ERIK PENSER BANK TEMADAG HEALTHCARE

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MEDIVIR AB

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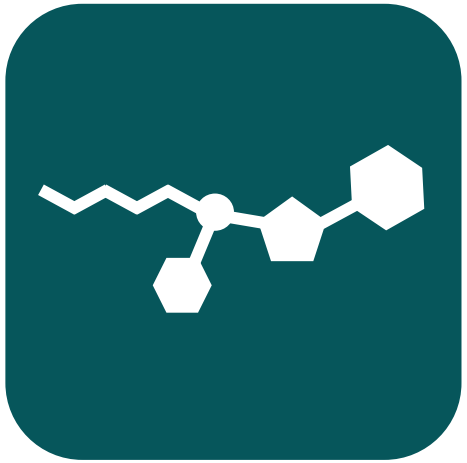
Medivir - A Swedish biotech focused on development of innovative treatments for cancer



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

Active partnering strategy for additional value creation across product portfolio

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)
IN-HOUSE PROGRAM									
Fostroxacitabine bralpamide	In-house development	HCC (mono) HCC (combo)						100% Medivir	▪ Selection of dose(s) ▪ Dose expansion
PARTNERING PROGRAMS									
Xerclear	GSK, SYB	Herpes						Royalties	▪ Registration in China
Remetinostat	TBD	CTCL, BCC, SCC						TBD	▪ Partnering agreement
MIV-711	TBD	Osteoarthirtis						TBD	▪ Partnering agreement
Birinapant	IGM Biosciences	Solid tumors						Milestones (up to $350m) & royalties	▪ Selection of dose ▪ Expansion cohort(s)
USP-1	Tango Therapeutics	Cancer						Milestones & royalties	▪ US IND
USP-7	Ubiquigent Limited	Cancer						Revenue share	▪ Partnering agreement for Ubiquigent
MBLI (MET-X)	INFEX Therapeutics	Infection						Revenue share	▪ Partnering agreement for INFEX

Projects developed by Medivir
Projects developed by external partner

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Highlights during last quarter

Continued progress for fostrox in liver cancer

- Initiatives launched to increase patient recruitment have yielded results and the fostrox study is progressing as expected
- We continue our efforts to further increase recruitment speed; intention to add additional sites and investigators in Korea
- Our preparations to open an Investigational New Drug (IND) in U.S. in 2023 is progressing according to plan
- Abstract, titled “Fostrox in combination with anti-PD-1 shows increased efficacy in nonclinical tumour models in vivo” accepted for presentation at SITC 37th annual meeting in Boston

Overall portfolio development

- The IGM-8444 + birinapant combination study continues to enroll patients, now in the fourth and final planned cohort. No DLTs observed to date.
- INFEX Therapeutics announced that the MBLI program (MET-X), licensed from Medivir, has been granted patented status in the U.S.

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Fostroxacitabine bralpamide (fostrox)

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

Significant unmet need & commercial potential with HCC market estimated to grow 5-fold in 10 years from $1 – 5bn

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

Strong potential for attractive combinations with both existing classes of drugs in liver cancer

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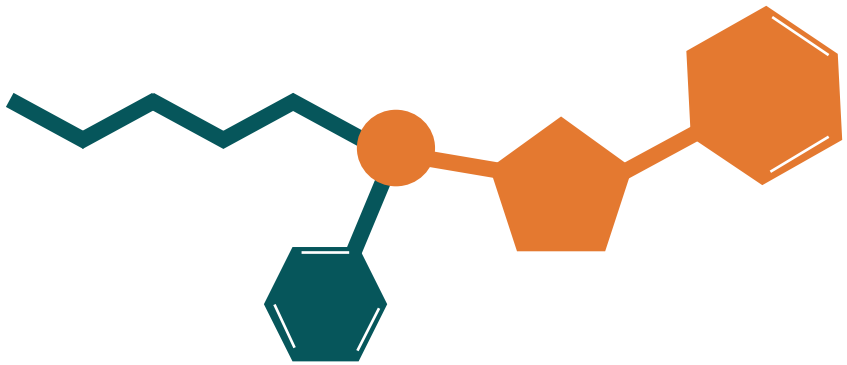
Fostrox – Combination of pro-drug technology & chemotherapy to minimise systemic side effects

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

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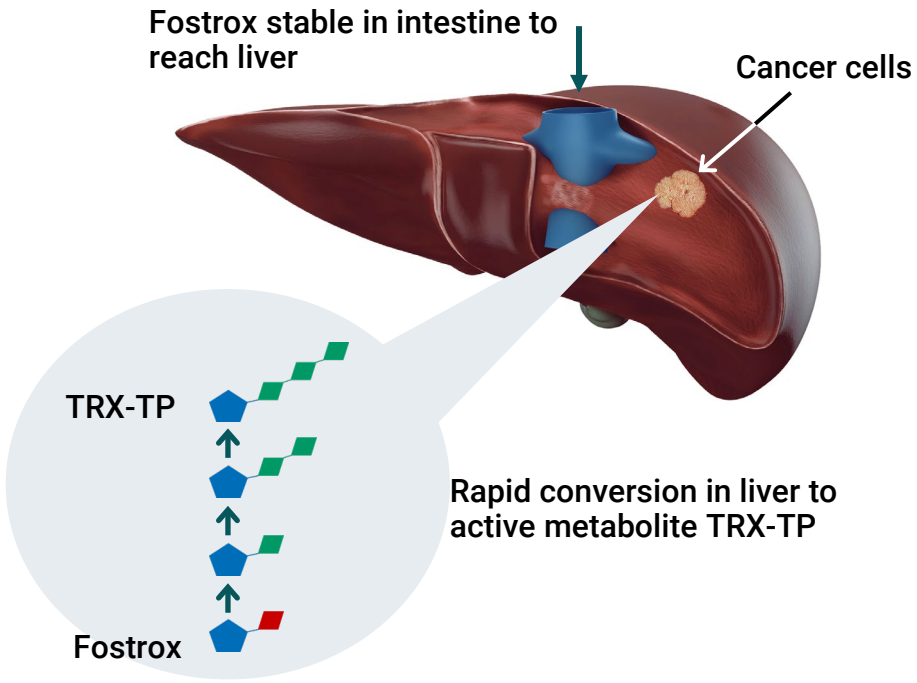
Fostrox – first-in-class, orphan drug inducing locally targeted DNA damage & cell death in the liver

Differentiated mechanism of action (MoA)



Designed to be liver targeted & minimise systemic exposure

- Fostrox enables oral administration that is stable in intestine to reach liver for maximum local exposure
- Fostrox rapidly converts in the liver to the active metabolite Troxacitabine-TP
- The active metabolite is incorporated into the DNA and results in chain termination
- This induction of DNA damage results in cell death, primarily in cells that are proliferating/multiplying frequently, which is typical for cancer cells

