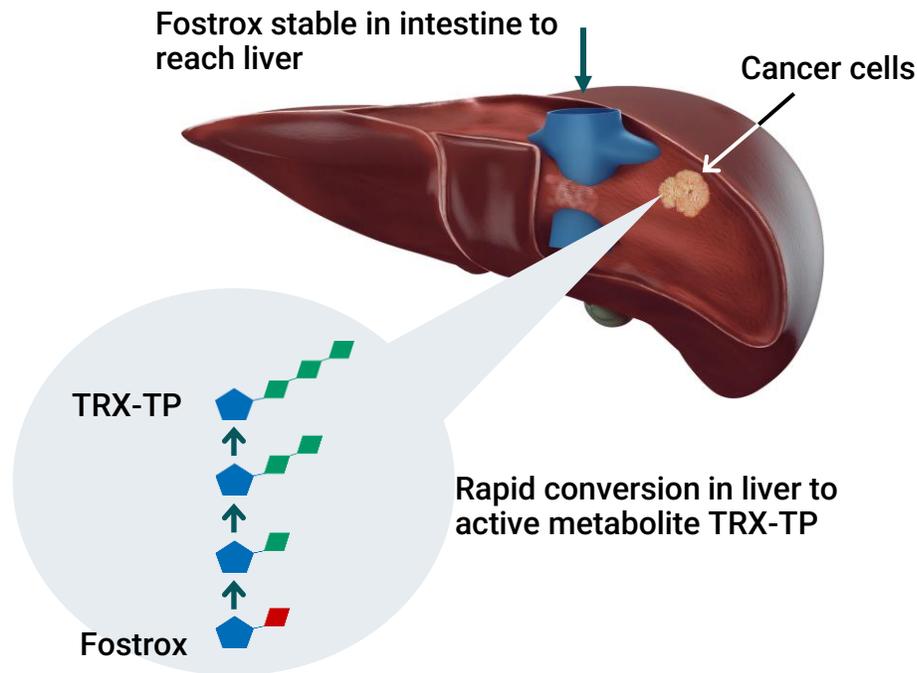
## Active substance - troxacitabine

- 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

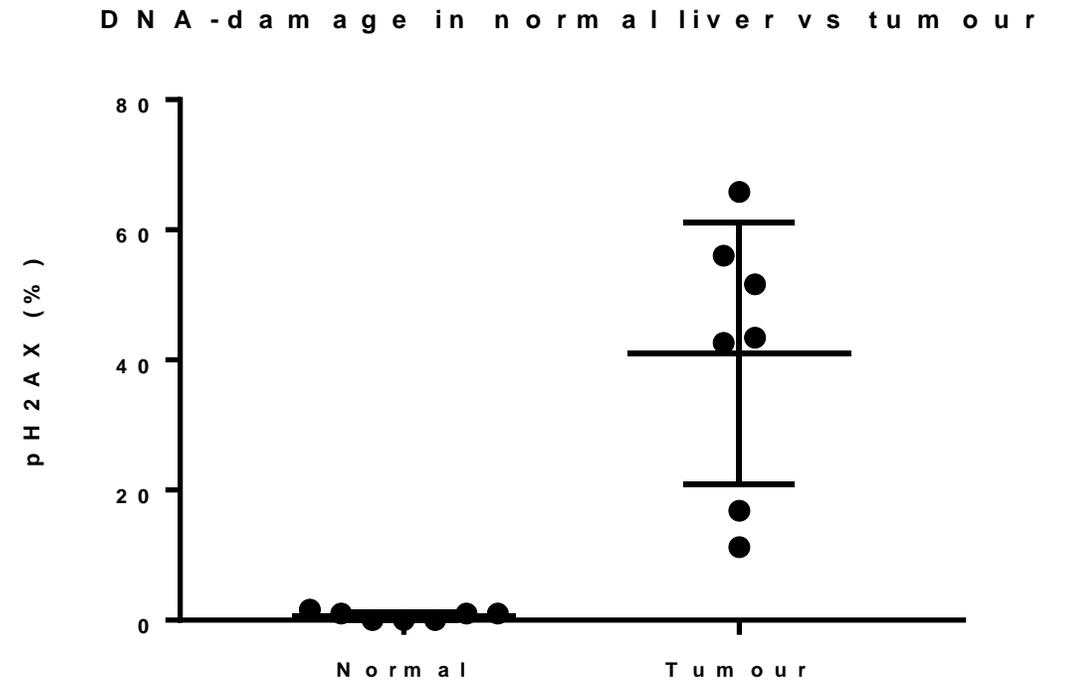
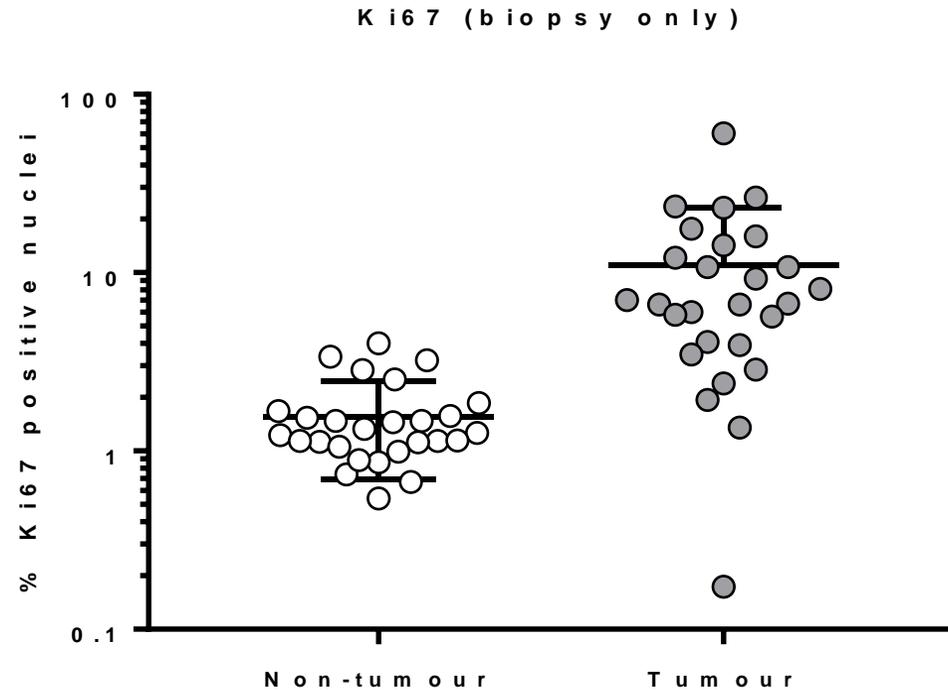


Compound	Route	Dose (μmol/kg)	AUC <sub>Liver</sub> (nmol*h/g)	AUC <sub>Plasma</sub> (μmol*h/L)	AUC ratio (Liver/Plasma)
Troxacitabine	<i>iv</i>	80	<1.2	80	<b>&lt;0.016</b>
Fostrox	<i>oral</i>	80	10	5.4	<b>1.9</b>

# 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>



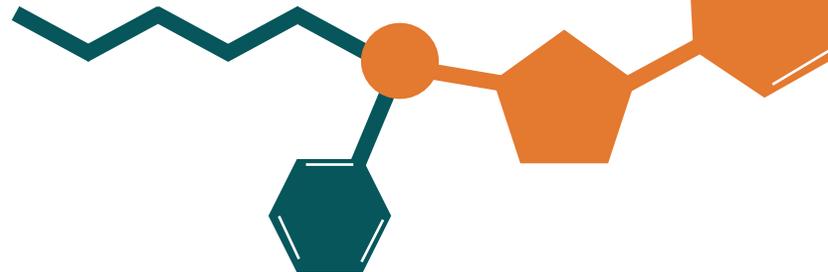
<sup>1</sup>Albertella, M. et al EASL Summit P01-05, 2017

