



MEDIVIR Q2 2022 WEBCAST

AUGUST 19, 2022

MEDIVIR

Today's presenters



CEO

- Jens Lindberg
- Joined Medivir 2022
- > 25 years pharma experience with focus in Oncology.
- Has led global product strategy development for late-stage compounds as well as product launch for multiple compounds.
- Experience includes interim CEO role for Sedana Medical AB.
- Medivir ownership; 25.000 shares & 240.000 warrants



CFO

- Magnus Christensen
- Joined Medivir 2019
- > 20 years experience in finance, including CFO at O'Learys Trademark AB.
- Previous interim CEO at Medivir
- Experience of working in listed-, private equity- and private companies.
- Medivir ownership; 15.000 shares & 172.500 warrants



CSO

- Fredrik Öberg
- Joined Medivir 2011
- > 25 years experience in cancer research from industry and academia
- > 50 scientific articles and holds several patents.
- Adjunct professor at Medical Faculty of Uppsala University
- Medivir ownership; 69.172 shares & 159.010 warrants

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Highlights during last quarter

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.



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 | | | | | | | | | | |
| Xerclear | GSK, SYB | Herpes |  | | | | | | Royalties | <ul style="list-style-type: none"> ▪ Registration in China |
| Remetinostat | TBD | CTCL, BCC, SCC |  | | | | | TBD | <ul style="list-style-type: none"> ▪ Partnering agreement | |
| MIV-711 | TBD | Osteoarthritis |  | | | | | TBD | <ul style="list-style-type: none"> ▪ Partnering agreement | |
| 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

Slide

Fostroxacitabine bralpamide (fostrox)

Initiatives launched to accelerate study recruitment and overcome slower than planned rate in Europe



Protocol amendment broadening & simplifying inclusion criteria



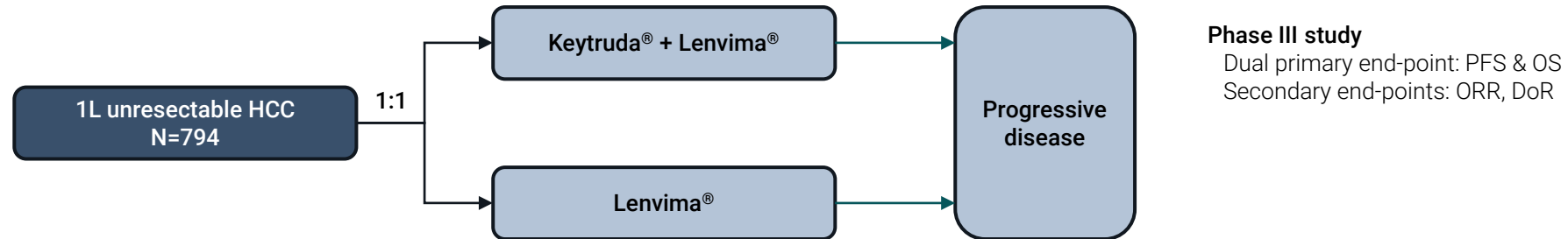
Additional investigators & sites in existing & new countries



Increased presence and activity at activated trial sites



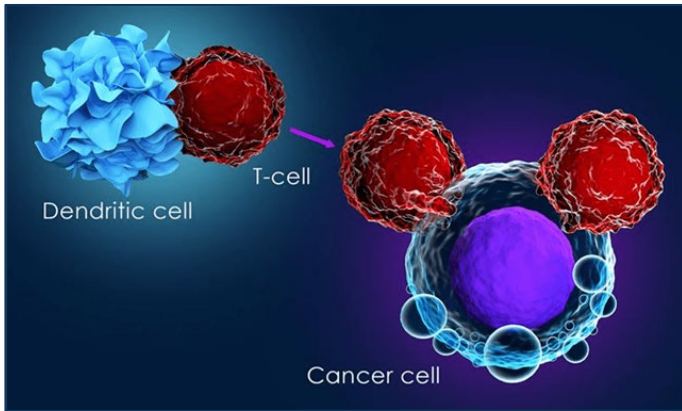
Negative outcome of LEAP-002 study, highlighting the need for alternative combination therapies



- 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.

