



# REDEYE ORPHAN DRUG

APRIL 27, 2022

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MEDIVIR

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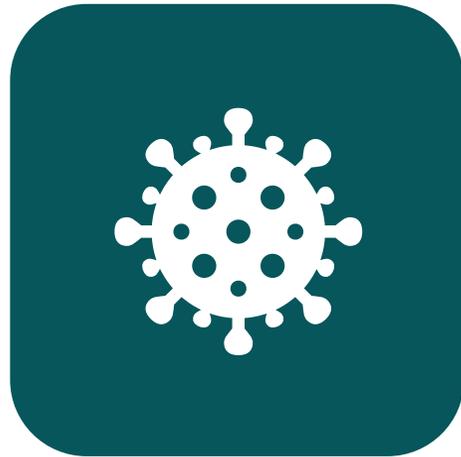
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# A unique, first-in-class, lead asset in liver cancer (HCC) & successful partnering strategy



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



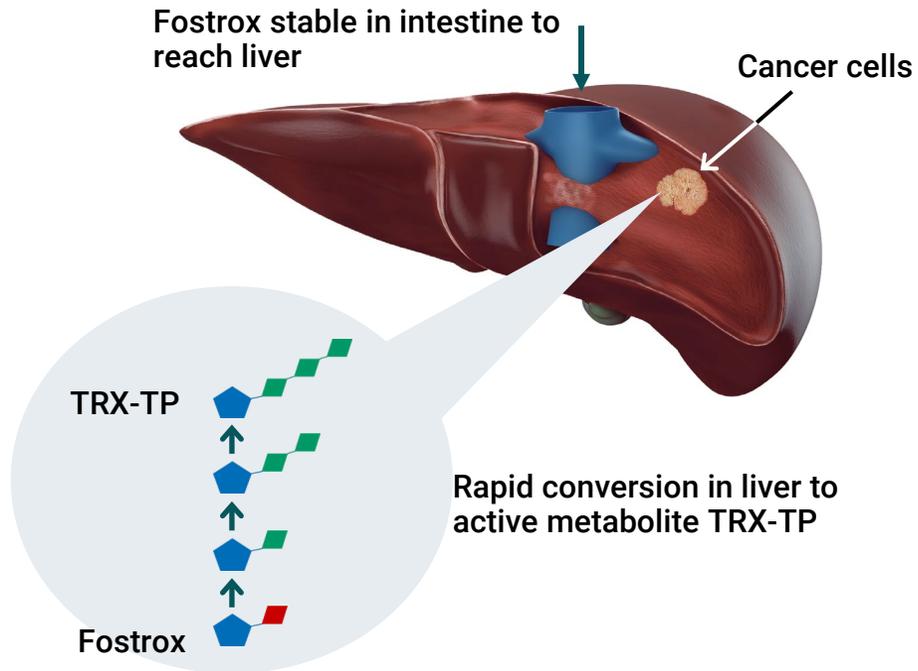
**Active partnering strategy for additional value creation across product portfolio**



