



# REDEYE LIFE SCIENCE DAY

NOVEMBER 24, 2022

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MEDIVIR AB

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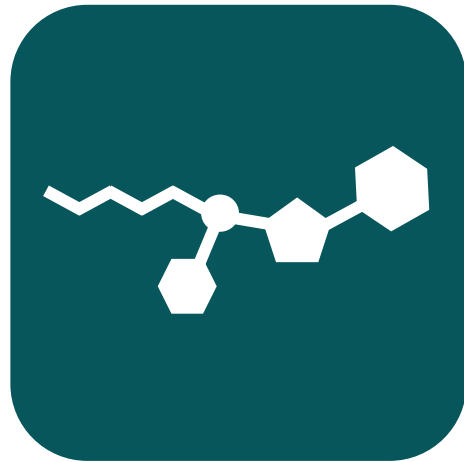
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# Medivir - A Swedish biotech focused on development of innovative treatments for cancer



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



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



# 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)
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MBLI (MET-X)	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

Slide

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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 37<sup>th</sup> 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.

# Fostroxacitabine bralpamide (fostrox)

# 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



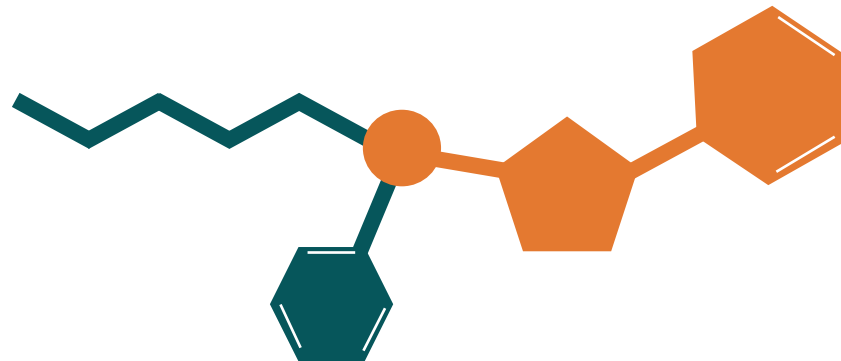
Strong potential for attractive combinations with both existing classes of drugs in liver cancer