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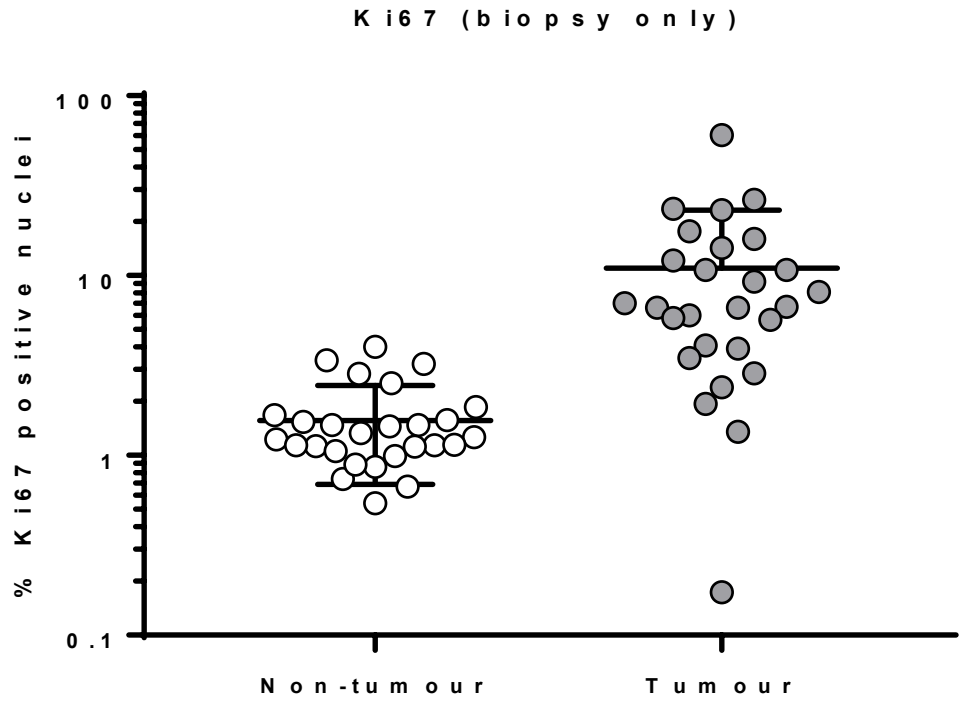
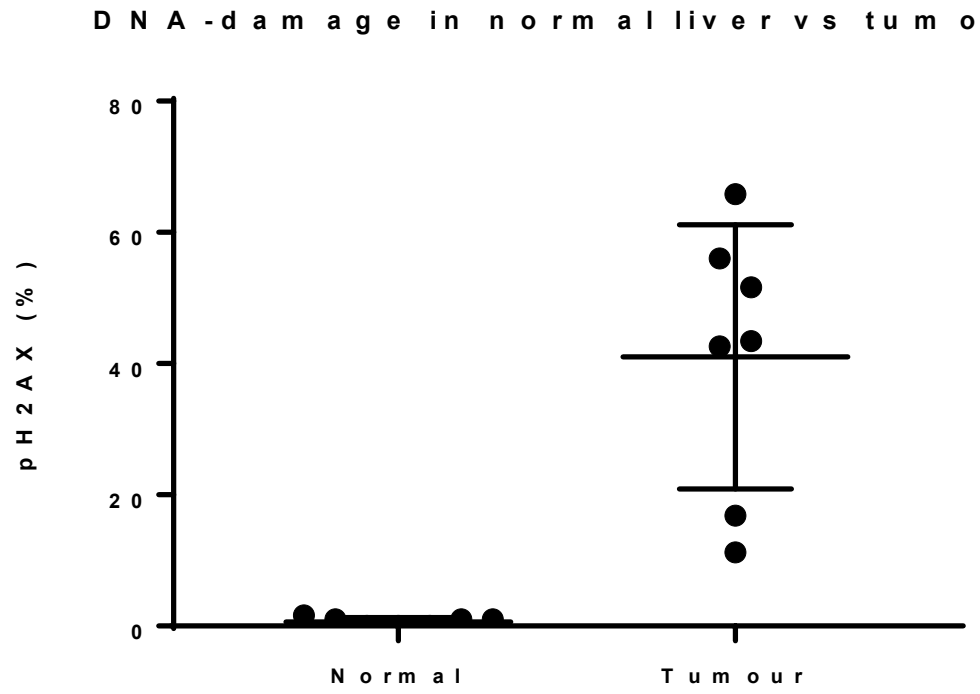
Fostrox – inducing DNA damage & cell death in HCC tumour cells, sparing normal liver tissue

Significantly higher proliferation rate in liver tumour cells vs normal liver cells[1], indicating vulnerability to chemotherapy



DNA-damage & cell death observed with Fostrox in tumor tissue but not in normal liver tissue[2]



[1]Albertella, M. et al EASL Summit P01-05, 2017
[2]Öberg F. et al, EASL PO-221, 2022

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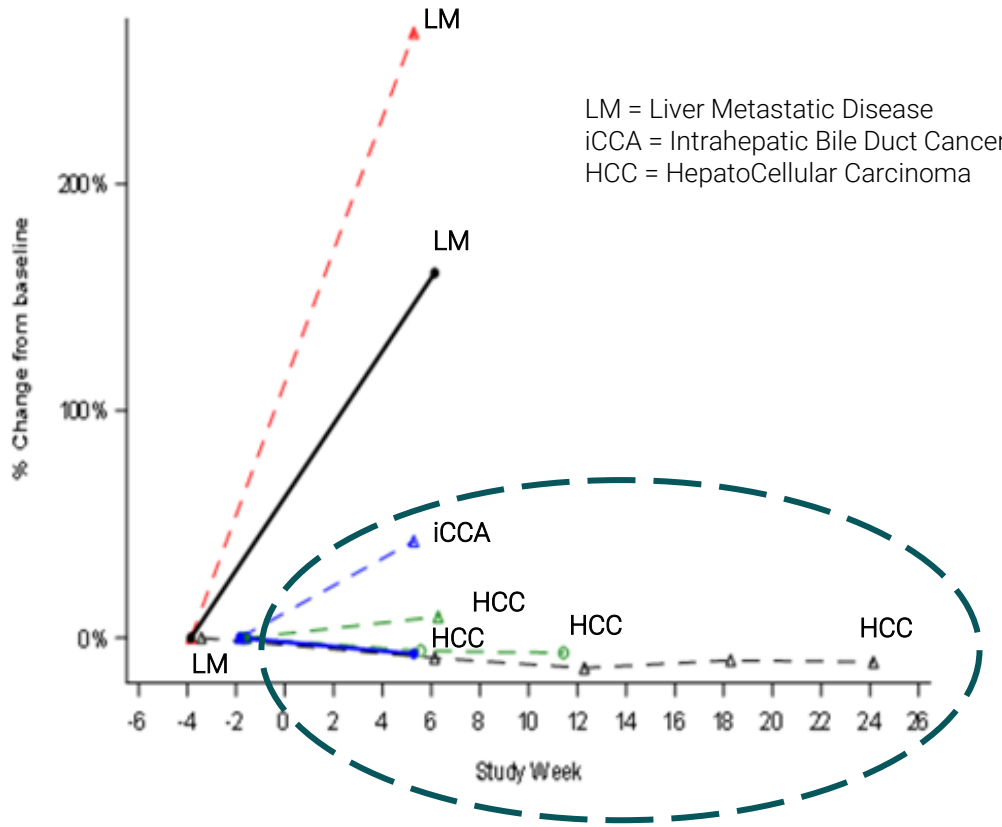
Clinical data indicating efficacy as monotherapy despite heavily pre-treated patient cohort

Encouraging changes in liver target lesions for HCC patients with 4 out of 7 reaching Stable Disease[1]