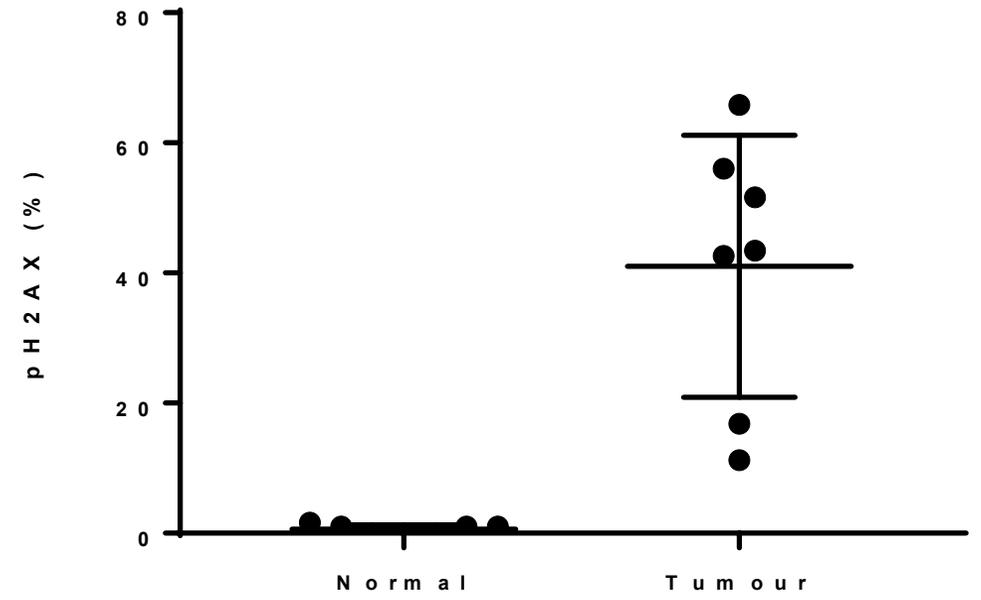
# Fostroxacitabine bralpamide (fostrox) – first-in-class, orphan drug inducing DNA damage & cell death selectively in liver tumor tissue

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



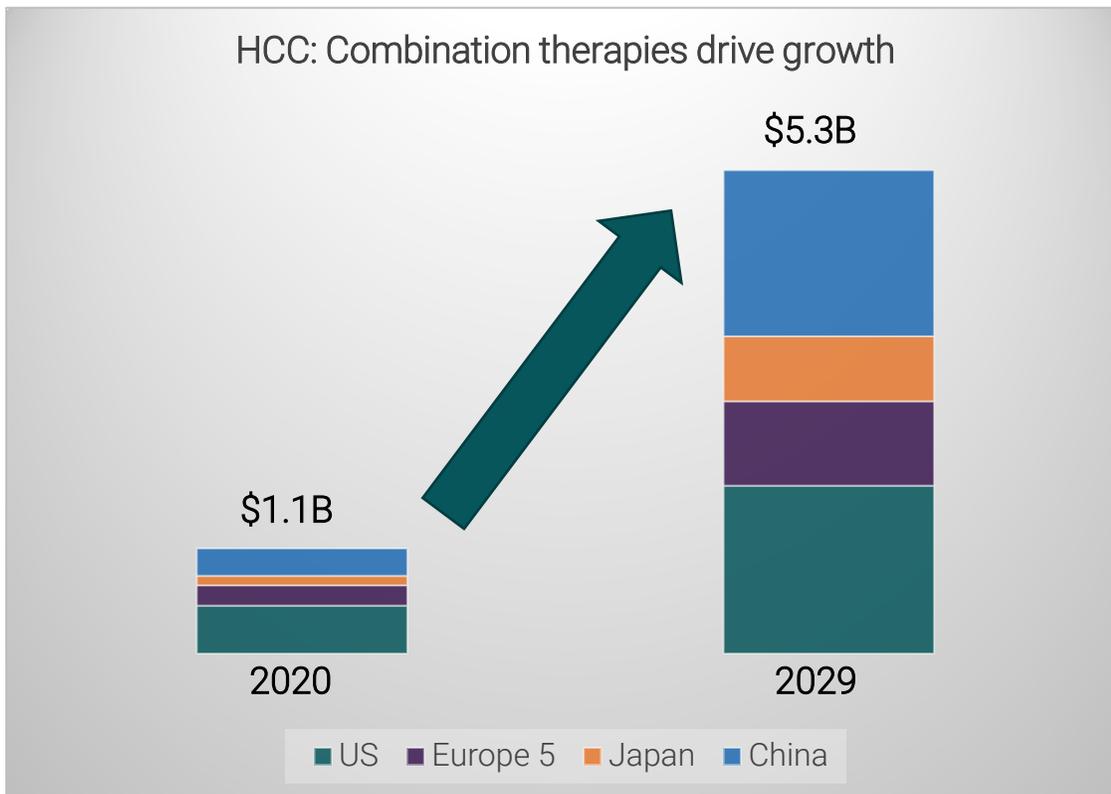
\*PD marker gH2AX (% positive cells/brown stain) shows fostrox induced DNA-damage in tumor cells and not normal liver tissue