<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

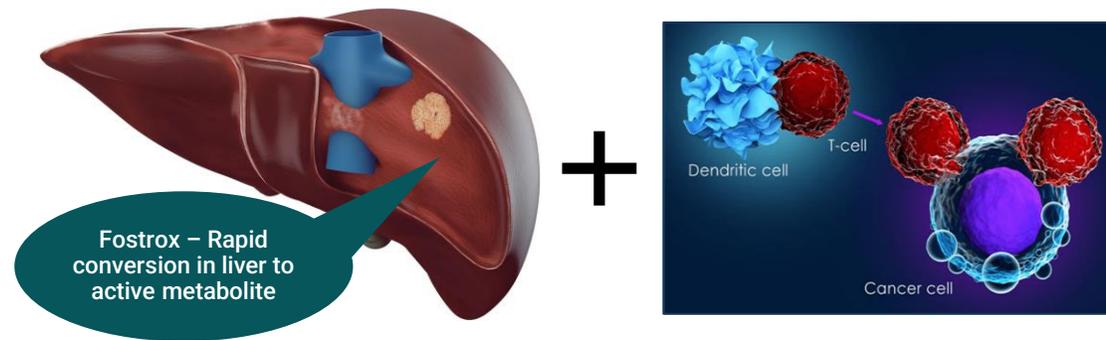


## Active substance - troxacitabine

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

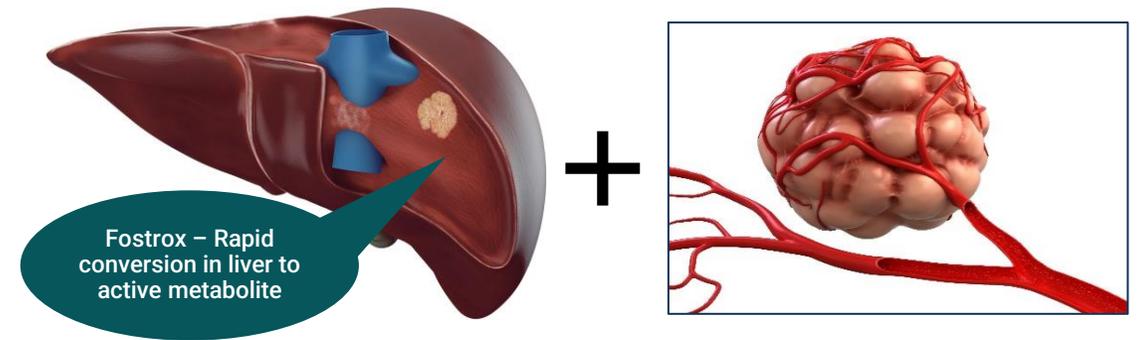
# Fostrox – A unique, differentiated MoA in HCC inhibiting DNA replication; strong potential for combinations

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**”

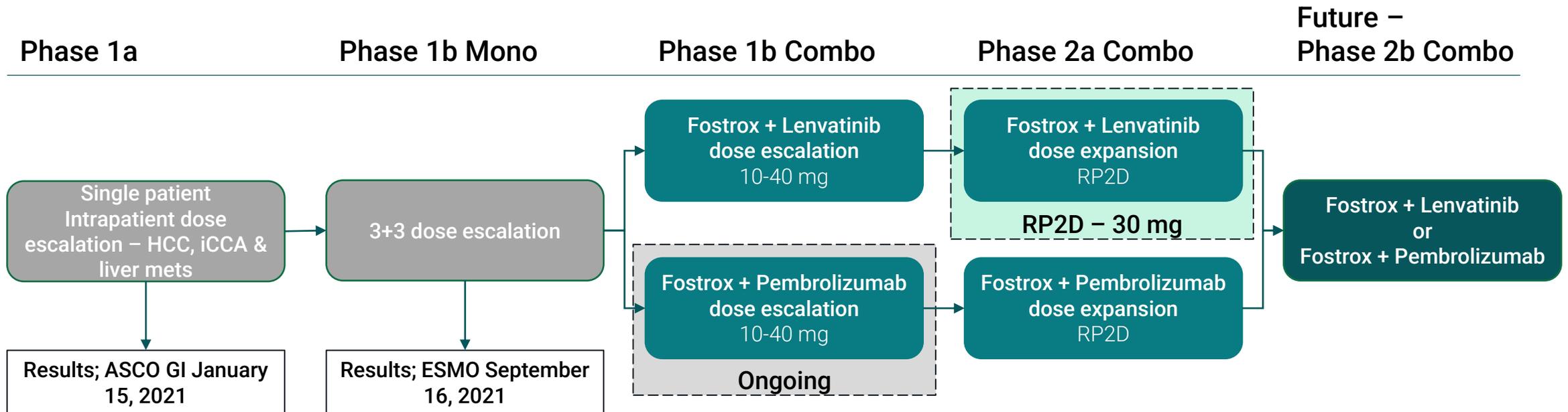
Fostrox + blocking blood supply to tumor (TKI)



