



HC WAINWRIGHT ANNUAL GLOBAL INVESTMENT CONFERENCE

SEPTEMBER 12-14, 2022

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MEDIVIR AB

MEDIVIR

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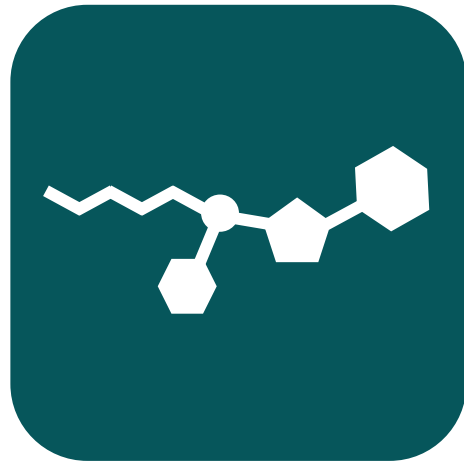
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Medivir - A Swedish biotech focused on development of innovative treatments for cancer



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



Active partnering strategy for additional value creation across product portfolio



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	<ul style="list-style-type: none"> Selection of dose(s) Dose expansion 	
PARTNERING PROGRAMS										
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Birinapant	IGM Biosciences	Solid tumors						Milestones (up to \$350m) & royalties	<ul style="list-style-type: none"> Selection of dose Expansion cohort(s) 	
USP-1	Tango Therapeutics	Cancer						Milestones & royalties	<ul style="list-style-type: none"> CD Selection US IND 	
USP-7	Ubiquigent Limited	Cancer						Revenue share	<ul style="list-style-type: none"> Partnering agreement for Ubiquigent 	
MBLI	INFEX Therapeutics	Infection						Revenue share	<ul style="list-style-type: none"> Partnering agreement for INFEX 	

Projects developed by Medivir
 Projects developed by external partner

Highlights during last quarter

Continued progress for fostrox in liver cancer

- 15 study sites now up and running across our three countries; UK, Spain and South Korea; intention to add additional sites and investigators in South Korea
- Initiatives launched to overcome slower than planned study recruitment in Europe, creating conditions for the recruitment rate to increase during second half of 2022
- Fostroxacitabine bralpamide approved as drug name by USAN
- Negative outcome of LEAP-002 study in 1L HCC, further highlighting the need for alternative combination therapies with different mechanisms of action

Overall portfolio development

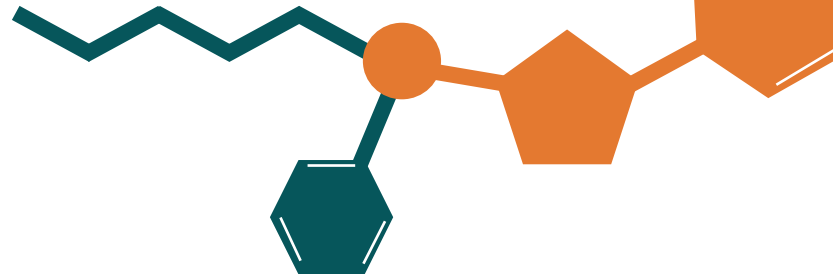
- The IGM-8444 + birinapant combination study has cleared the third dose escalation cohort with no DLTs and are recruiting the fourth cohort.
- Medivir's MBLI program, previously out-licensed to AMR Centre, today INFEX Therapeutics, has in 2022 presented additional preclinical data and communicated its intention to initiate a phase 1 program in 2022/23.



Fostrox – Innovative combination of proven technology & MoA to improve probability of success

Pro-drug tail

- Enables oral administration
- Ensures increased, liver targeted absorption, minimizing systemic exposure
- Very similar approach as used by Sovaldi in Hepatitis C