# 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%<sup>1,2</sup>
- Despite recent advances in treatment of HCC, still only ~1/3 of patients responding to systemic treatment
- The HCC market growth is driven by combination therapies and patients treated in earlier disease stages

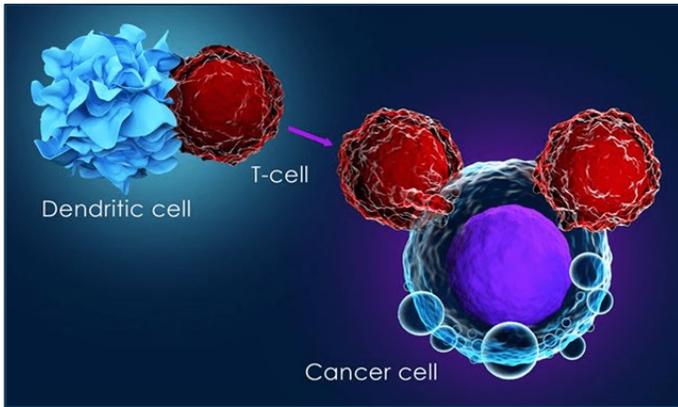
Source: GlobalData 2021

<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

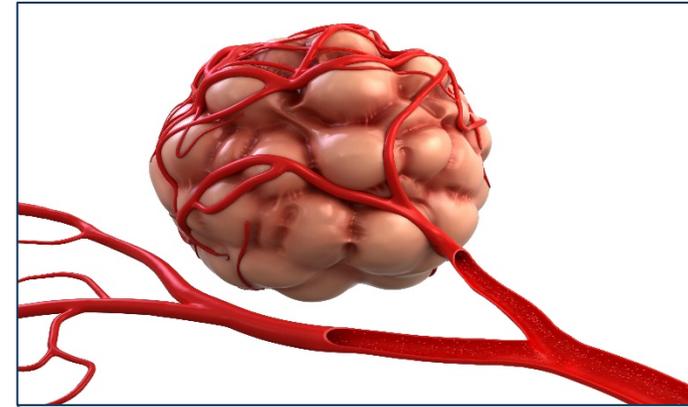
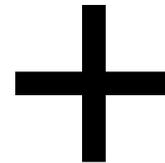


# Current pipeline of new HCC therapies consists of a variation of combination trials with two key mechanisms of actions



## 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

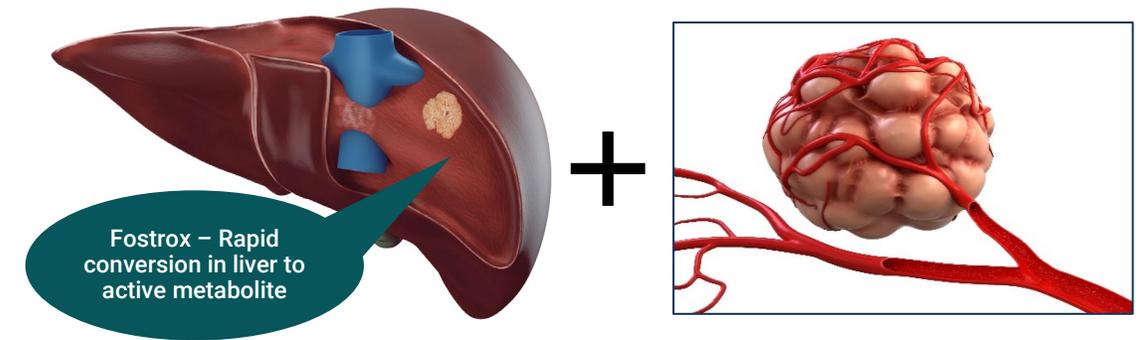
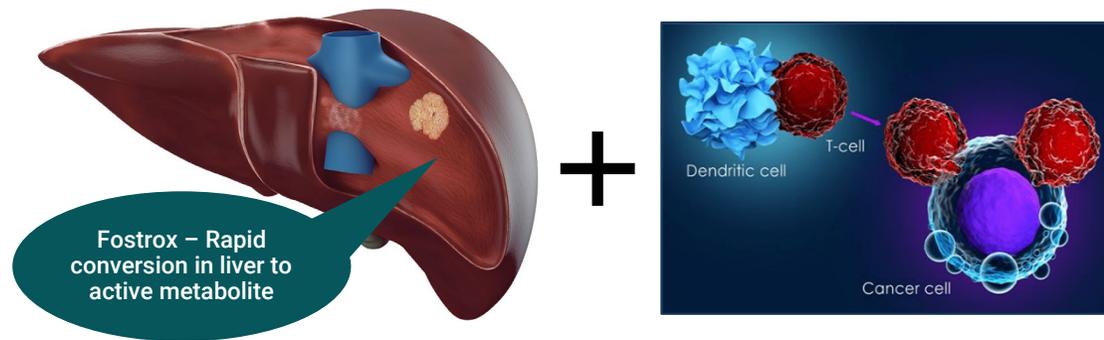
\*Some of these drugs are multifunctional and have additional functions