Heavily pre-treated patient cohort predicting limited clinical benefit

- Treatment-refractory HCC, including fibrolamellar HCC, iCCA, or metastatic liver disease with limited extrahepatic tumour burden were recruited to phase 1 monotherapy study
- Patients had on average 2.8 years since diagnosis and on average >2 lines of previous therapy

[1]Sarker D. et al, ESMO PO-527P, 2021

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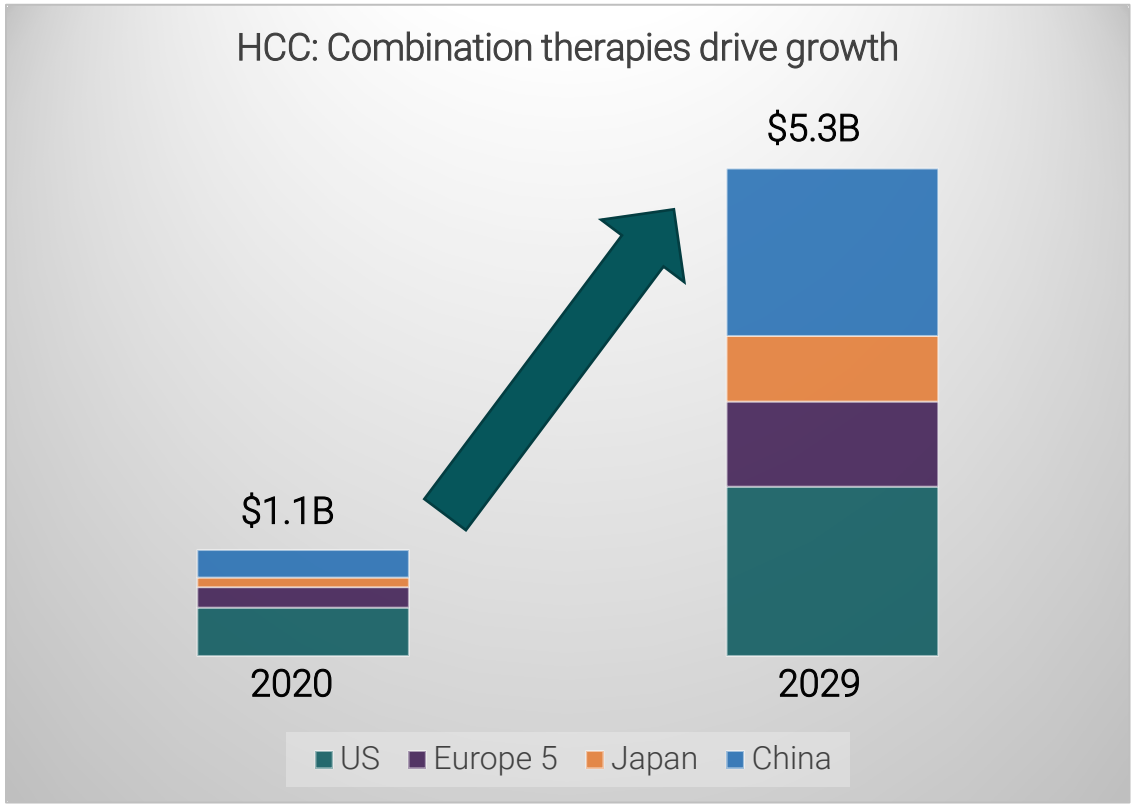
HCC is a significantly growing market with large unmet need

HCC market estimated to grow almost five-fold until 2029



Source: GlobalData 2021

Despite recent advancements, unmet need is still high

- Liver cancer incidence and mortality are increasing with liver cancer the third leading course of cancer death worldwide 3%[1,2]
- Despite recent advances in treatment of HCC, still only ~1/3 of patients respond to the best approved combination therapies
- The HCC market growth is driven by combination therapies and patients treated in earlier disease stages

[1](https://seer.cancer.gov/statfacts/html/livibd.htm)
[2.] Sayiner M, et al. Digestive Diseases and Sciences. 2019; 64: 910-917

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Large unmet need remains despite recent advances in HCC

1L – Combinations with some incremental improvements

Study (phase)	HIMALAYA (III)	IMbrave150 (III)	REFLECT (III)	SHARP (III)
Drug	Imfinzi/ tremelimumab	Tecentriq/ Avastin	Lenvima	Nexavar
Current status	Phase III	Approved 2020	Approved 2018	Approved 2007
Control	Nexavar	Nexavar	Nexavar	Placebo
MoA	anti PDL1/ anti CTLA4	anti PDL1/ anti VEGF	MKI	MKI
mOS (months)	16.4	19.2	13.6	10.7
PFS (months)	NA	6.8	7.3	5.5
ORR	20%	28-33%	19-41%	NA
Company	AZ	Roche	Eisai	Bayer

2L – Room for improvement, monotherapy ORR below 20%

Study (phase)	KEYNOTE-224/394 (II/III)[2]	RESOURCE (III)	CHECKMATE-040 /459 (I/II)[1]
Drug	Keytruda	Stivarga	Opdivo
Current status	Accelerated approval 2018	Approved 2017	Accelerated approval (withdrawn)
Control	NA	Placebo	Nexavar
MoA	Anti PD1	MKI	anti PD1
mOS (months)	NA/14.6	10.6	NA/16.39
PFS (months)	NA/2.6	3.1-3.4	NA
ORR	17%/13%	11%	14%/15%
Company	Merck&Co	Bayer	BMS

[1] Ongoing phase III study for first line therapy, CheckMate 9DW
[2] Several ongoing phase III studies in different settings and in combination with Lenvima
Sources: FDA, BIOMEDTRACKER

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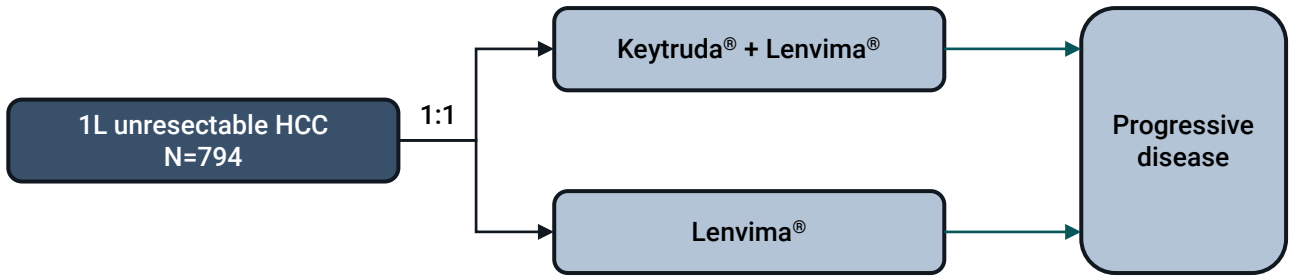
Negative outcome of LEAP-002 study, highlighting the need for alternative combination therapies



Phase III study
Dual primary end-point: PFS & OS
Secondary end-points: ORR, DoR

- On August 3, MSD announced that LEAP-002 did NOT meet its dual primary endpoints of OS and PFS and additional details were presented at the ESMO conference in Paris in September 2022.
- The negative outcome further **cements the combination of Tecentriq + Avastin from Roche as the SoC in 1L** and further **highlights the need for alternative combinations** with compounds that have different modes of action.
- In addition, the data presented at ESMO also outlined better than anticipated efficacy of Lenvima as monotherapy, further **supporting the emergence of Lenvima as the best TKI & the preferred monotherapy option in 2L**.