Active substance - troxacitabine

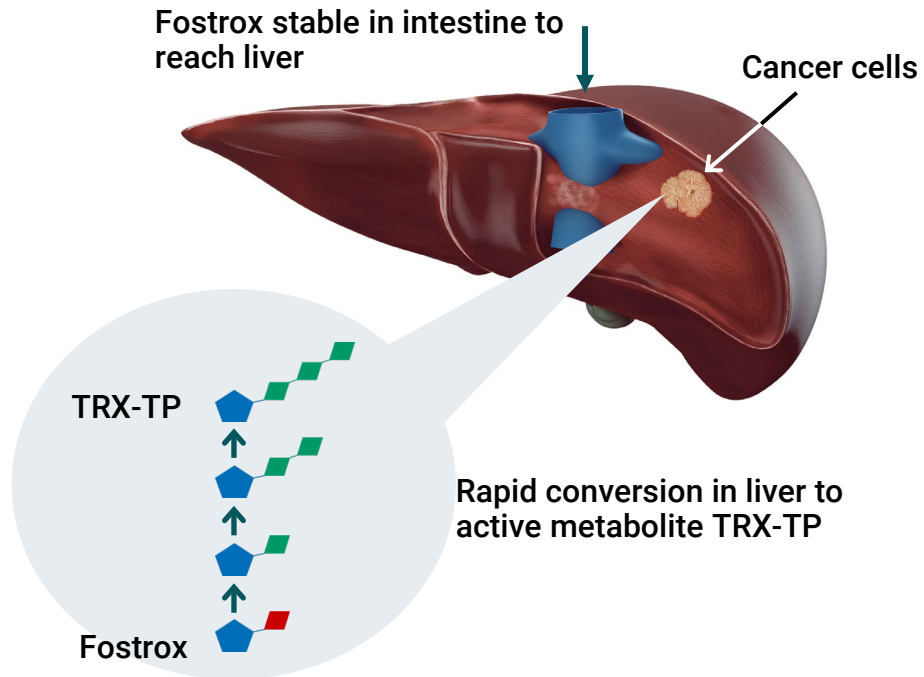
- Chemotherapy that induces tumour selective DNA-damage & cell death, sparing normal liver tissue
- Backbone therapy in most tumour types but so far not in liver cancer due to challenges, addressed by pro-drug solution



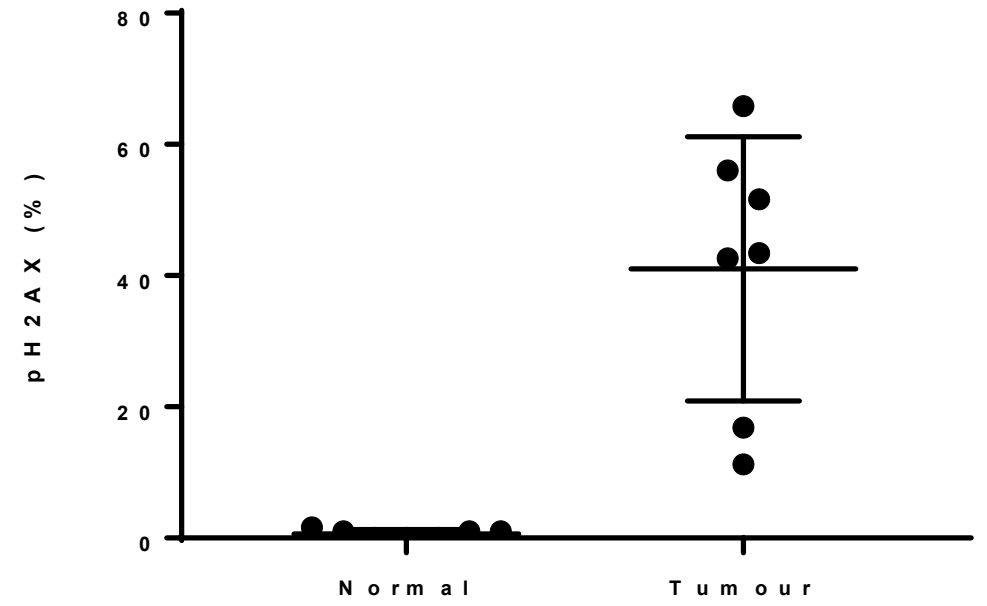
Fostroxacitabine bralpamide (fostrox) – first-in-class, orphan drug inducing DNA damage & cell death selectively in liver tumor tissue

