



VDs ANFÖRANDE - ÅRSSTÄMMA

5 MAJ, 2022

MEDIVIR

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Tar mig an rollen med stor tillförsikt och entusiasm



- Gift med 3 barn (19, 17 och 13)
- > 25 års erfarenhet inom läkemedelsbranschen.
- Global och lokal erfarenhet av läkemedelsutveckling & kommersialisering.
- Fokus senaste 10 åren inom onkologi, tidigare ffa inom andra specialist-läkemedelsområden som RA, CNS och anesthesi & intensivvård.
- Erfarenhet även från tf VD för Sedana Medical AB.

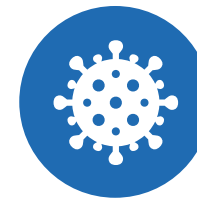
- Medivir ägande; 25.000 aktier & 240.000 optioner



**Pionjärföretag med
spännande lead produkt**



**Erfaret och
entusiastiskt team**



**Återvända "hem"
till onkologi**

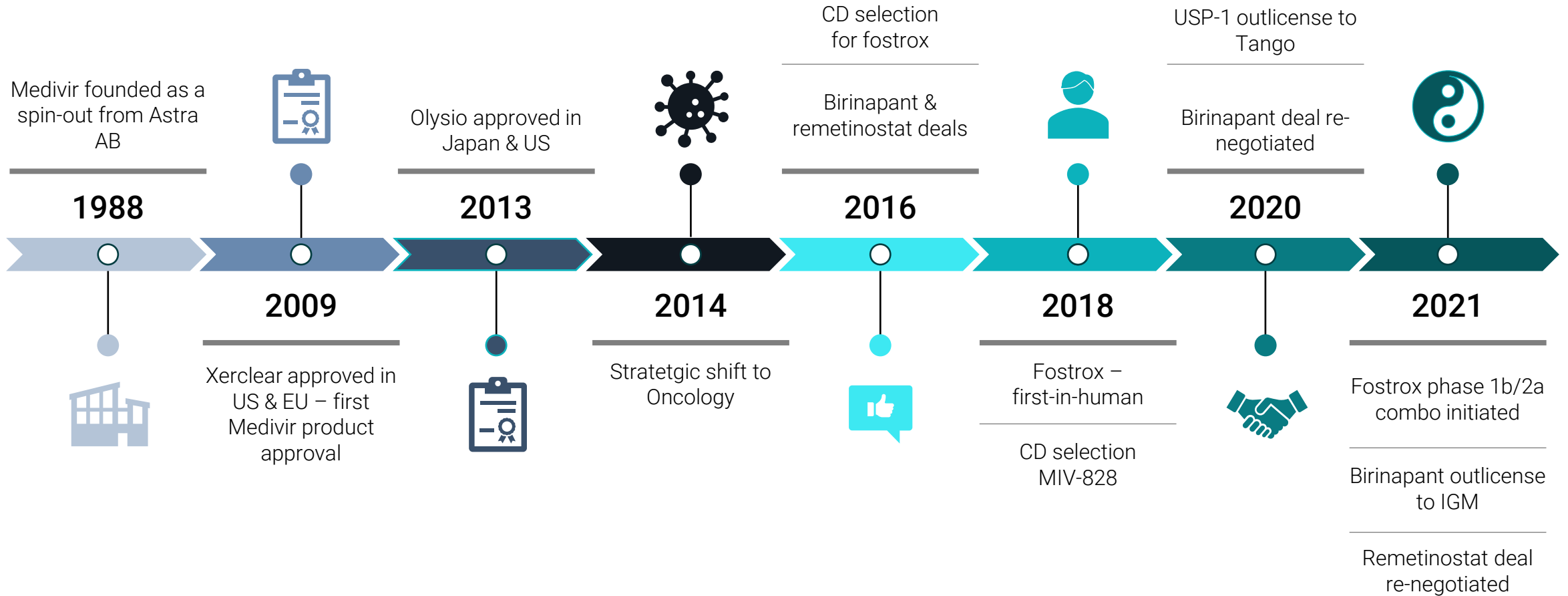


- **Spetskompetens inom läkemedelsutveckling**

- **Gedigen erfarenhet från pre-klinik till sen fas**









- **Fokus på samarbete med externa partners & leverantörer**



Oncology strategy gathering momentum on the back of historically successful R&D team & in-house compounds