“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

# Exploring two different combinations in ongoing phase 1b/2a study in 2L HCC; fostrox + lenvatinib now in expansion phase



### Patient Population:

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

Currently ongoing at 14 sites in UK, Spain & Korea

# Recommended phase II dose for fostrox + Lenvatinib, now entering expansion phase at 30 mg



Ability to increase fostrox dose to 30 mg in combination with lenvatinib, without DLTs



6 patients on active treatment across arms with fostrox + lenvatinib patient now in end of cycle 7



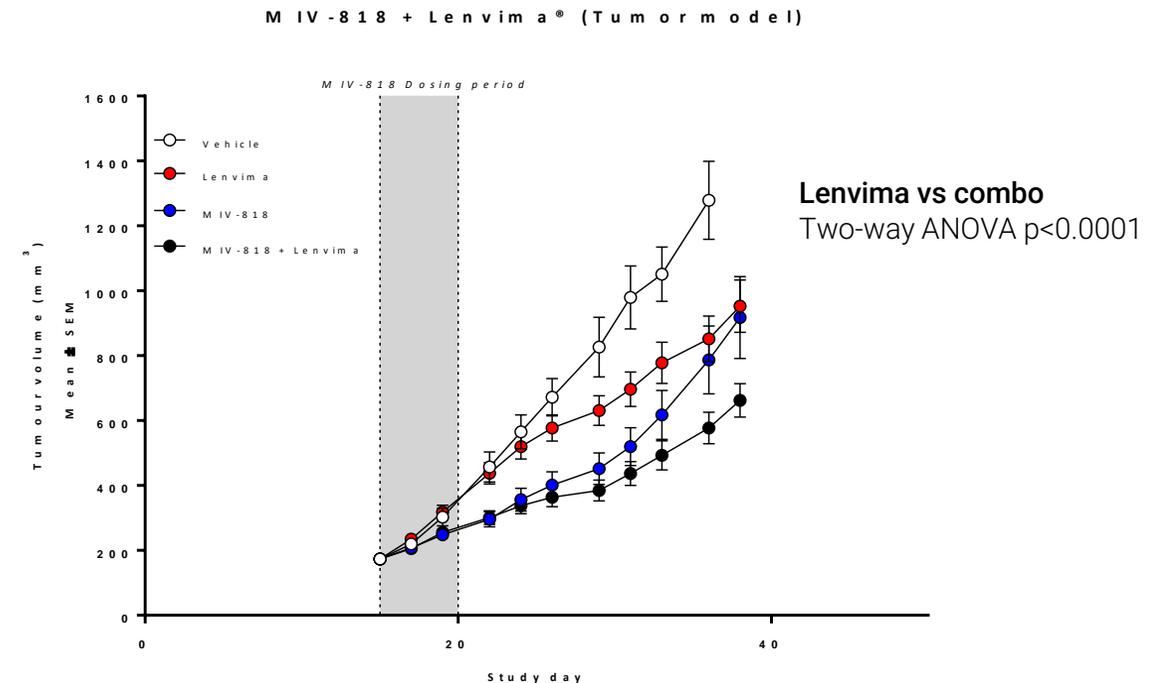
Further safety & outcome details to be shared later in 2023

# Combination with Lenvima<sup>®</sup> enhances efficacy in tumor models

Strong rationale supporting fostrox + TKI's

- The enzyme PKG1 mediates the last step in generating the fostrox active metabolite. PKG1 expression is increased by lack of oxygen, leading to higher levels of active metabolite
- Tyrosine kinase inhibitors such as Lenvima<sup>®</sup> induce lack of oxygen in tumors
- Addition of fostrox to Lenvima<sup>®</sup> in a preclinical model significantly enhances tumor growth inhibition