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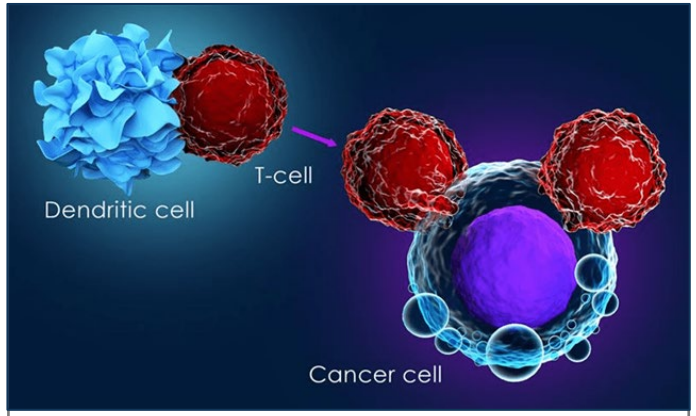
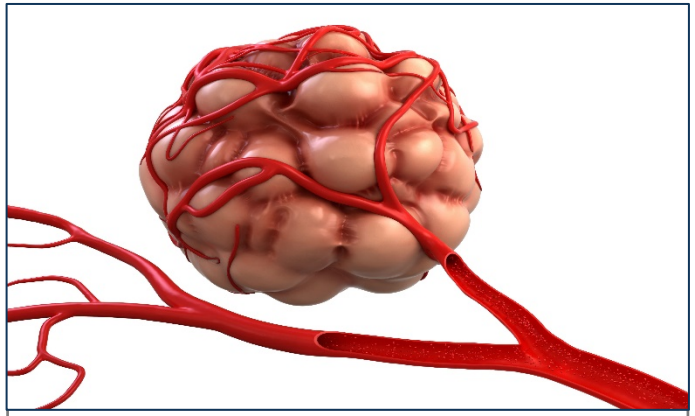
Current pipeline of new HCC therapies consists of a variation of combination trials with two key mechanisms of actions



Stimulation of immune system

- Keytruda (PD-1)
- Tezentriq (PD-L1)
- Opdivo (PD-1)
- Imfinzi (PD-L1)
- Yervoy (CTLA-4)
- Tremelimumab (CTLA-4)

+



Blocking blood supply to tumor*

- Avastin
- Nexavar
- Lenvima
- Stivarga
- Cometriq/Cabometyx

*Some of these drugs are multifunctional and have additional functions

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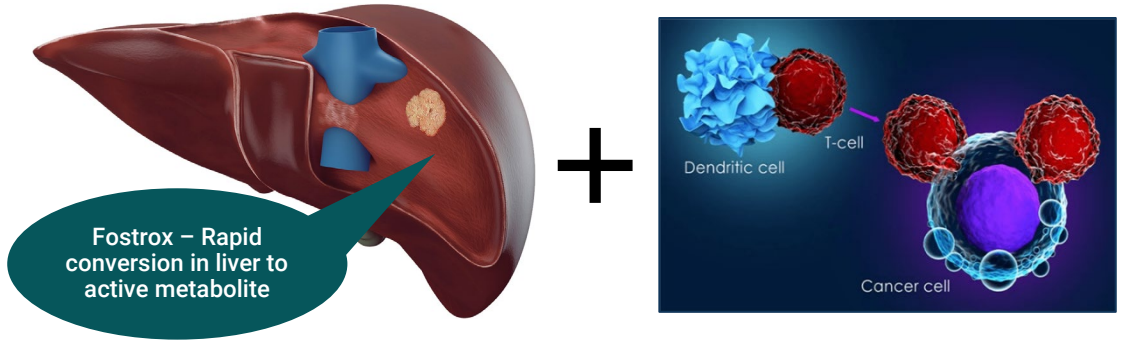
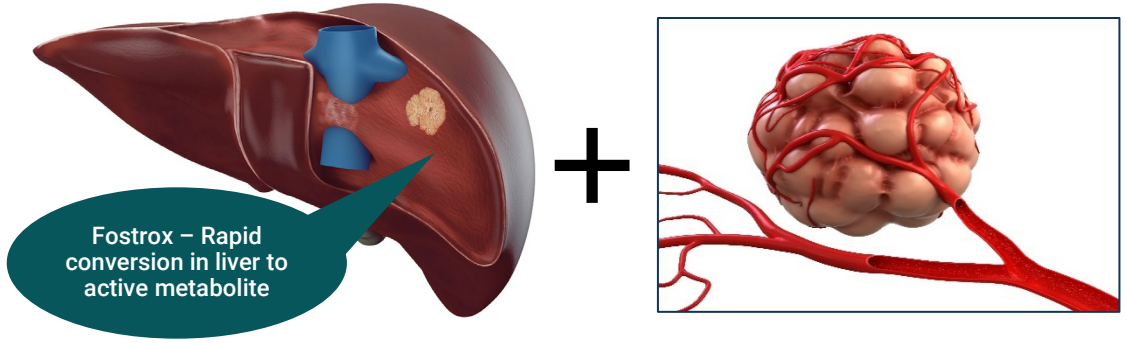
Fostrox – A unique, differentiated mechanism in HCC inhibiting DNA replication; strong potential for combinations

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

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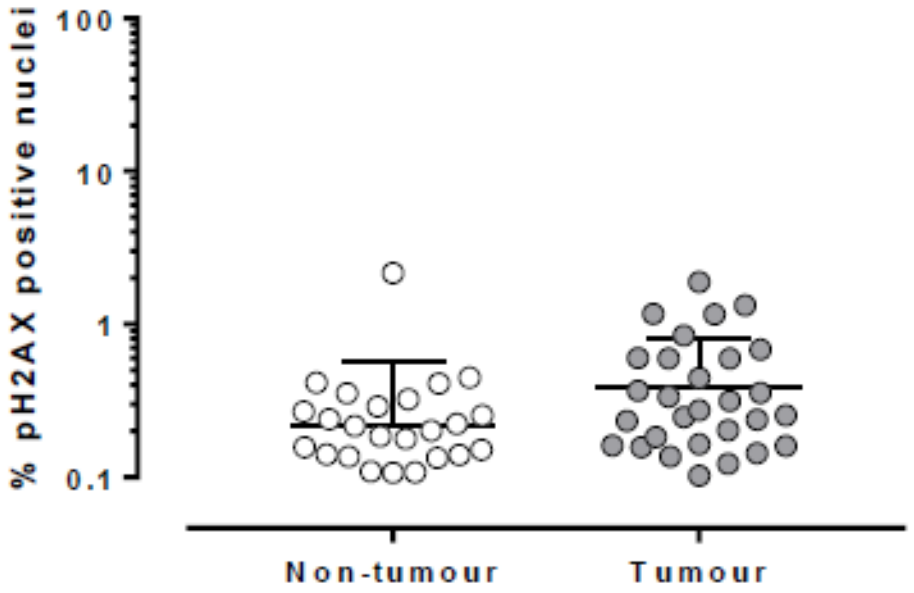
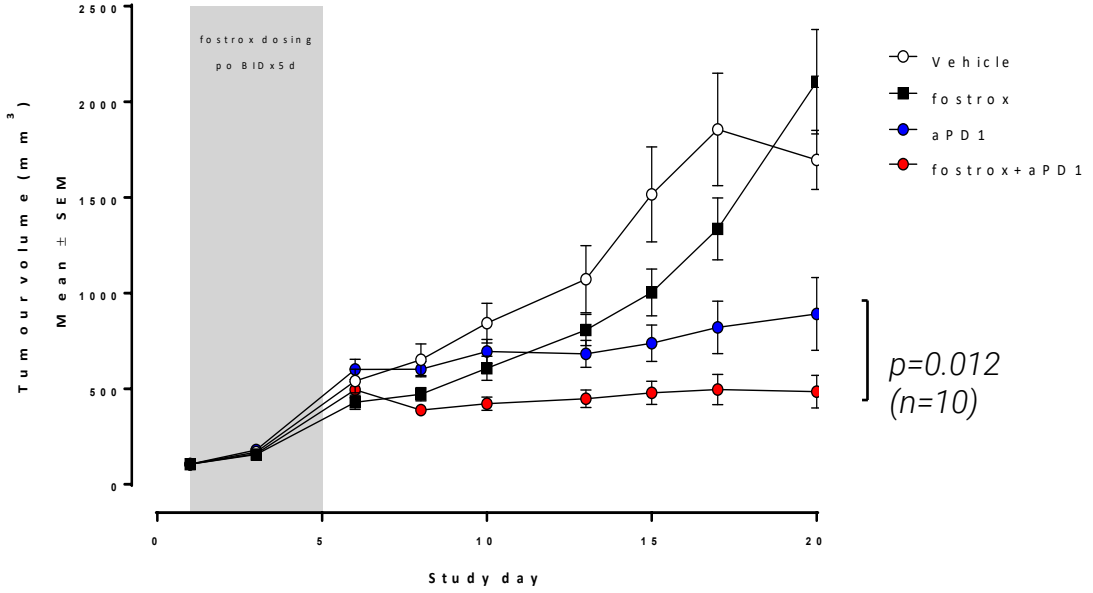
Low baseline DNA damage in HCC cells supports rationale for combining Fostrox with anti-PD-1