# 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

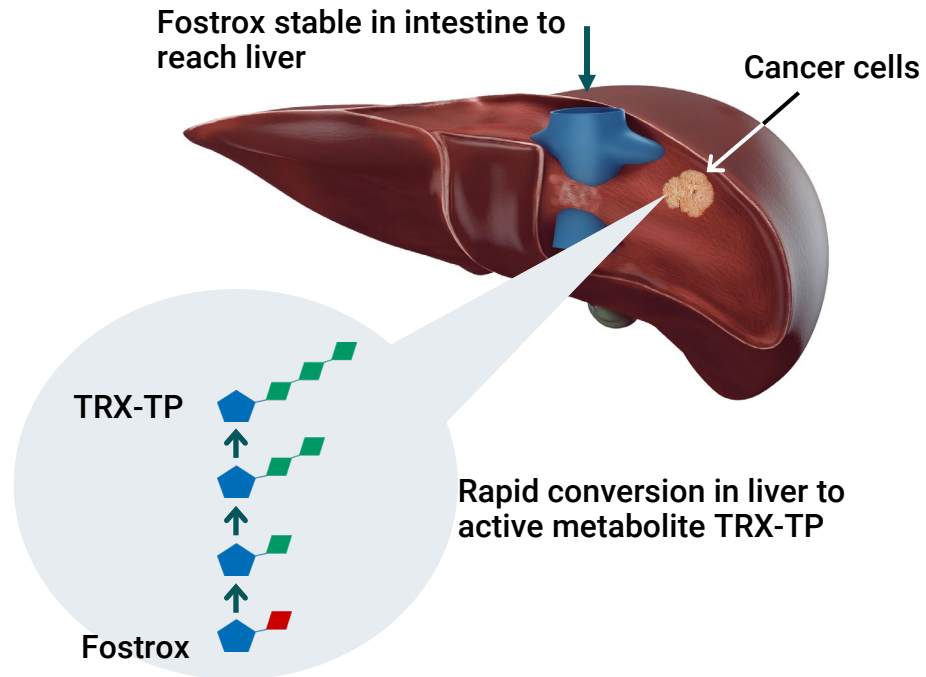




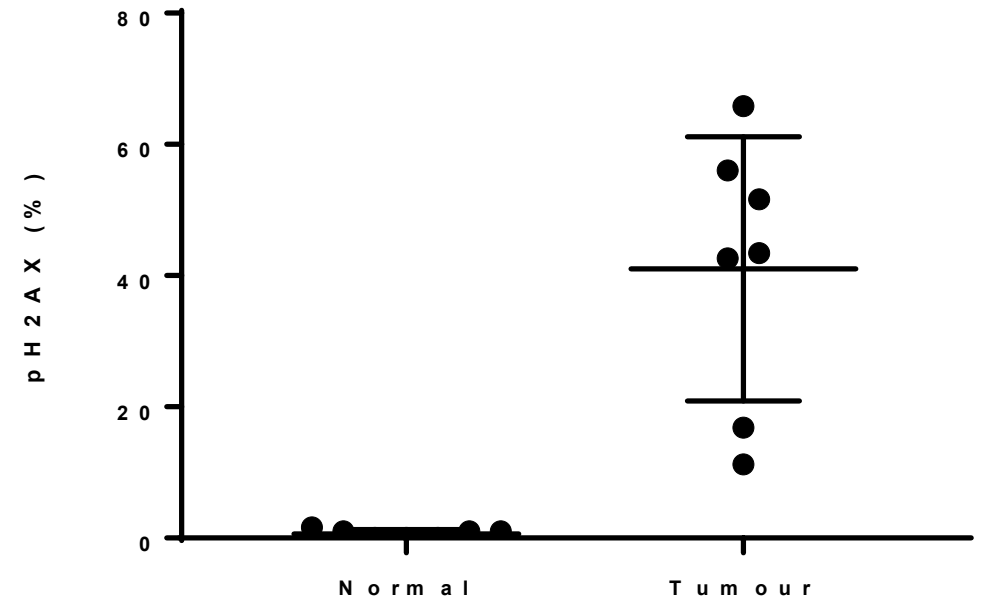
# Fostrox – first-in-class, orphan drug inducing DNA damage & cell death selectively in liver tumor tissue