Fostrox + Lenvima<sup>®</sup> combo supporting additive efficacy\*



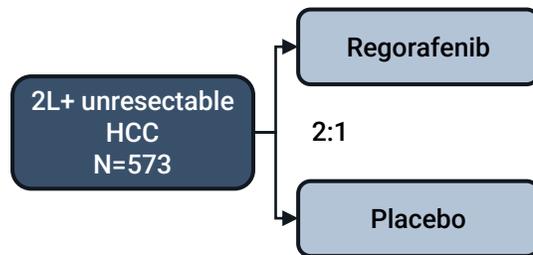
## Dosing:

- Fostrox 30mg/kg BID 5 days
- Lenvima 3mg/kg QD 21 days

\*Anti-tumor efficacy of fostrox (30mg/kg BID 5 day plus Lenvatinib (3mg/kg QD 21 days) in the HepG2 mouse HCC model.

# Study read-outs from various 2L HCC studies highlighting current unmet medical need

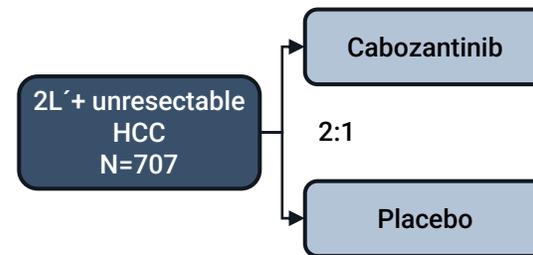
## RESORCE



### Study results

- **ORR – 11.0%** vs 4.0%
- PFS – 3.1 months vs 1.5 months
- **OS – 10.6 months** vs 7.8 months

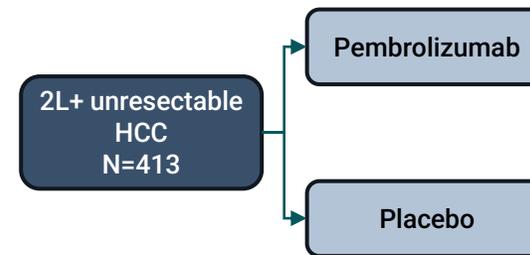
## CELESTIAL



### Study results

- **ORR – 4%** vs <1%
- PFS – 5.2 months vs 1.9 months
- **OS – 10.2 months** vs 8.0 months

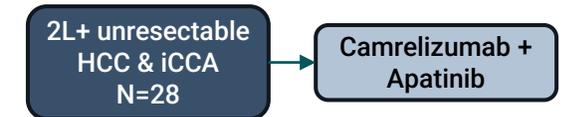
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### Study results

- **ORR – 18.3%** vs 4.4%
- PFS – 3.0 months vs 2.8 months
- **OS – 13.9 months** vs 10.6 months

## Camrelizumab + Apatinib



### Study results

- **ORR – 10.7%**
- PFS – 3.7 months
- **OS – 13.2 months**

- 1 Single to low double-digit response rates across 2L studies indicating high unmet medical need
- 2 Anti-PD-1 + TKI showing similar response rates, highlighting need for different modes of action
- 3 All existing treatment alternatives come from 2 categories; anti-PD-(L)1's & TKI's, alternative options needed

# 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



# 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> </ul>
USP-7	Ubiquigent Limited	Cancer						Revenue share	<ul style="list-style-type: none"> <li>Partnering agreement for Ubiquigent</li> </ul>
MBLI	INFEX Therapeutics	Infection						Revenue share	<ul style="list-style-type: none"> <li>Partnering agreement for INFEX</li> </ul>