Low baseline DNA damage in both normal & tumour cells in the liver[1], limited efficacy with mono anti-PD-1 in HCC



Fostrox + anti-PD-1 combination data presented at SITC conference 2022 supporting additive efficacy[2]



[1] Albertella, M. et al EASL Summit P01-05, 2017

[2] 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)

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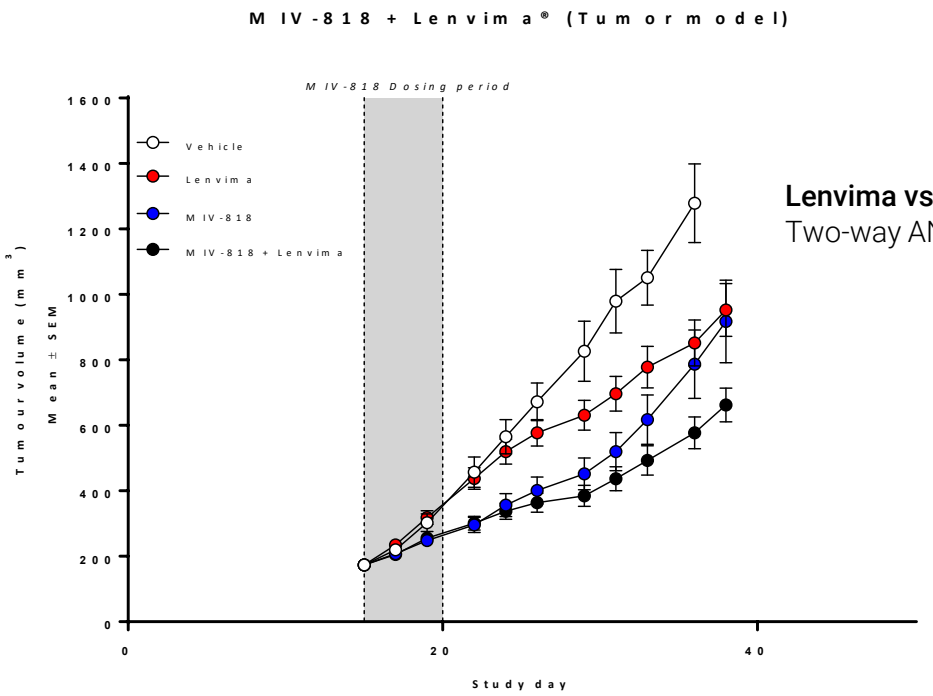
Combination with Lenvima® enhances efficacy in tumor models

Strong rationale supporting fostrox + TKI's

- The enzyme PKG1 mediates the last step in generating the fostrox active metabolite. PGK1 expression is increased by lack of oxygen, leading to higher levels of active metabolite
- Tyrosine kinase inhibitors such as Lenvima® induce lack of oxygen in tumors
- Addition of fostrox to Lenvima® in a preclinical model significantly enhances tumor growth inhibition

Fostrox + Lenvima ® combo supporting additive efficacy*



Lenvima vs combo
Two-way ANOVA p<0.0001

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.

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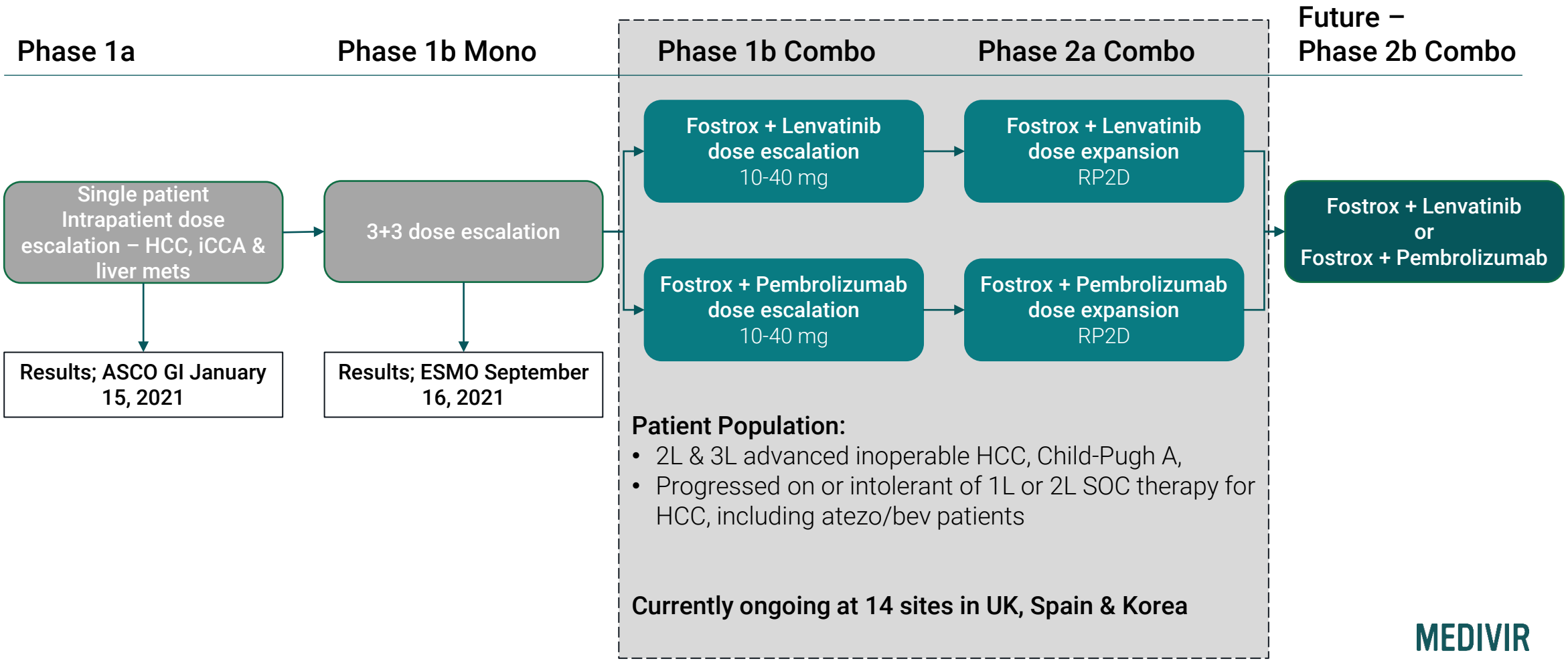
Ongoing phase 1b/2a combination study in 2nd line HCC exploring combinations with both anti-PD-1 & TKI