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

DNA-damage & cell death observed in tumor tissue but not in normal liver tissue*



DNA-damage in normal liver vs tumour



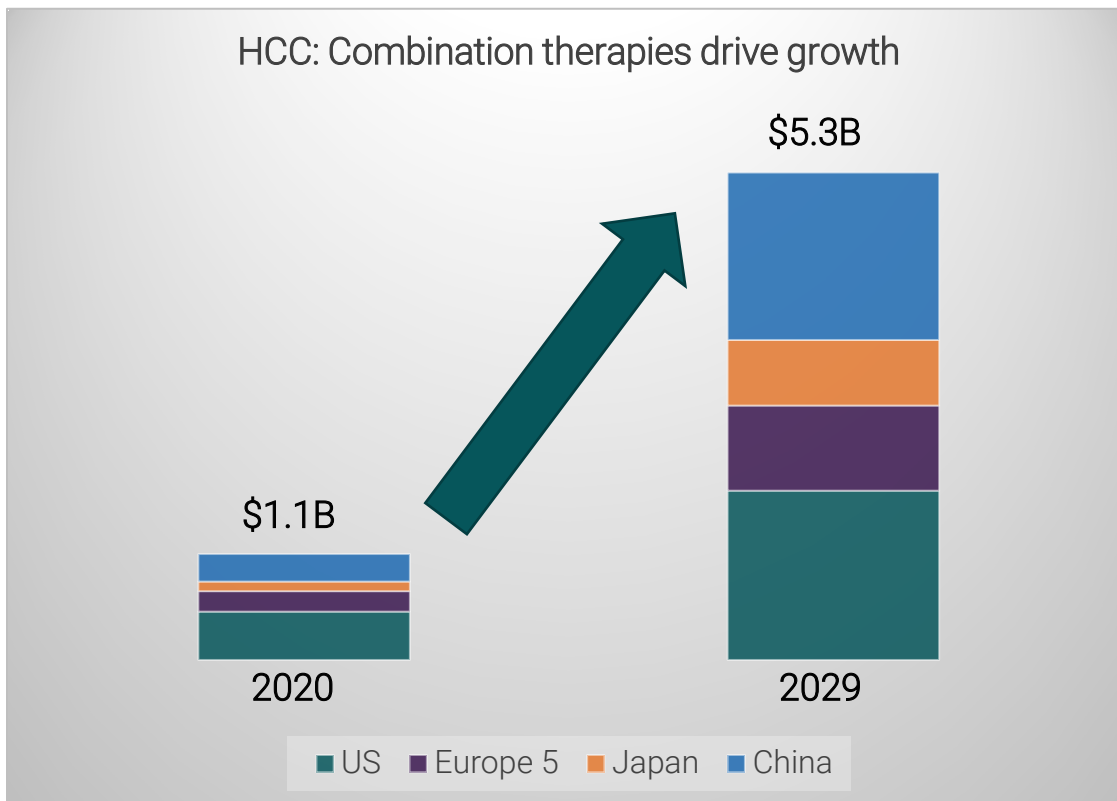
*PD marker gH2AX (% positive cells/brown stain) shows fostrox induced DNA-damage in tumor cells and not normal liver tissue



HCC is a significantly growing market with large unmet need

HCC market estimated to grow almost five-fold until 2029

Despite recent advancements, unmet need is still high



- Liver cancer incidence and mortality are increasing with liver cancer the third leading cause 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

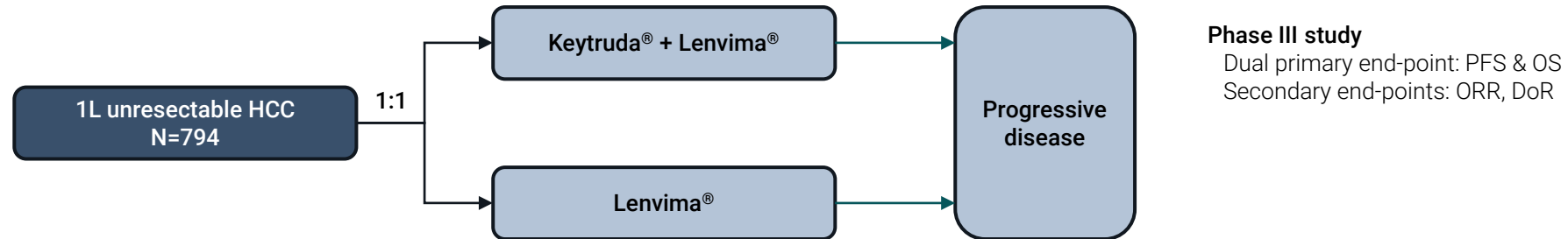
Source: GlobalData 2021

¹(<https://seer.cancer.gov/statfacts/html/livibd.htm>)

² Sayiner M, et al. Digestive Diseases and Sciences. 2019; 64: 910-917



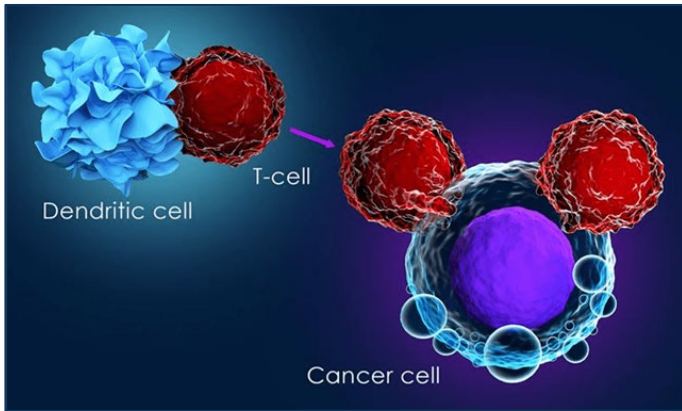
Negative outcome of LEAP-002 study, highlighting the need for alternative combination therapies



- On August 3, MSD announced that LEAP-002 did NOT meet its dual primary endpoints of OS and PFS.
- Too early to speculate on the reasons for a negative outcome and data will be presented in detail at an upcoming medical conference.
- As the focus of clinical development in HCC centres around combination therapies, the negative outcome does highlight a need for alternative combinations with compounds that have a different mechanism of action than the currently used classes of drugs.