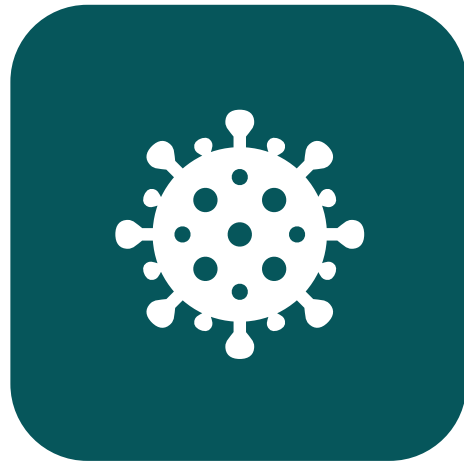
Product Portfolio & Strategy

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

 Projects developed by Medivir
 Projects developed by external partner

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

Fostrox – *for the treatment of liver cancer*

Three focus areas in pharmaceutical drug development



**Commercial potential &
unmet need**



**Differentiation /
uniqueness**



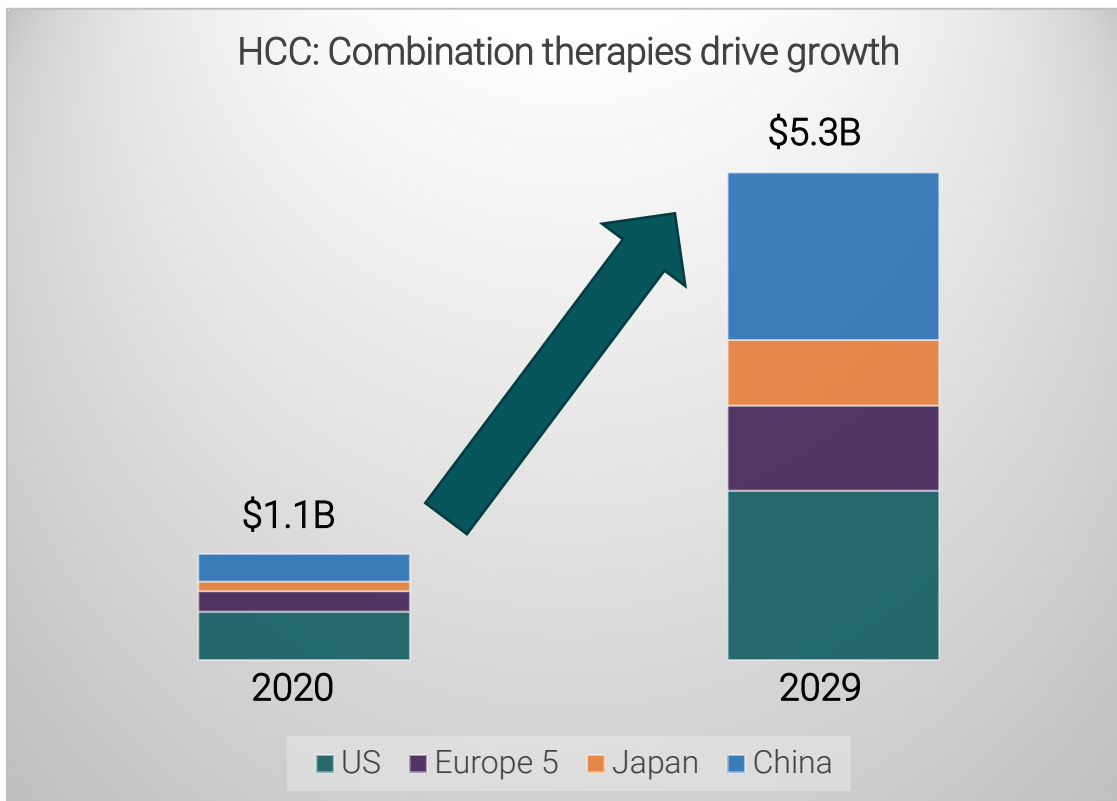
**Maximise probability
of success**



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