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Site visits at Korean study sites confirming high study engagement and strategy aligned with clinical practice

- **Current treatment praradigm well aligned with recruitment of patients to fostrox study**; both arms attractive to patients as well as investigators
- **Highest unmet need currently in 2L setting** where combination approach to improve clinical benefit is seen as the preferred approach
- **HCC a clear area of priority in Korea & Asia** due to high unmet need and high incidence

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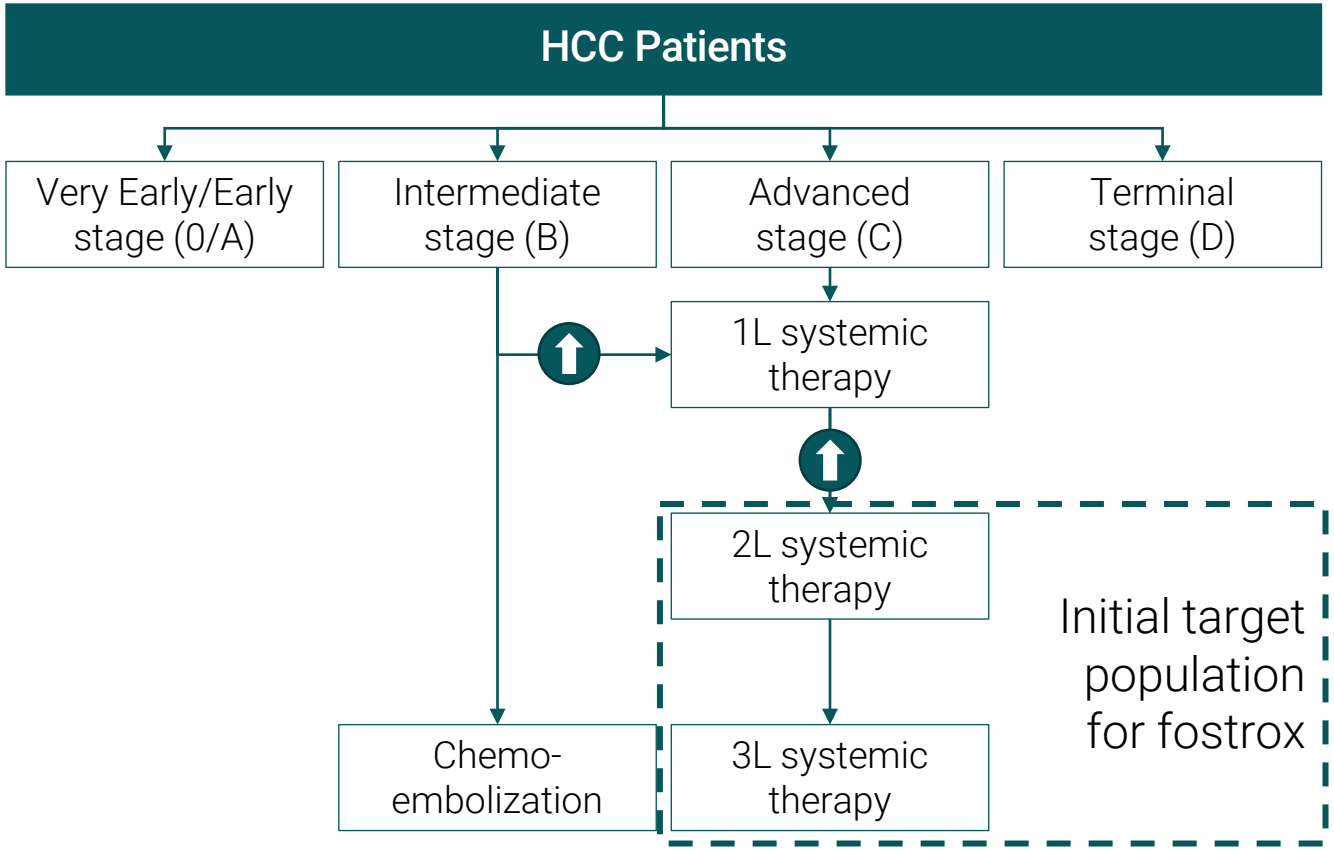
Initial focus for fostrox in 2L combination with Lenvima or Keytruda



- A majority of patients receive Tecentriq + Avastin
- Could be potential for future triple combination

- Lenvima preferred option for most patients
- Our initial focus for fostrox combination

- Other TKI options used & single-agent PD-1

*G8 countries, Global data, HCC opportunity analysis

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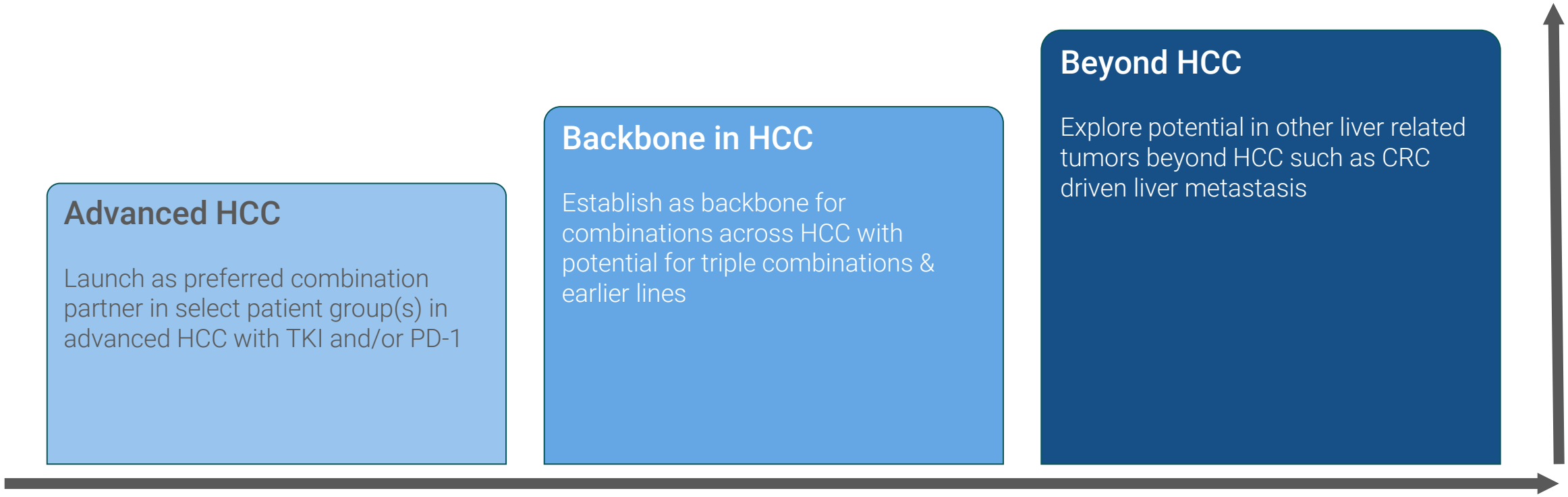
Strategic evolution & vision for fostroxacitabine bralpamide in liver cancer