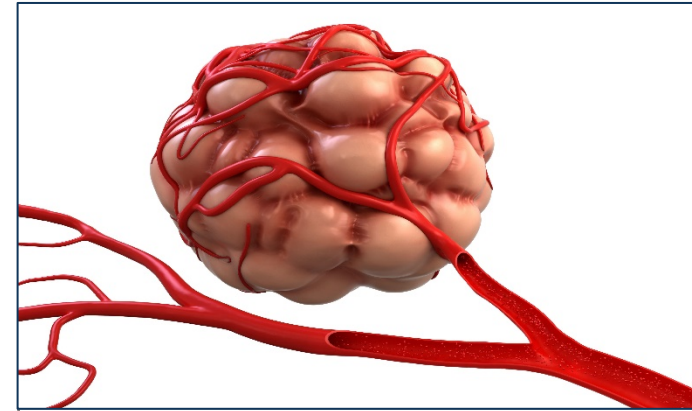
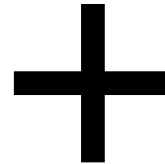


Current pipeline of new HCC therapies consists of a variation of combination trials with two key mechanisms of actions



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

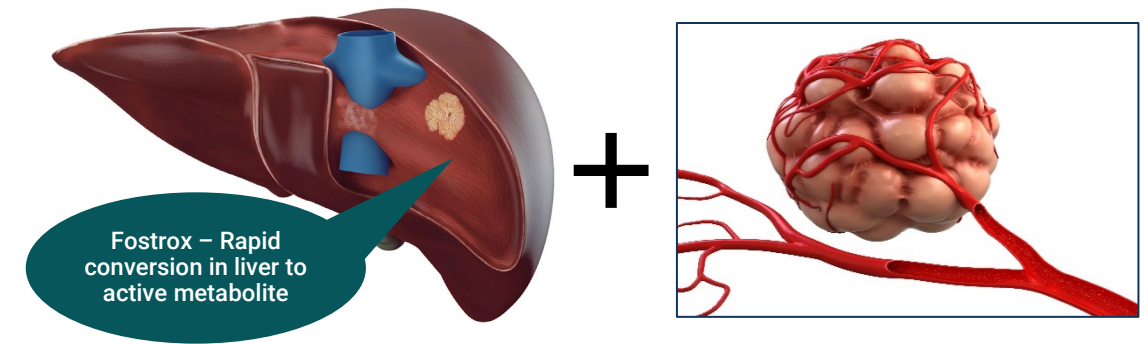
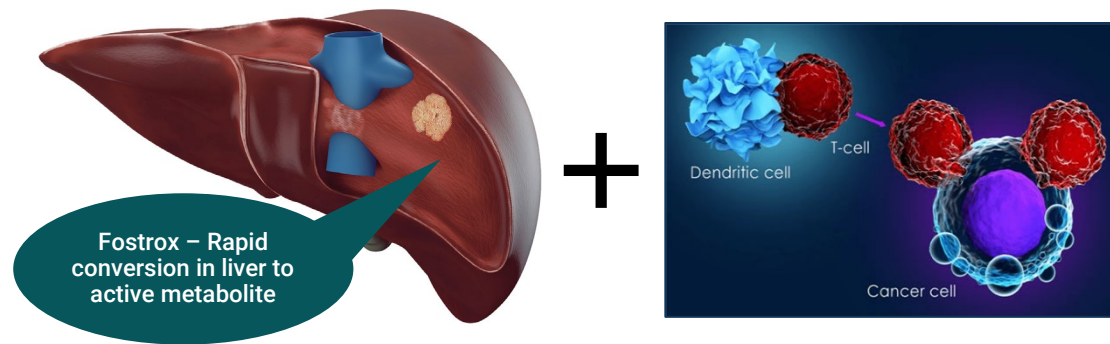
*Some of these drugs are multifunctional and have additional functions



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

Fostrox + stimulation of immune system (PD-1)

Fostrox + blocking blood supply to tumor (TKI)