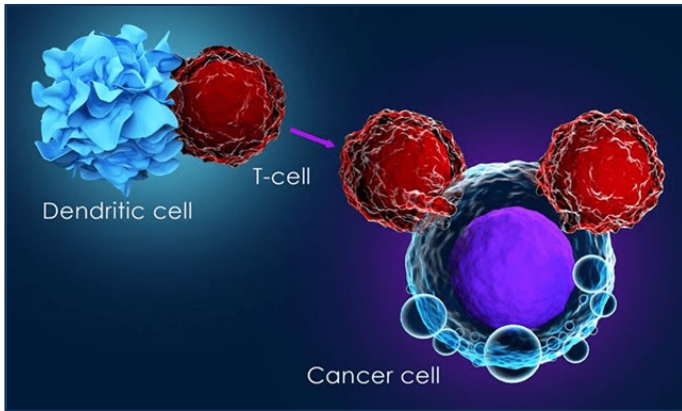
Source: GlobalData 2021

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

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

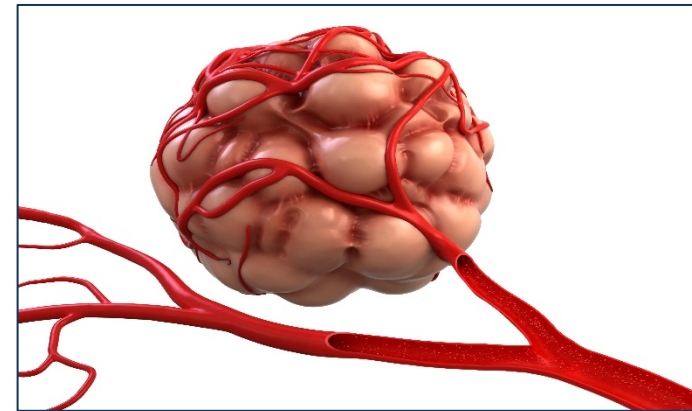
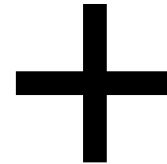


Current pipeline of new HCC therapies consists of a variation of combination trials with two key mechanisms of actions



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

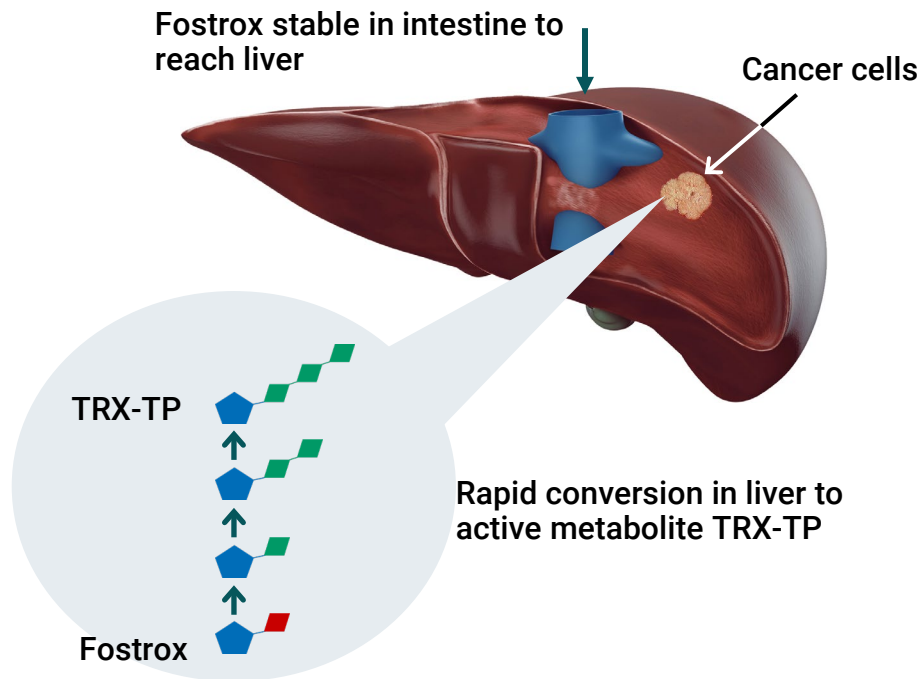
*Some of these drugs are multifunctional and have additional functions