Fostrox; Go-To option for combinations across liver related tumours



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Clinical portfolio and partnerships

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Pipeline overview – in-house development & assets for partnering

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Projects developed by Medivir
Projects developed by external partner

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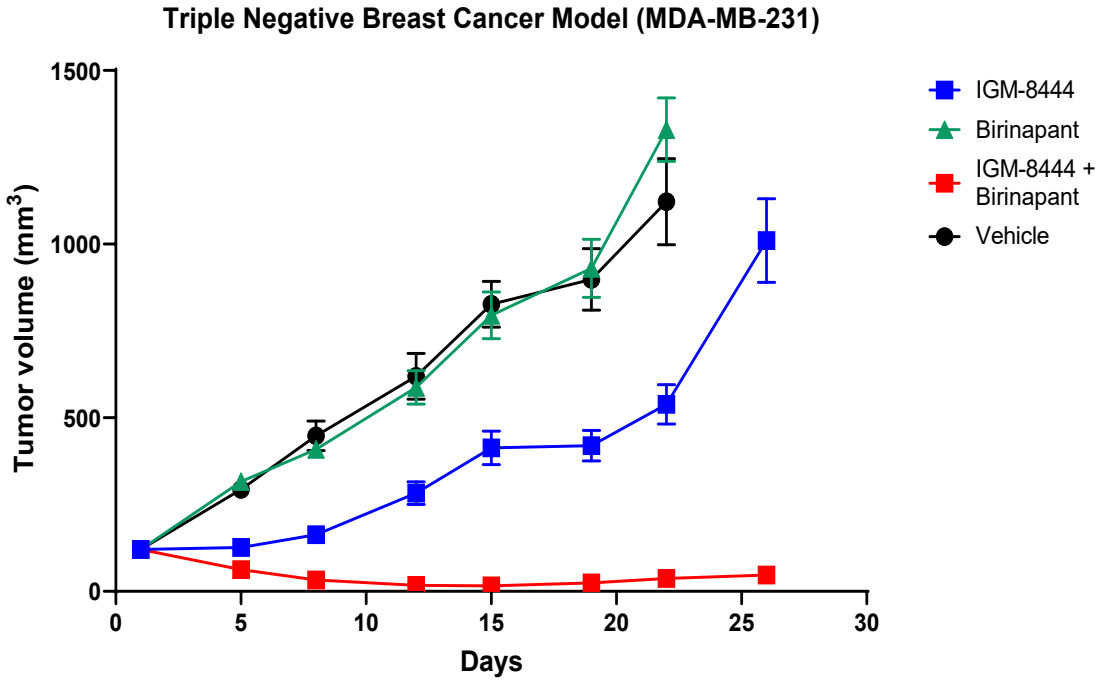
Birinapant – Licensing agreement with IGM Biosciences[1]

Licensing agreement with clear upside potential

- Clinical testing of birinapant (IGM-9427) in combination with IGM-8444, a Death Receptor 5 (DR5) agonist initiated during 2021 in patients with solid tumors[2]
- The third of four planned birinapant combination dose escalation cohorts cleared with no DLTs, currently enrolling in fourth cohort.
- Potential development, regulatory and sales milestone payments up to a total of approximately USD 350 million plus tiered royalties from the mid-single digits up to mid-teens on net sales

Preclinical models support synergistic anti-tumor activity



1) IGM is a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies
2) Open-label, Multicenter, phase I Study in patients with solid tumors in two stages: a dose-escalation stage and an expansion stage (NCT04553692)

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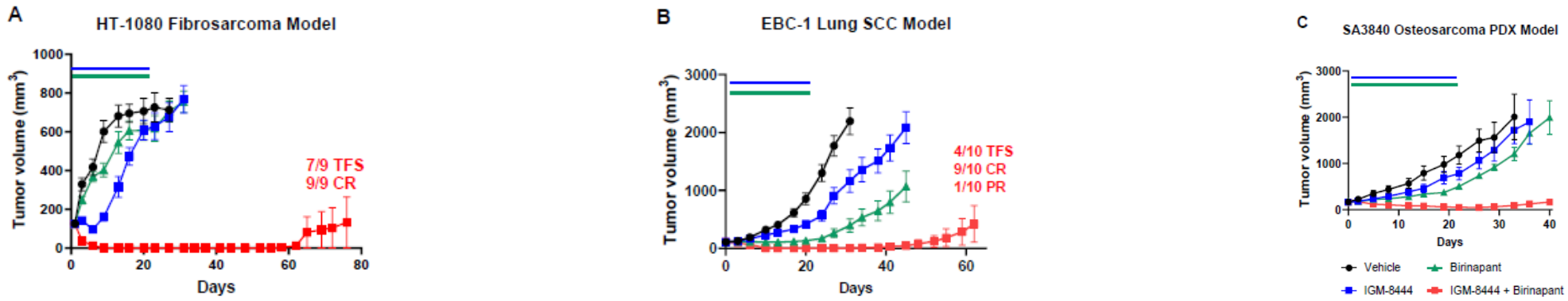
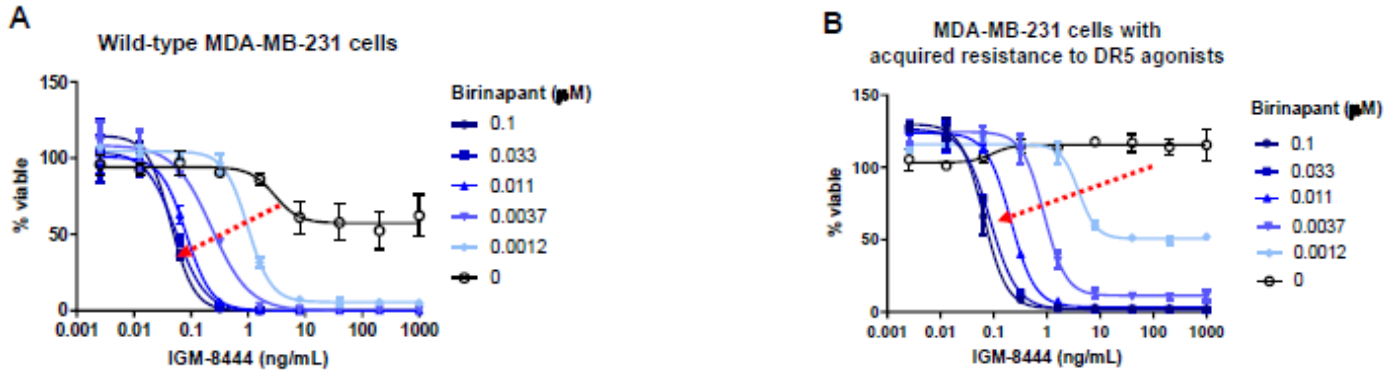
Birinapant + IGM-8444 pre-clinical data at AACR 2022 confirms strong synergistic tumour cytotoxicity[1]

Synergy demonstrated across multiple solid tumor indications



IGM-8444 + Birinapant Induced Synergistic Killing in Cell Line with Acquired Resistance to DR5 Agonists



- The third of four planned birinapant combination dose escalation cohorts cleared with no DLTs and no clinically significant liver toxicity observed to date.
- IGM is currently enrolling patients in the fourth dose escalation cohort.