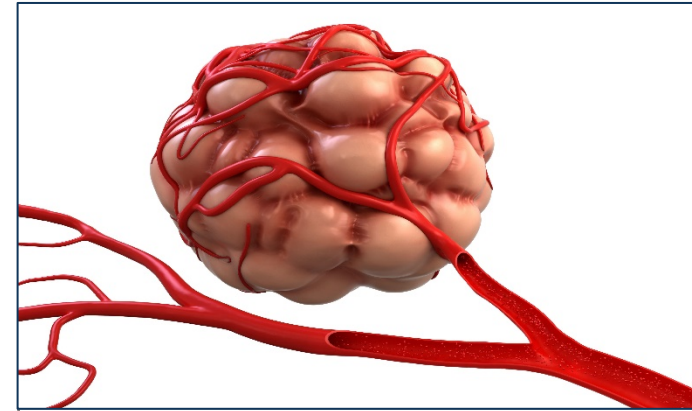
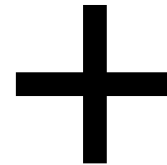


Current pipeline of new HCC therapies consists of a variation of combination trials with two key mechanisms of actions



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

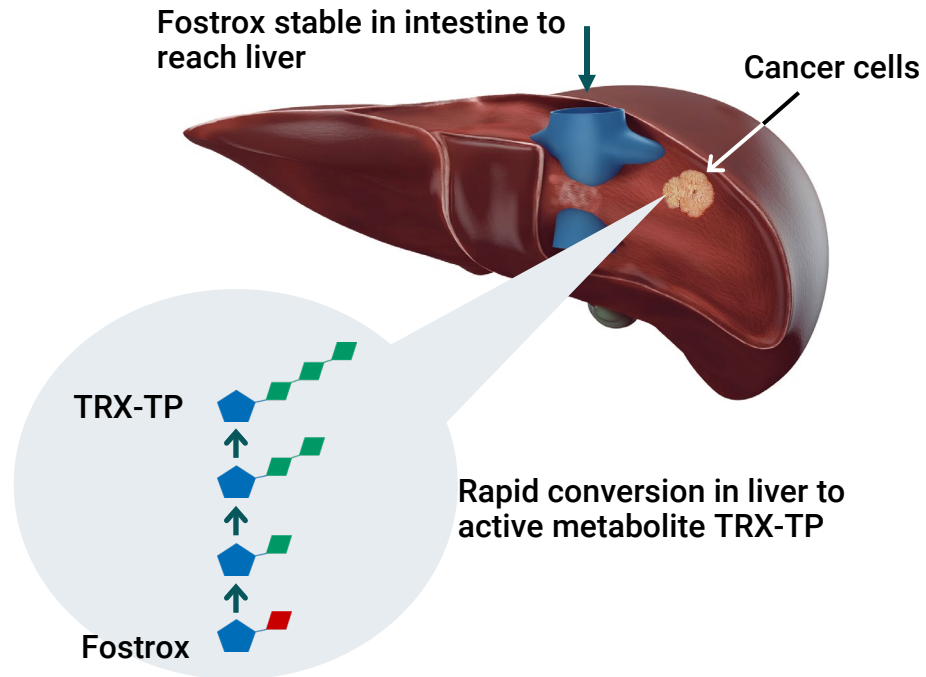
*Some of these drugs are multifunctional and have additional functions