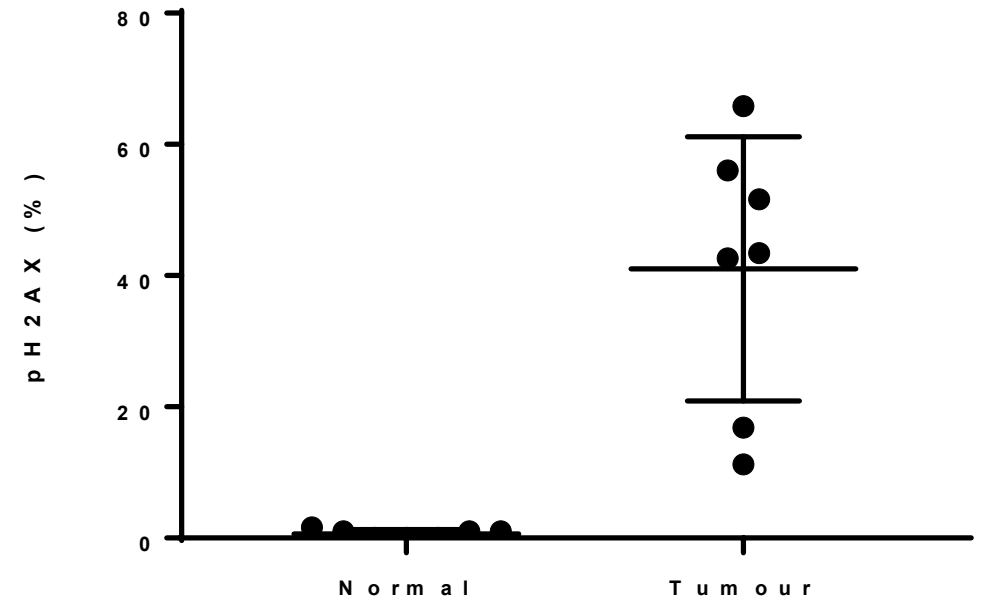
Fostroxacitabine bralpamide (fostrox) – first-in-class, orphan drug inducing DNA damage & cell death selectively in liver tumor tissue

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



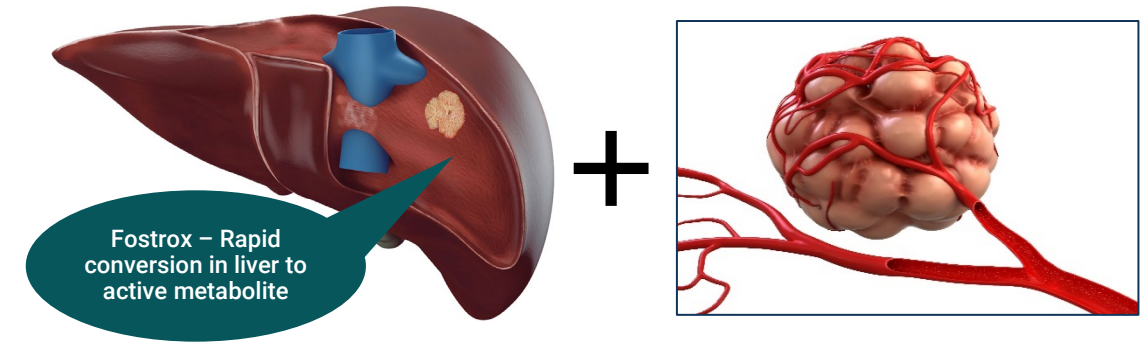
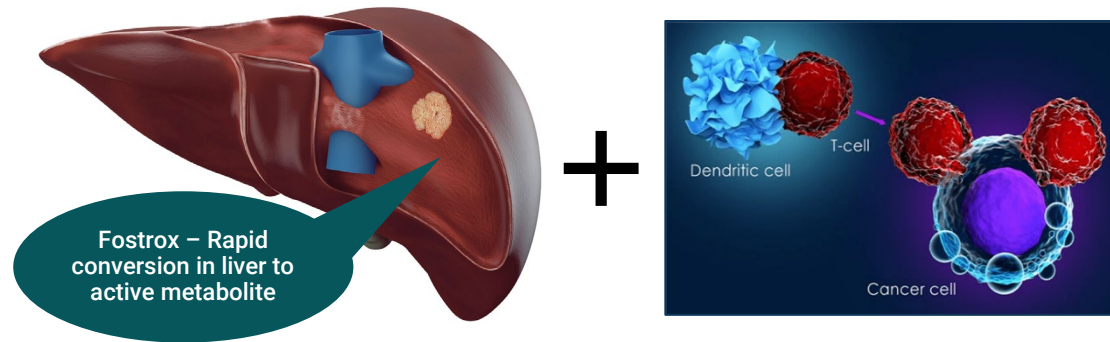
*PD marker gH2AX (% positive cells/brown stain) shows fostrox induced DNA-damage in tumor cells and not normal liver tissue



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 – 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