Projects developed by Medivir  
 Projects developed by external partner

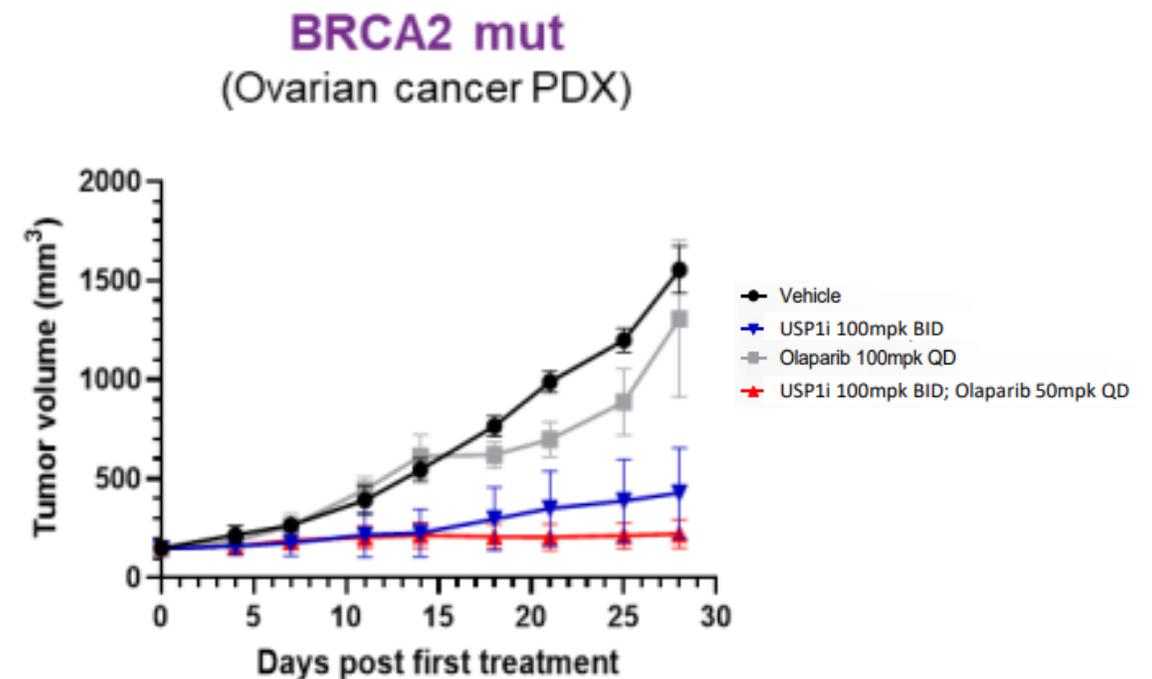


# USP1 (TNG348) – CD selected & IND filing planned for 2023

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



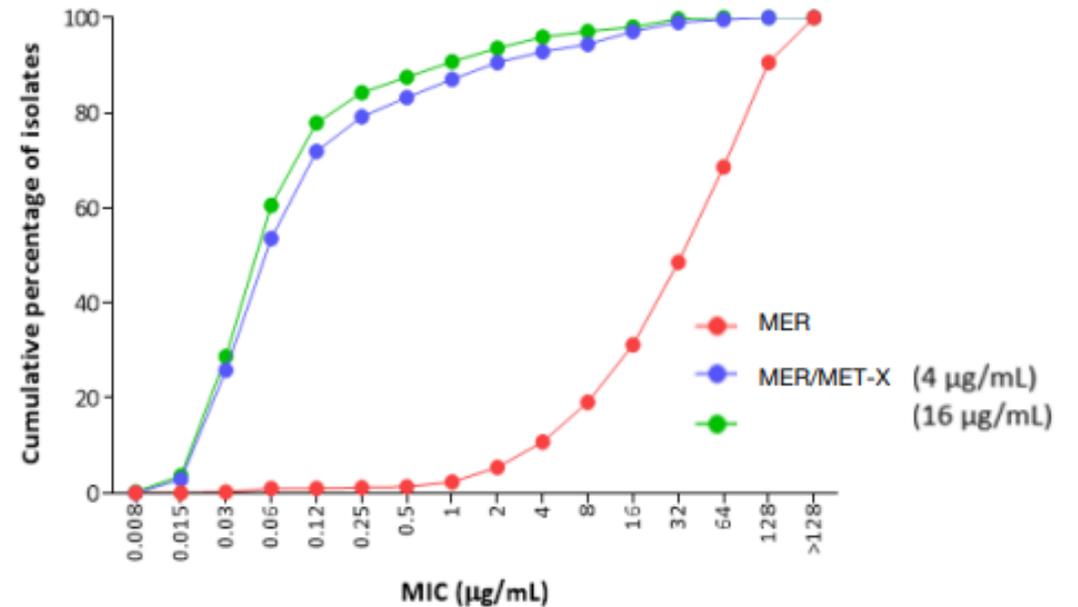


# MET-X (MBLI) – FDA QIDP Designation received

## 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

# 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, **recommended phase II dose now established for fostrox + lenvatinib combination arm**
- 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



**Thank You!**