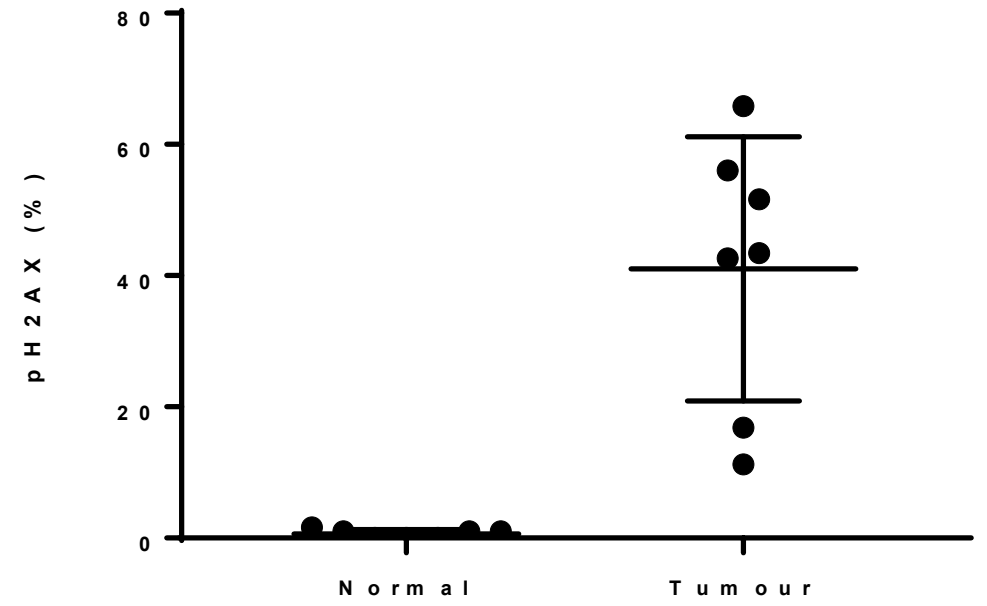
Fostrox – first-in-class, orphan drug inducing DNA damage & cell death selectively in liver tumor tissue

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



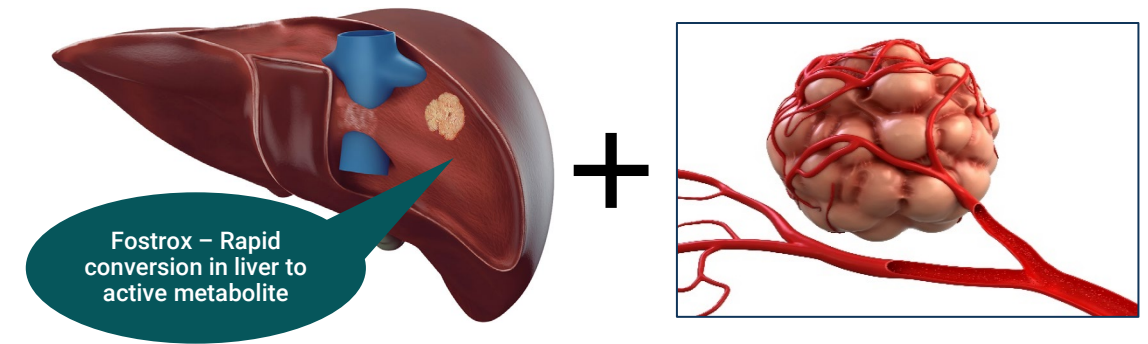
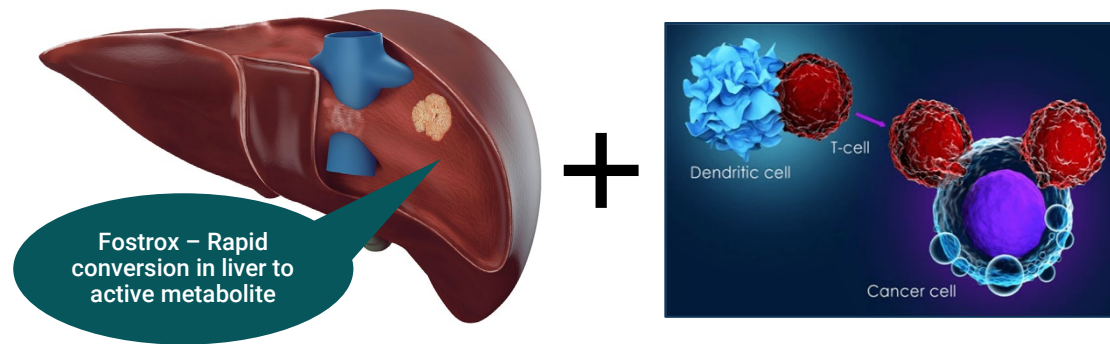
*PD marker gH2AX (% positive cells/brown stain) shows fostrox induced DNA-damage in tumor cells and not normal liver tissue