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

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



DNA-damage in normal liver vs tumour



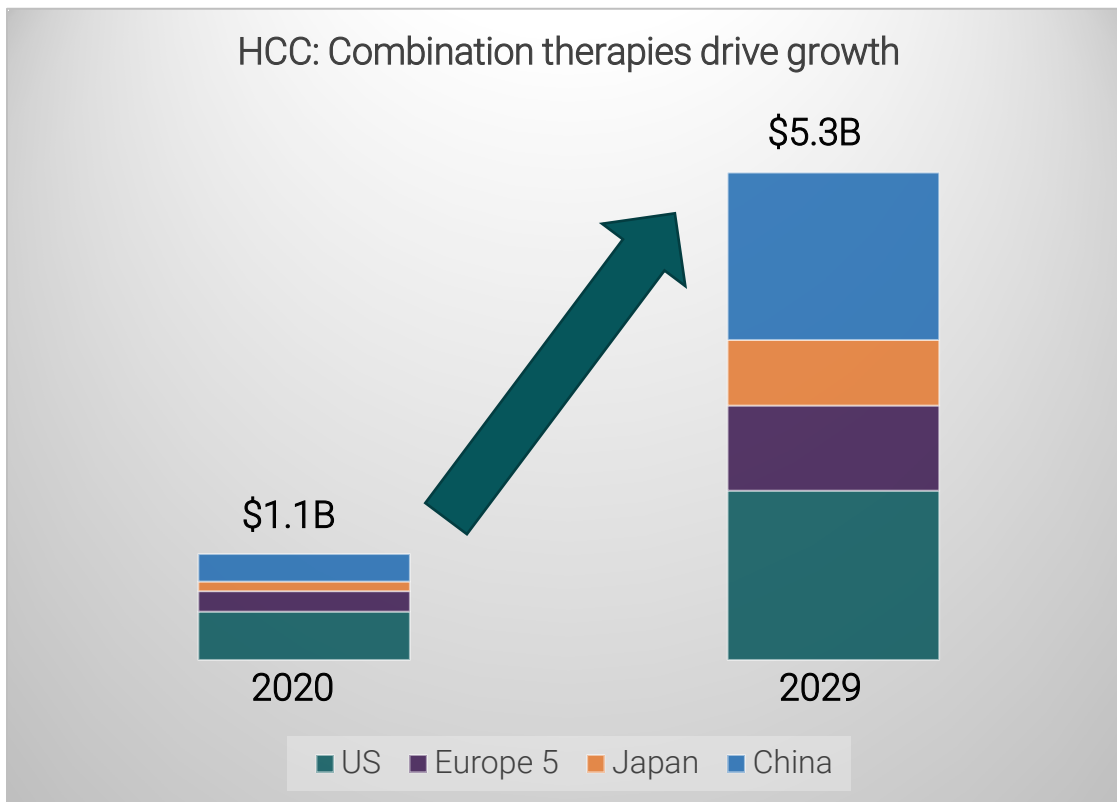
\*PD marker gH2AX (% positive cells/brown stain) shows fostrox induced DNA-damage in tumor cells and not normal liver tissue



# 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%<sup>1,2</sup>
- 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

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

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



# 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) <sup>2</sup>	RESOURCE (III)	CHECKMATE-040 /459 (I/II) <sup>1</sup>
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

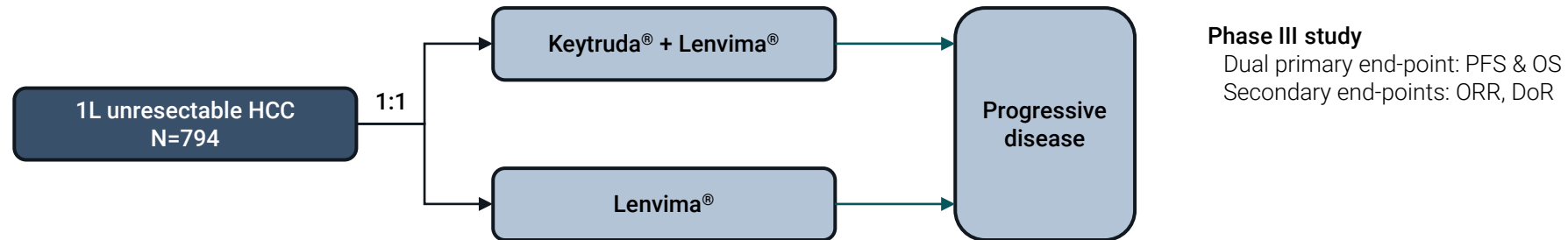
<sup>1</sup> Ongoing phase III study for first line therapy, CheckMate 9DW

<sup>2</sup> Several ongoing phase III studies in different settings and in combination with Lenvima Slide 11