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

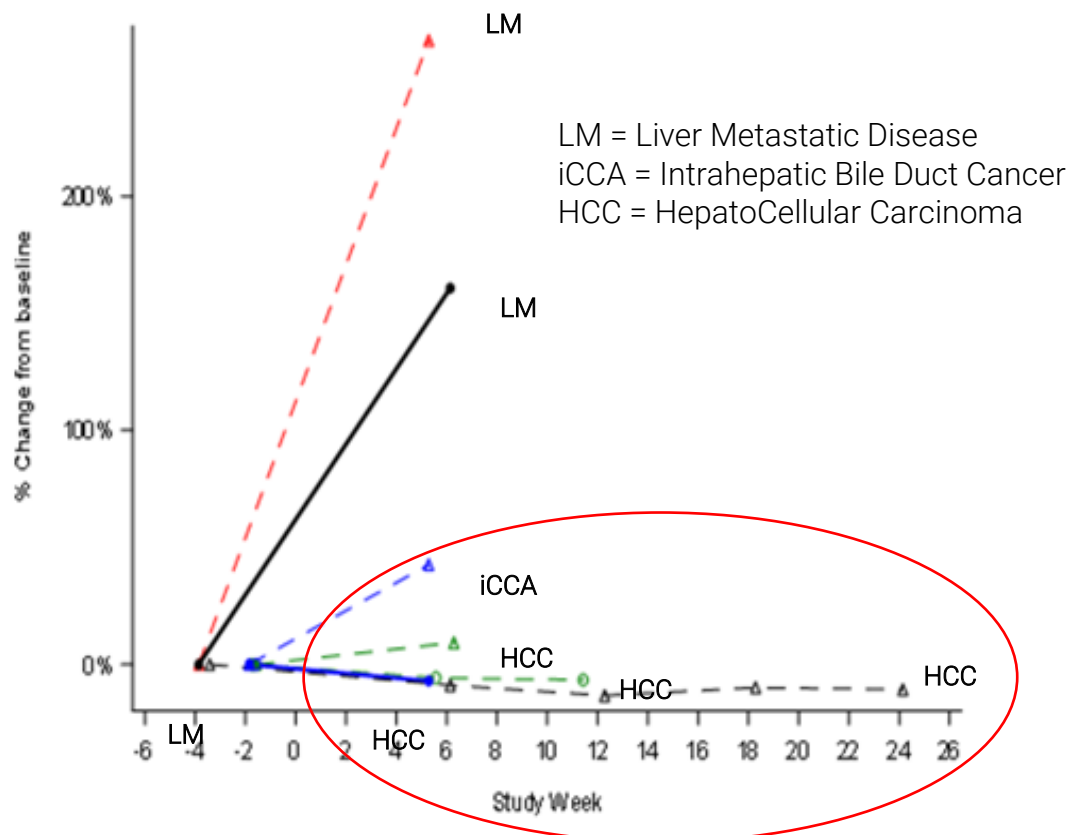
“TKI’s induce lack of oxygen in tumors leading to increased PGK1* expression and most importantly **higher levels of fostrox active metabolite**”

*Phosphoglycerate kinase 1 – hypoxia inducible gene



Phase 1b monotherapy results presented at ESMO supports continued development of fostroxacitabine bralpamide

Encouraging changes in liver target lesions*



**Out of 10 enrolled patients, one did not complete safety follow up and one lacked independent radiologist assessment

Safety profile supports moving forward with development

- Decreases in blood cell counts were the most common side effects, these resolved quickly
- In phase 1b four patients out of seven with primary liver cancer (e.g. HCC, iCCA) had stable disease as best overall response; one stayed on treatment for eight months
- Liver biopsy data has demonstrated delivery of fostrox to the liver, and a selective effect of fostrox on cancer cells vs normal liver tissue, across different types of cancer



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

Dose escalation – phase 1b

Dose expansion – phase 2a

Study Details & Objectives

Decision point

- Finalise phase 2 dose for each combination
- Which combination(s) to take into phase 2, one or both

Fostrox + Lenvima®

10-40 mg, dose cohorts of 3 patients

Fostrox + Lenvima®

Recommended Ph 2 dose, n=15/30*

Fostrox + Keytruda®

10-40 mg, dose cohorts of 3 patients

Fostrox + Keytruda®

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Investigator sites split 60/40 EU & Asia

Patient Population:

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

Primary Objective:

- assess safety and tolerability as combination therapy
- determine recommended phase 2 doses