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

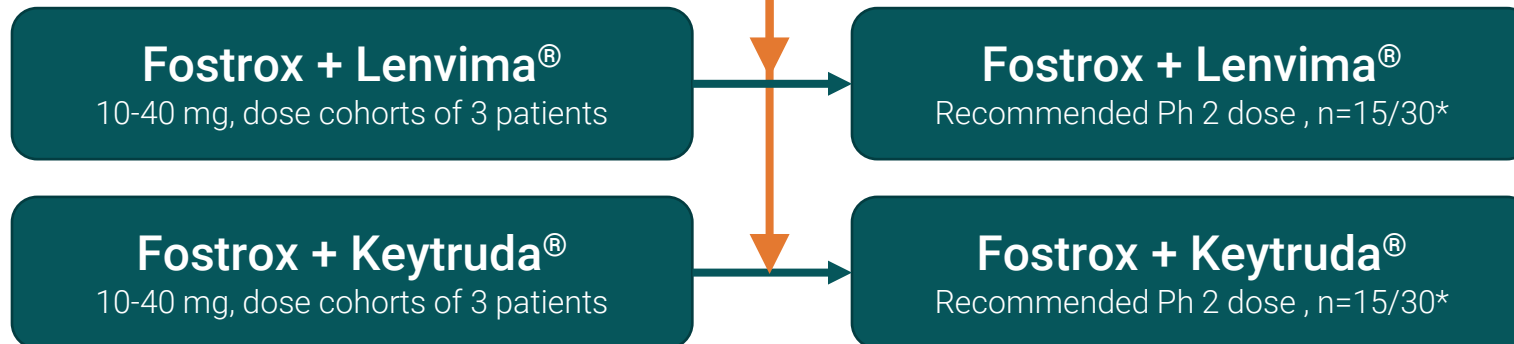
Dose escalation – phase 1b

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



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

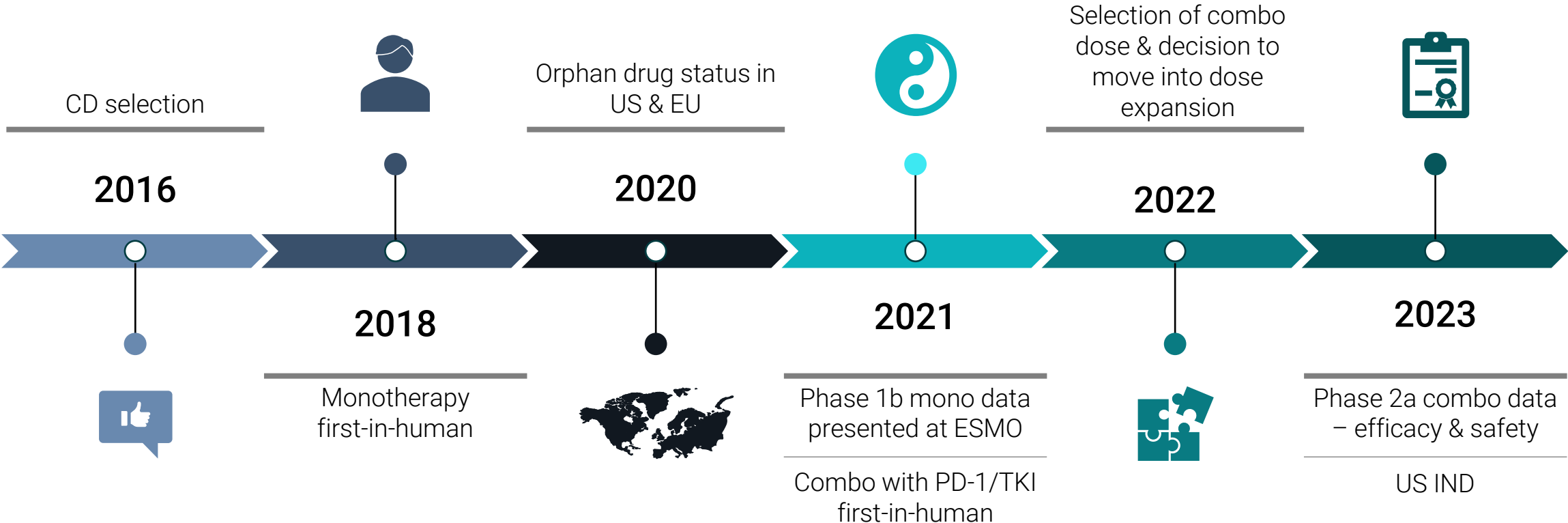
Secondary Objective:

- 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

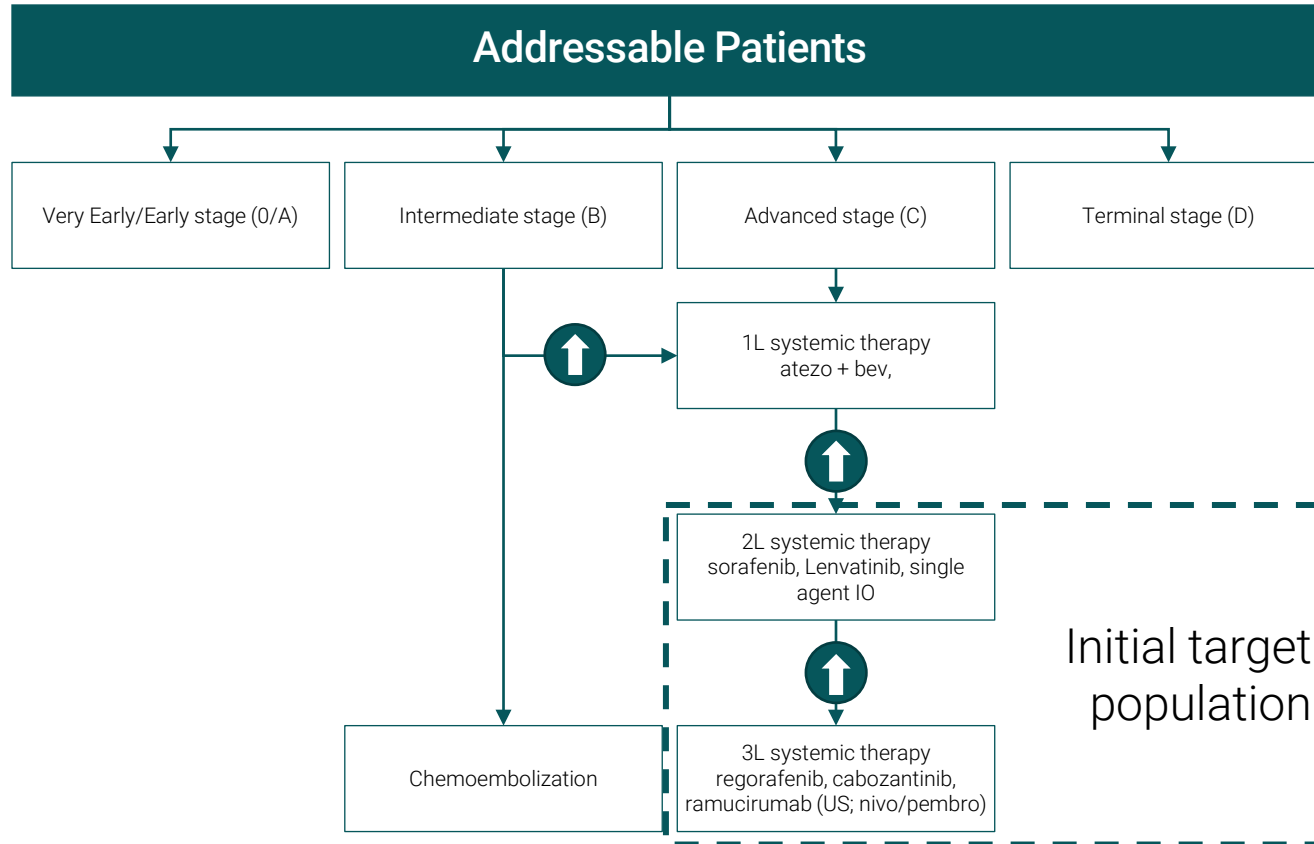


Fostrox – continued momentum moving into 22/23





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 – 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