[1]Wang, Beatrice T. et al, Poster no. 1068, 2022 AACR meeting, New Orleans, April 8-13

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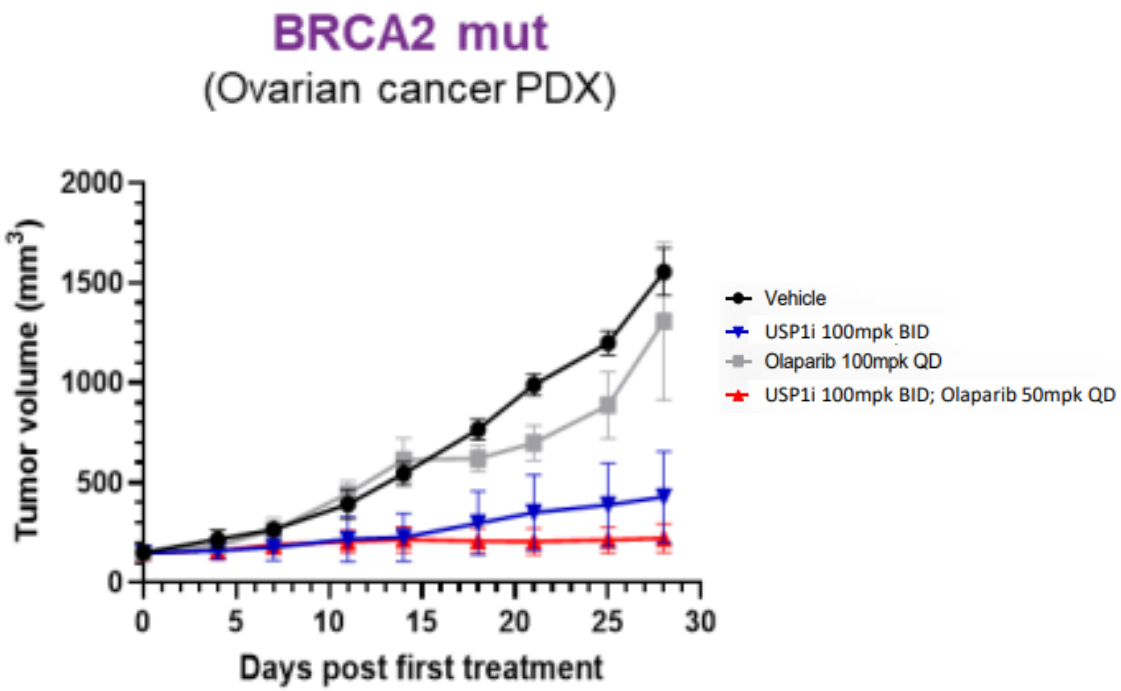
USP1 (TNG348) – IND filing planned for 2023

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 occuring 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



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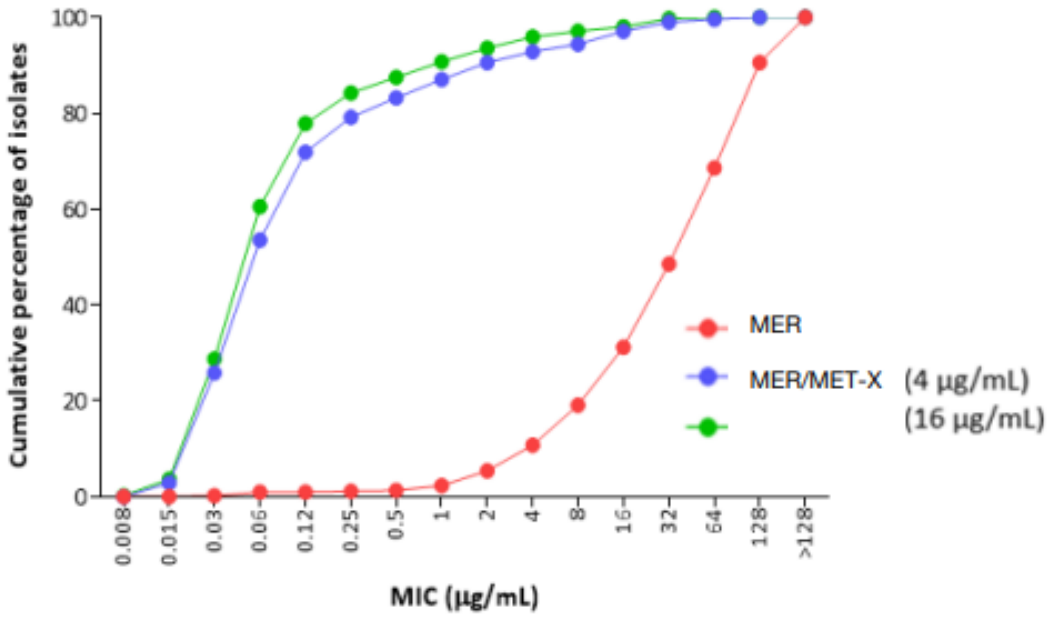
MET-X (MBLI) – Licensing agreement INFEX THERAPEUTICS

Potential best-in-class Metallo-β-Lactamase Inhibitor

- MET-X is a potent broad-spectrum MBL inhibitor in combination with β-lactams to restore their activity, targeting one of the most serious global threats from AMR. (Anti Microbial Resistance)
- Moving towards clinic in 2022/2023, recently granted patented status in US.
- 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 Enterobacterales). Clinical isolate panel containing NDM (n=385), IMP (n=44) and VIM (n=90) producers

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

	2022 progress across product portfolio	Potential future key events
Accelerating fostrox	▪ All sites active and Initiatives launched to increase patient recruitment have yielded results; intention to add additional sites and investigators in Korea to further increase recruitment speed. ▪ Our preparations to open an Investigational New Drug (IND) in U.S. in 2023 is progressing according to plan ▪ Additional data presentation from the negative LEAP-002 study in 1L HCC confirms the need for alternative combination therapies & fostrox development strategy	▪ 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) ▪ Initial steps to prepare for IND filing ▪ Asia development plan
Maximise value of assets for partnering & out-licensing	▪ The IGM-8444 + birinapant combination study continues to enroll patients, now in the fourth and final planned cohort. No DLTs observed to date. ▪ INFEX Therapeutics announced that the MBLI program (MET-X), licensed from Medivir, has been granted patented status in the U.S. ▪ CD selection for USP1 by Tango Therapeutics	▪ Birinapant + IGM8444 first data & decision which tumors to continue development in ▪ Phase 1 initiation for MET-X ▪ IND-filing for USP-1 ▪ Value added partnering opportunities for remaining assets

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Thank You!

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