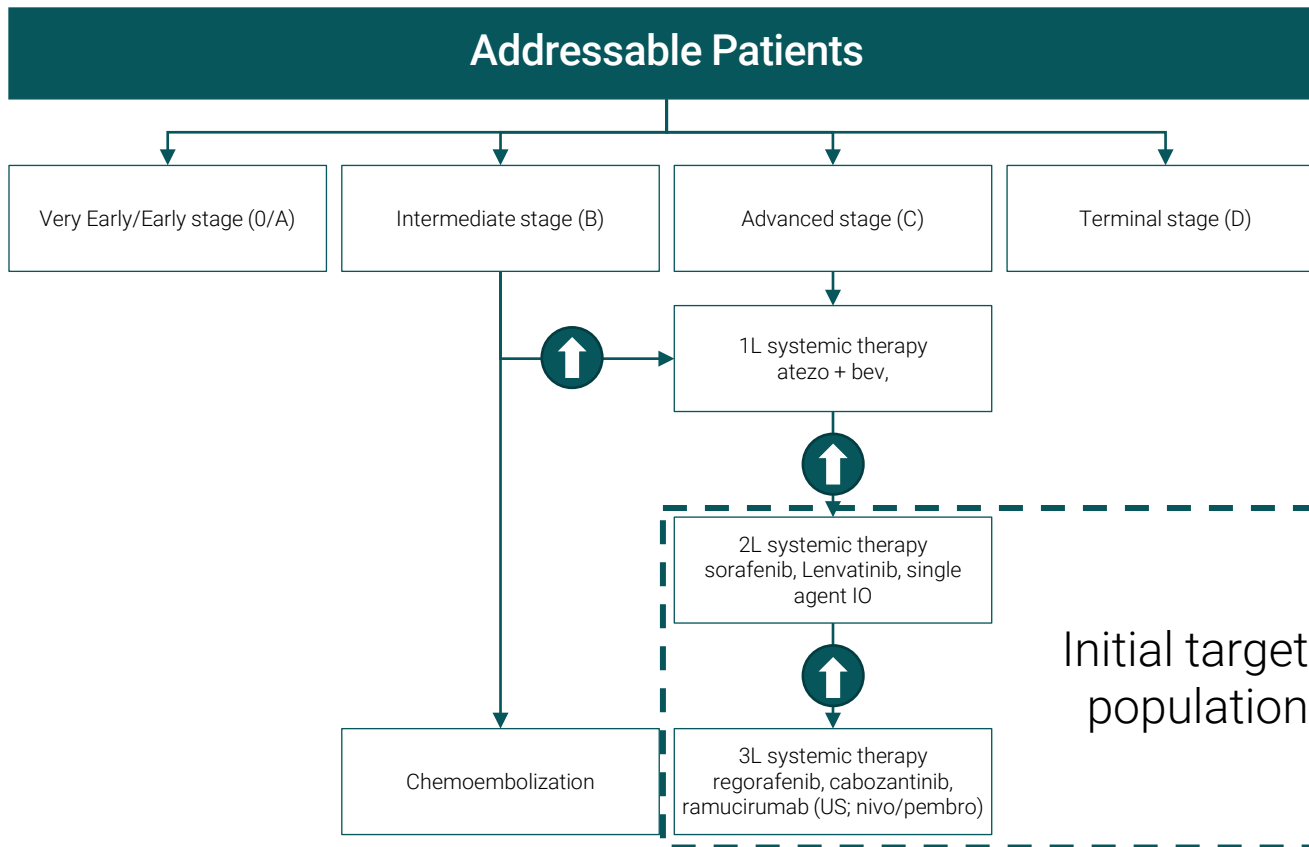
Secondary Objective:

- to evaluate tumor response rate based on RECIST v1.1

*15 patients per arm if both arms are taken forward or potentially 30 if one combination is chosen



As combination treatment continues to improve, more and more patients will receive systemic treatments earlier



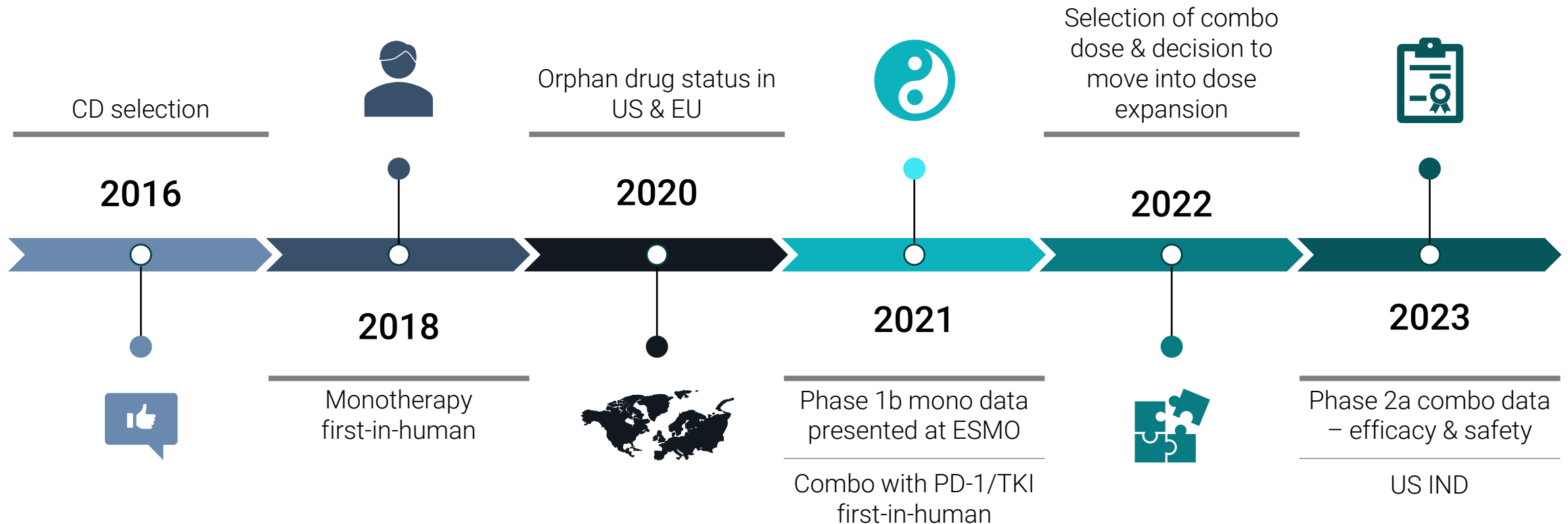
- Estimated treatment duration ~10+ months
- Atezo/bev established as standard of care for majority of patients
- Clear trend towards more patients receiving systemic treatment earlier