Other Program Highlights

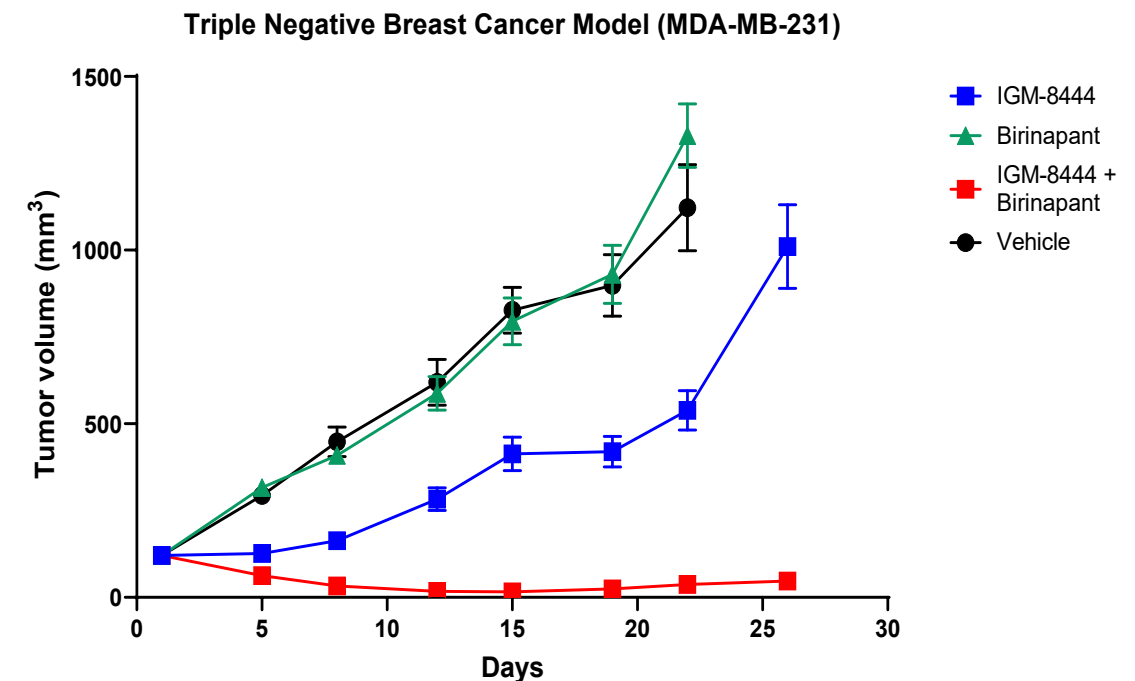


Birinapant – Licensing agreement with IGM Biosciences¹

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)

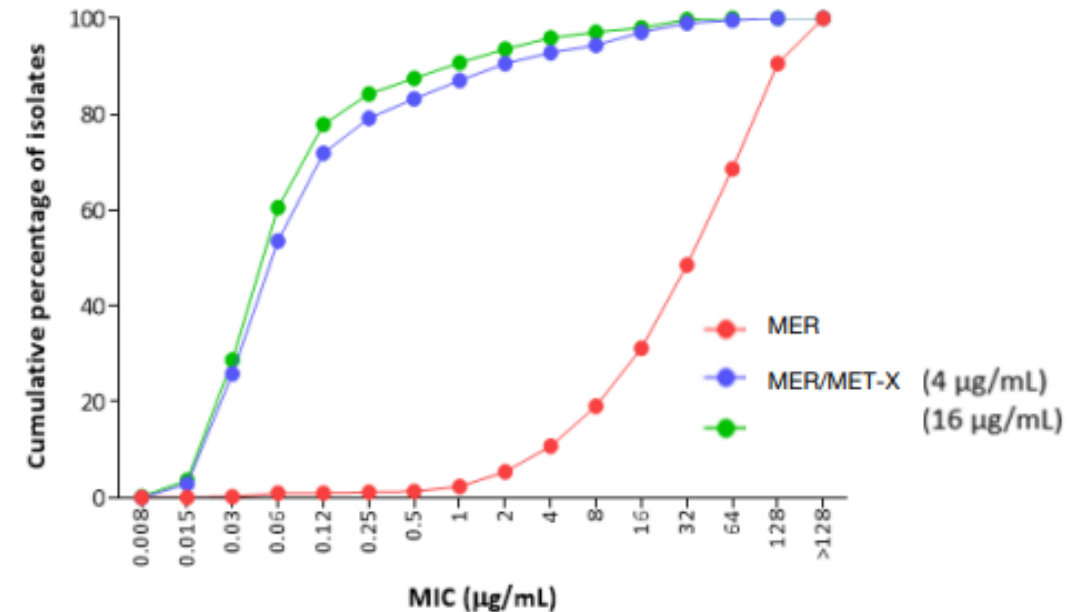


MET-X (MBLI) – Licensing agreement INFEX THERAPEUTICS

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

Financial highlights Q2

Financial summary Q2, 2022

Consolidated Income Statement, summary

(SEK m)