Sources: FDA, BIOMEDTRACKER



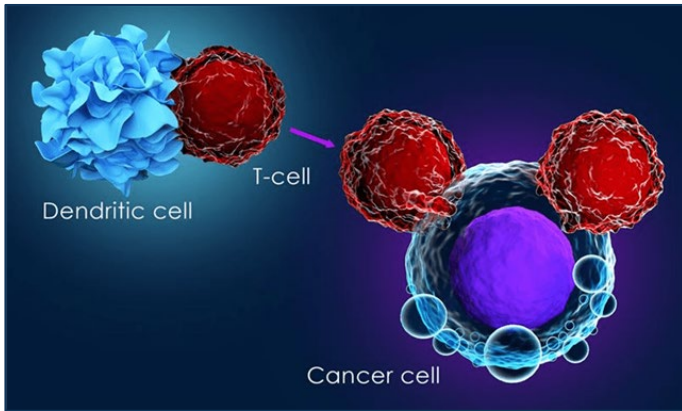
# Negative outcome of LEAP-002 study, highlighting the need for alternative combination therapies



- On August 3, MSD announced that LEAP-002 did NOT meet its dual primary endpoints of OS and PFS 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.

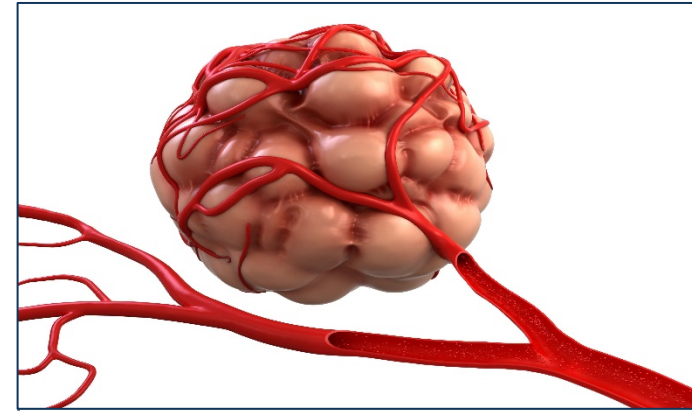
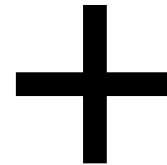


# Current pipeline of new HCC therapies consists of a variation of combination trials with two key mechanisms of actions



## 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

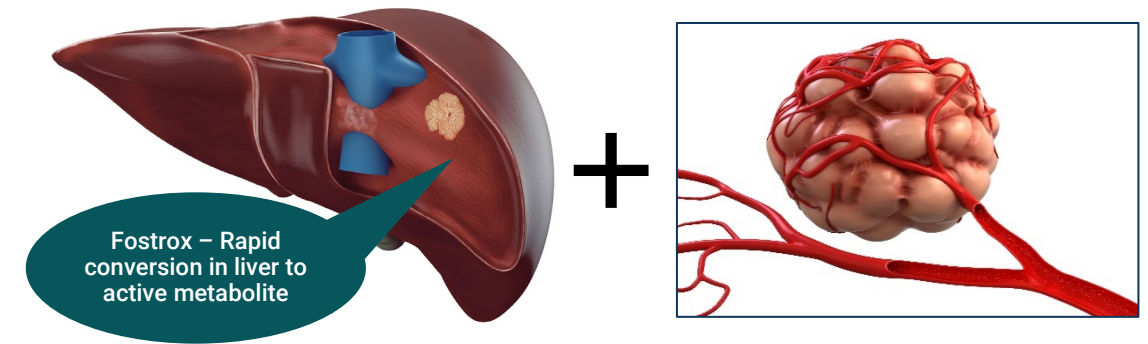
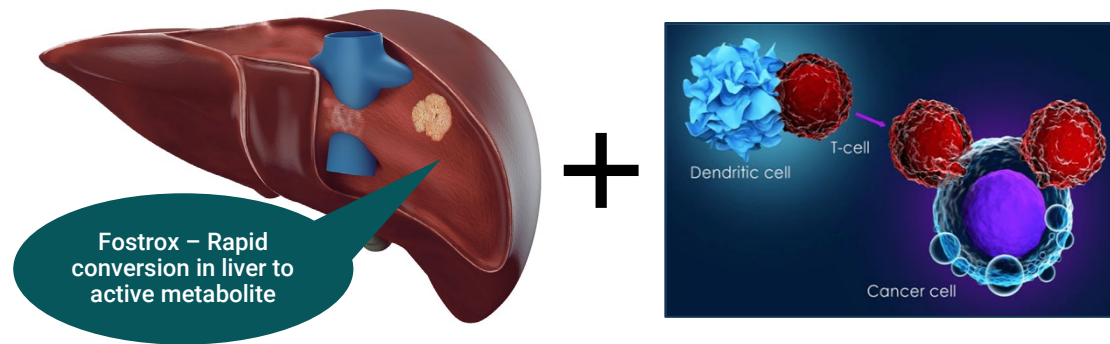
\*Some of these drugs are multifunctional and have additional functions