- Estimated treatment duration ~6+ months
- Single-agent TKI or IO agent becoming standard options
- Patients are treated earlier with better 1L therapy, more will be eligible for 2L

- Treatment duration ~3+ months
- More patients will become eligible for 3L with improved treatment regimens



Fostrox – continued momentum moving into 22/23





Strategic evolution & vision for fostroxacitabine bralpamide in liver cancer

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

Early lines HCC

Launch as preferred combination partner in select patient groups in early lines HCC with either TKI or PD-1

Backbone in HCC

Establish as backbone for combinations across HCC with potential for triple combinations & earlier lines

Beyond HCC

Explore potential in other liver related tumors beyond HCC such as CRC driven liver metastasis

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



Significant unmet need & commercial potential



Unique, first-in-class approach in liver cancer with strong potential for attractive combinations



Well established cytotoxic mechanism with an innovative, liver targeted approach to minimize systemic side effects

Clinical portfolio and partnerships



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 Projects developed by external partner

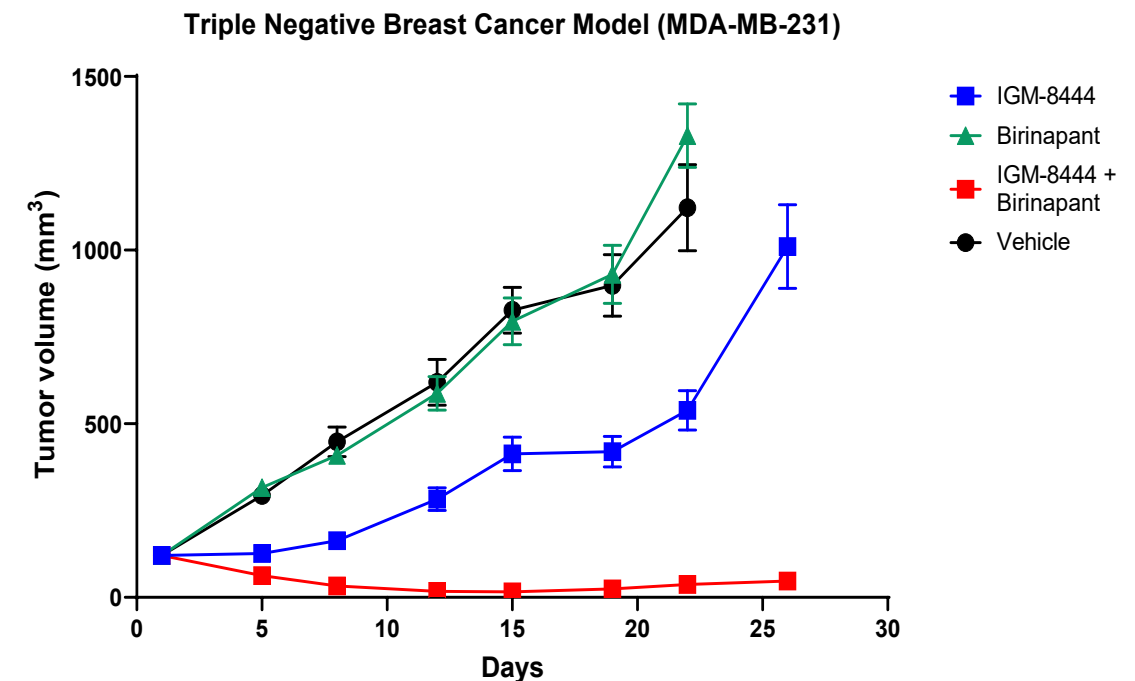


Birinapant – Licensing agreement with IGM Biosciences¹

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 tumors²
- The third of four planned birinapant combination dose escalation cohorts cleared with no DLTs and no clinically significant liver toxicity observed to date.
- 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)



Remetinostat – Efficacy and safety shown in three skin cancers

Three phase II trials completed

Cutaneous T-Cell Lymphoma (MF-CTCL)

- Open label, multicenter phase II study (60 patients) results showed 40% ORR, and reduced pruritus (itching) in 80% of patients

Basal Cell Carcinoma (BCC)