| | Q2 | | Q1 - Q2 | | Full year |
|--|--------------|--------------|--------------|--------------|--------------|
| | 2022 | 2021 | 2022 | 2021 | 2021 |
| Net turnover | 0.5 | 0.9 | 1.0 | 10.8 | 25.5 |
| Other operating income | 0.4 | 0.5 | 0.8 | 8.0 | 10.2 |
| Total income | 0.9 | 1.4 | 1.8 | 18.8 | 35.7 |
| Other external expenses | -16.4 | -13.1 | -42.2 | -31.9 | -73.3 |
| Personnel costs | -5.8 | -5.4 | -12.1 | -11.2 | -21.4 |
| Depreciations and write-downs | -0.6 | -0.7 | -1.2 | -1.4 | -2.6 |
| Other operating expenses | -0.1 | - | -0.4 | - | -0.6 |
| Operating profit/loss | -22.1 | -17.8 | -54.1 | -25.7 | -62.1 |
| Net financial items | -1.1 | 0.4 | -1.8 | 0.3 | -0.5 |
| Profit/loss after financial items | -23.1 | -17.4 | -55.9 | -25.4 | -62.6 |
| Tax | - | 0.0 | - | -0.1 | -0.5 |
| Net profit/loss for the period | -23.1 | -17.4 | -55.9 | -25.5 | -63.1 |

- Net turnover for Q2 2022 was SEK 0.5 million
- Operating loss for the Q2 2022 was SEK -22 million
- Cash flow from operating activities for Q2 2022 was SEK -18 million
- Cash balance end of Q2 2022 was SEK 163 million

Significant 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

Q/A

Upcoming activities

- Erik Penser Healthcare Day, August 24
- Pareto Securities' Healthcare Conference, September 7
- HC Wainwright Conference, September 12-14



Thank You!