# 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)



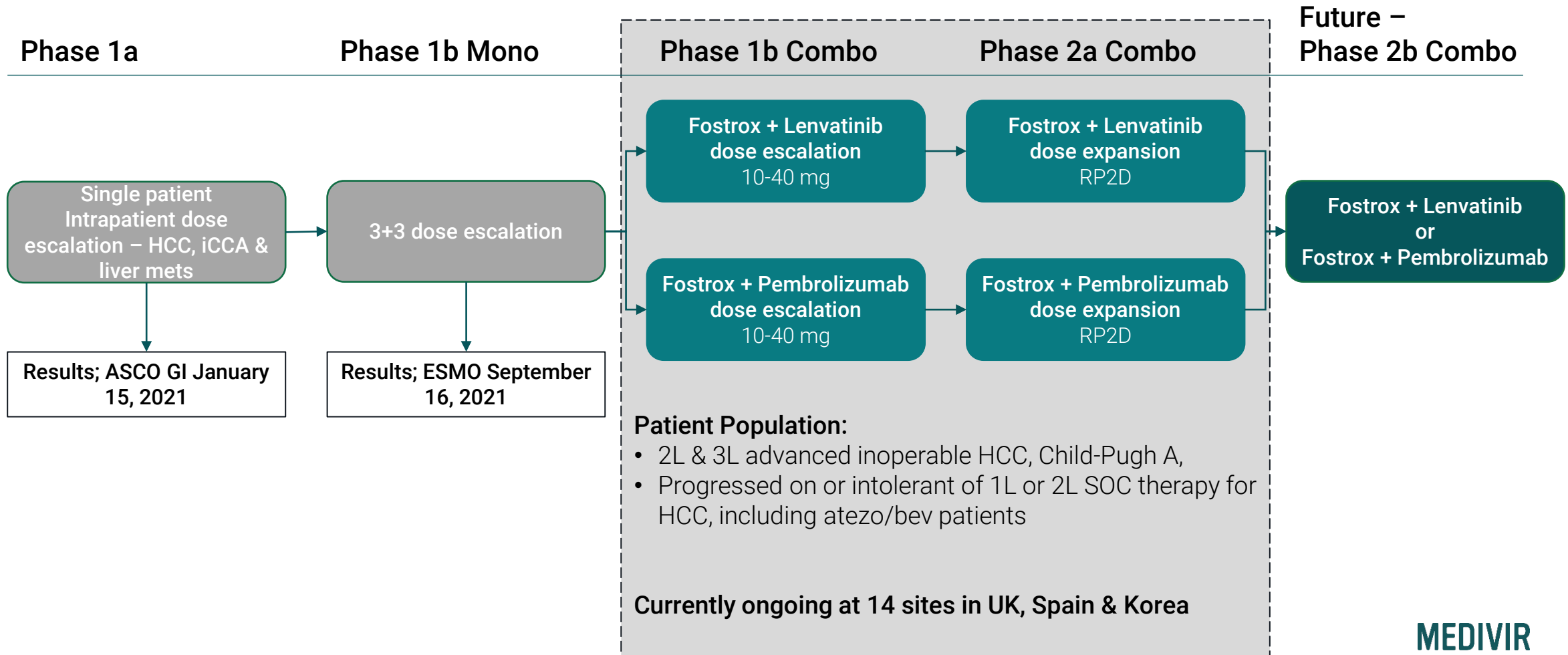
“Fostrox induces DNA damage and tumor cell death, potentially leading to **increased tumor antigen presentation and increased immune response**”