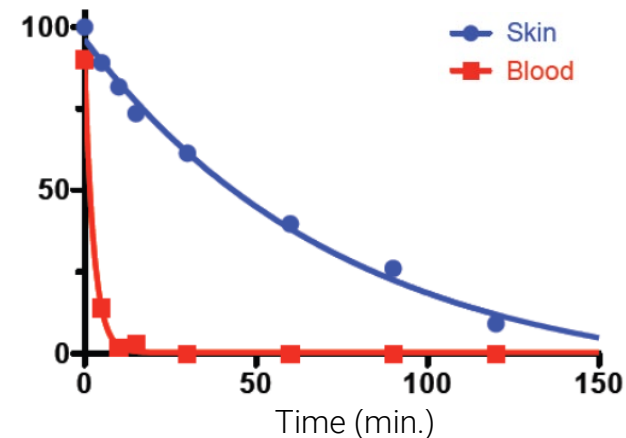
- Open label phase II study (25 patients, Stanford ISS) results showed 70% ORR

Squamous cell Carcinoma (SCC)

- Open label phase II study (4 patients, Stanford ISS) results showed 100% ORR

Unique topical HDAC-inhibitor

Stability of remetinstat



- Rapid breakdown by esterases in human blood ($t_{1/2}$ ~4 mins)
- Negligible levels of systemic exposure translates to reduced risk of HDACi class-associated toxicities

Re-negotiated revenue share agreement with Tetralogic enabling business development potential

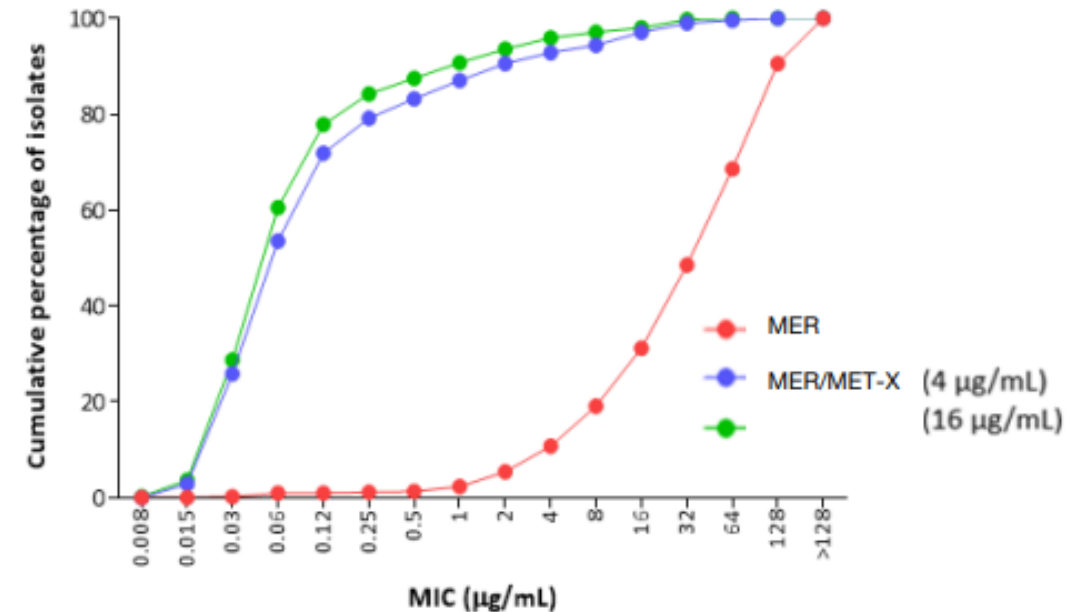


MET-X (MBLI) – Licensing agreement INFEX THERAPEUTICS

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

- INFEX is UK-based biotechnology company focusing on development of innovative drugs to treat pandemic infections.
- 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)
- cGMP manufacture complete to support Phase 1 initiation on MET-X and in combination with β -lactam partners in 2022/23.
- Revenue share agreement on all commercialisation revenue received with INFEX therapeutics. (September 2017)
- 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

Looking ahead

Momentum across portfolio delivering on key strategic priorities; more to come

2022 progress across product portfolio

Potential future key events

Accelerating fostrox

- Phase 1b monotherapy data presented at ESMO & additional proof-of-concept data at EASL with phase 1b/2a combo study recruiting with Keytruda® or Lenvima®
- 15 study sites now up and running across our three countries; UK, Spain and South Korea; intention to add additional sites and investigators in South Korea
- Negative outcome of LEAP-002 study in 1L HCC, further emphasizing the need for alternative combination therapies & mechanisms of action

- 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 third IGM-8444 + birinapant combination dose escalation cohort cleared with no DLTs.
- Subgroup analysis of phase II study with MIV-711 showing significantly reduced osteoarthritis-related pain.
- MBLI program advancing with additional pre-clinical data; INFEX communicating intention to initiate phase 1

- Birinapant + IGM8444 first data & decision which tumors to continue development in
- CD selection and IND-filing for USP-1 by Tango
- Value added partnering opportunities for remaining assets