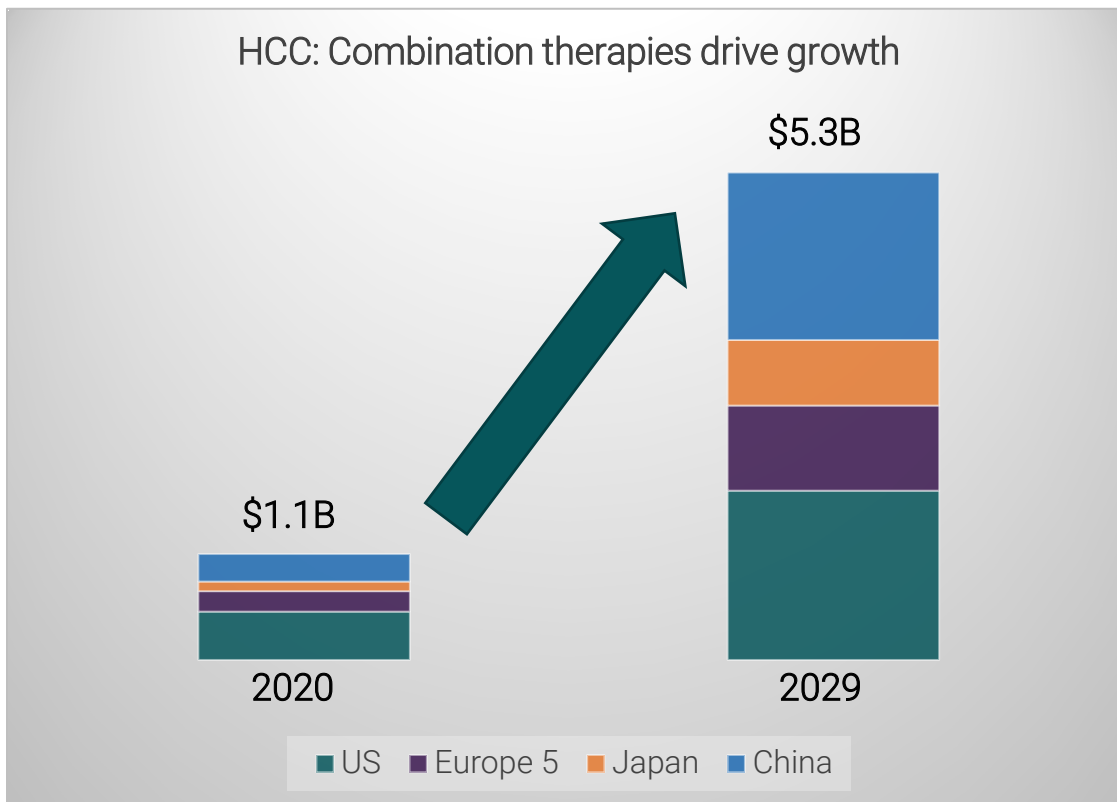
Back-Ups



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 responding to systemic treatment
- The HCC market growth is driven by combination therapies and patients treated in earlier disease stages

Source: GlobalData 2021

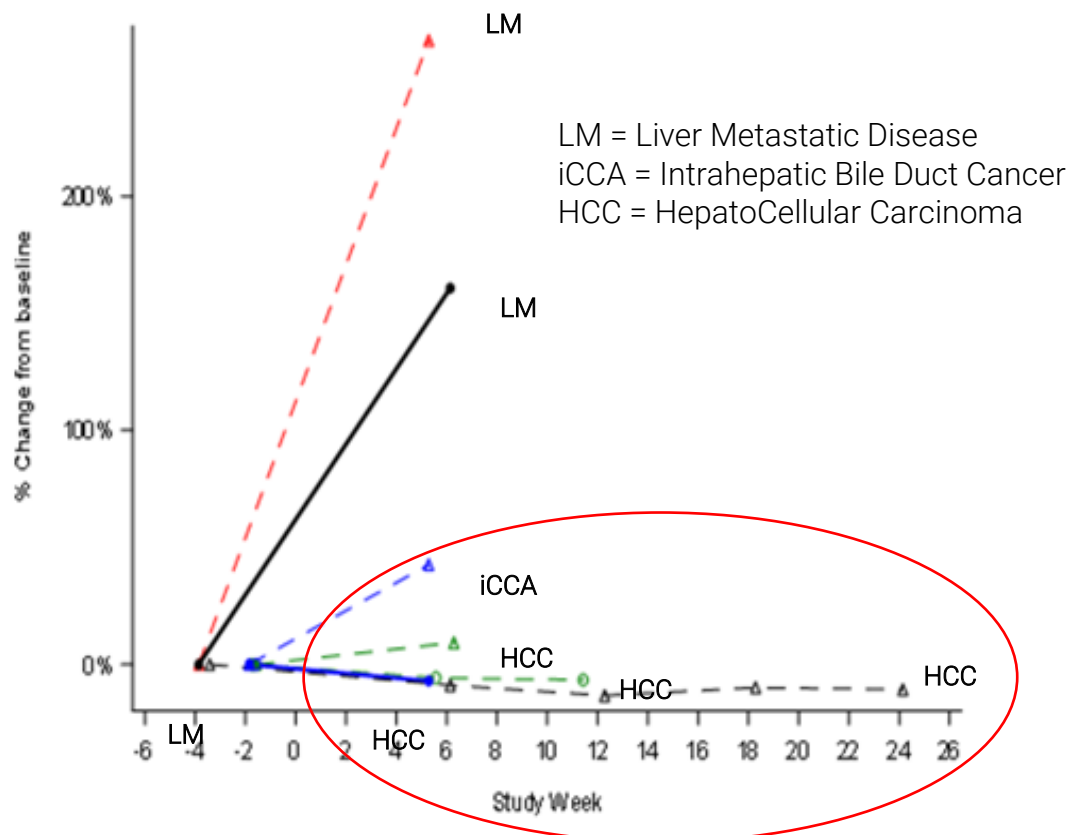
¹(<https://seer.cancer.gov/statfacts/html/livibd.htm>)

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



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