“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



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



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

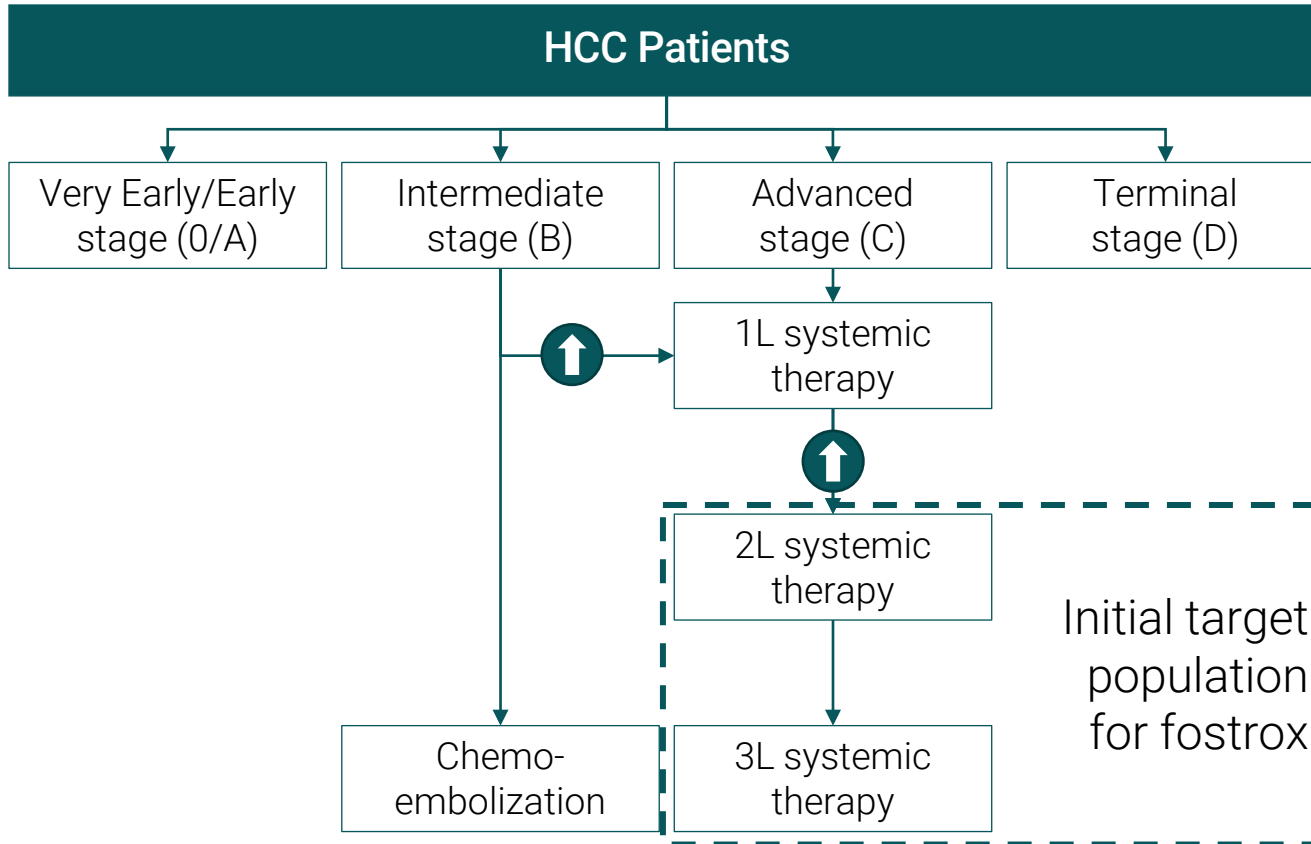


- Current treatment paradigm well aligned with recruitment of patients to fostrox study; both arms attractive to patients as well as investigators
- Highest unmet need currently in 2L setting where combination approach to improve clinical benefit is seen as the preferred approach
- HCC a clear area of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