# 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**”

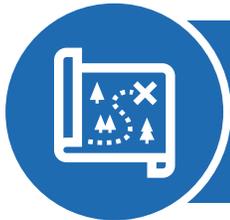
\*Phosphoglycerate kinase 1 – hypoxia inducible gene



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



Induction of DNA-damage & cell death well established in cancer



Proven, liver targeted pro-drug mechanism as in anti-HCV (Sovaldi)

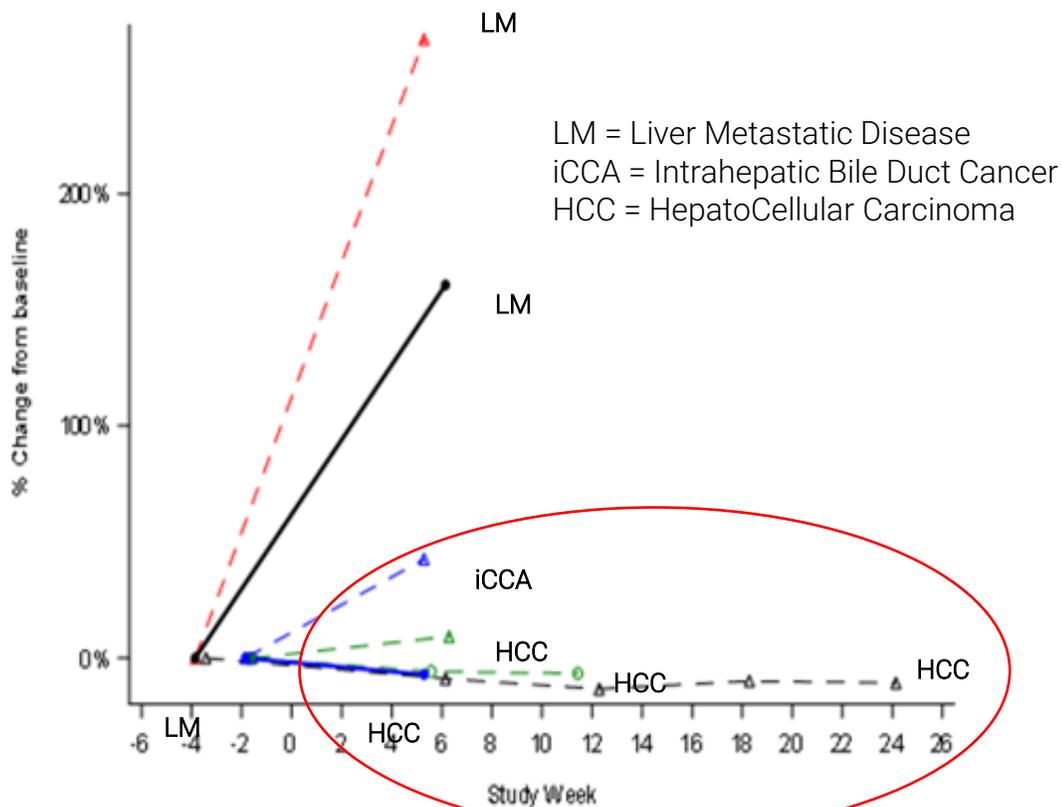


Pro-drug approach bypasses resistance mechanisms for increased efficacy



# Phase 1b monotherapy results presented at ESMO supports continued development of fostrox

Encouraging changes in liver target lesions\*



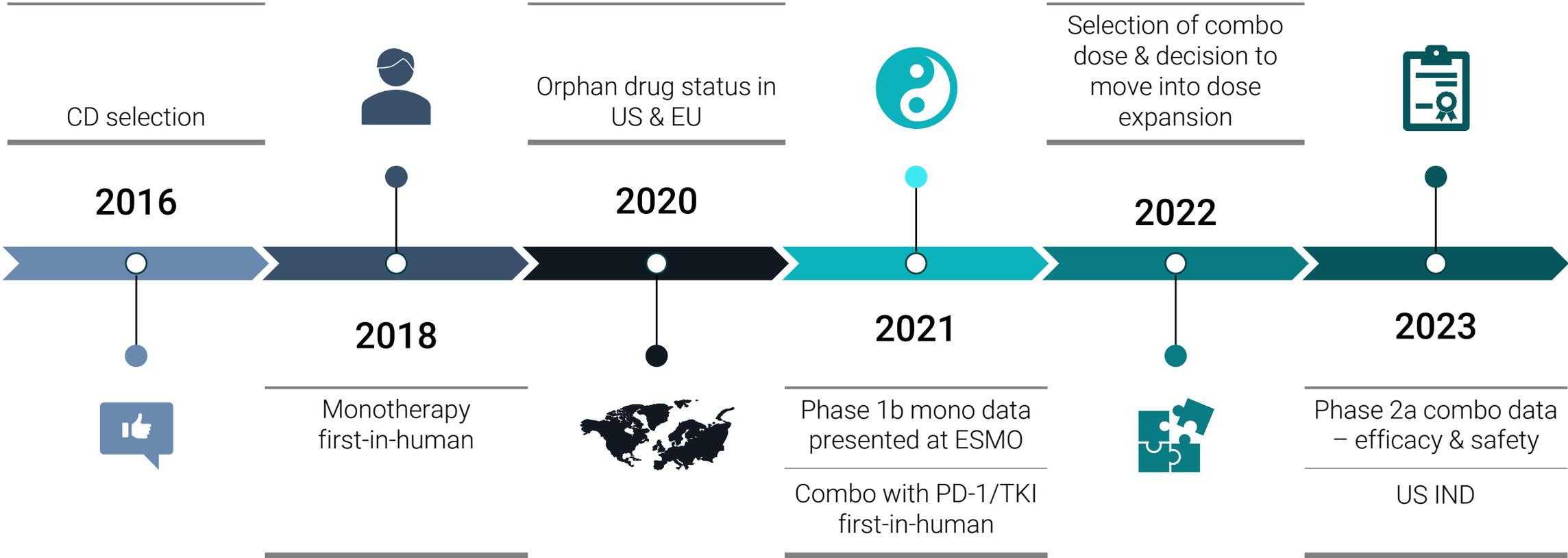
\*\*Out of 10 enrolled patients, one did not complete safety follow up and one lacked independent radiologist assessment

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



# Fostrox – continued momentum moving into 22/23





# 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®

Recommended Ph 2 dose , n=15/30\*

Investigator sites split 60/40 EU & Asia

Patient Population:

- 2L 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



# Strategic evolution & vision for fostrox in liver cancer

**Fostrox; Go-To option for combinations across liver related tumors**

## 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; fostrox complementing, not replacing, existing therapies



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



Induction of DNA-damage & cell death well established in cancer, strong potential for attractive combinations

# Q&A