# 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



# 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

# Clinical portfolio and partnerships



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

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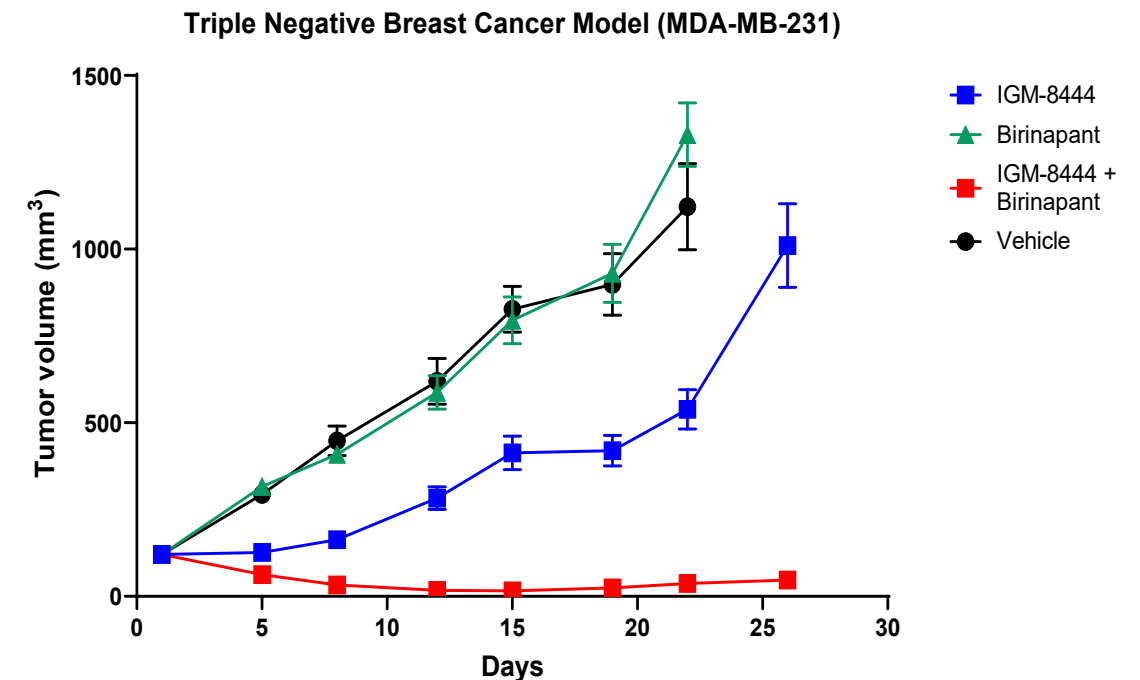


# Birinapant – Licensing agreement with IGM Biosciences<sup>1</sup>

## 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<sup>2</sup>
- 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)



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

- USP1 pre-clinical program outlicensed to Tango Therapeutics Q1 2020
- TNG348 nominated as development candidate, well tolerated in non-GLP preclinical safety studies
- Distinct mechanism of action from PARPi, with efficacy mediated through ub-PCNA and replication stress
- USP1i single agent activity equivalent to or better than Olaparib in several models
- Synergy in both PARPi-sensitive and resistance models suggests potential to meaningfully expand patient benefit from PARP inhibitors
- BRCA1/2 mutations occur in ~15% ovarian, 10% breast, 10% prostate, 5% endometrial and 5% pancreatic cancers

# 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

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- CD selection for USP1 by Tango Therapeutics

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



**Thank You!**