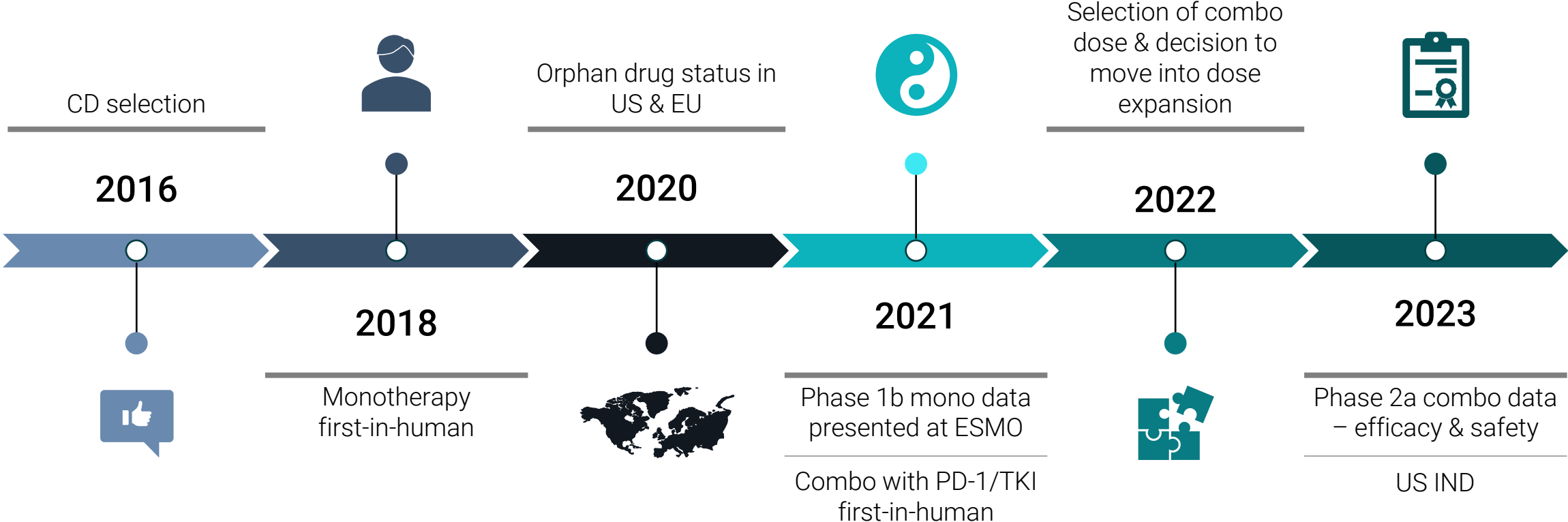


Induction of DNA-damage & cell death well established in cancer, strong potential for attractive combinations

Fostrox – *looking ahead*



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

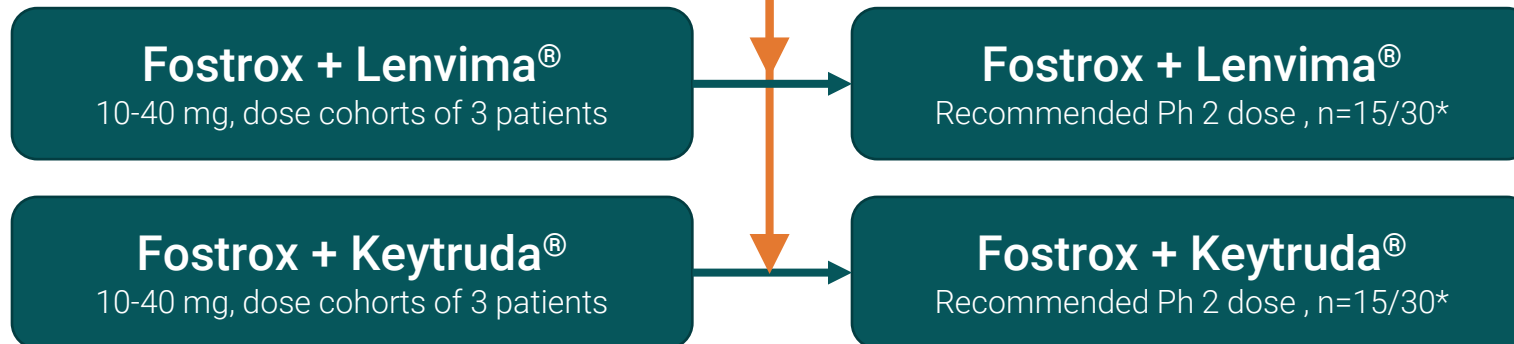
Dose escalation – phase 1b

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



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

Portfolio for partnering

Pipeline overview – in-house development & assets for partnering

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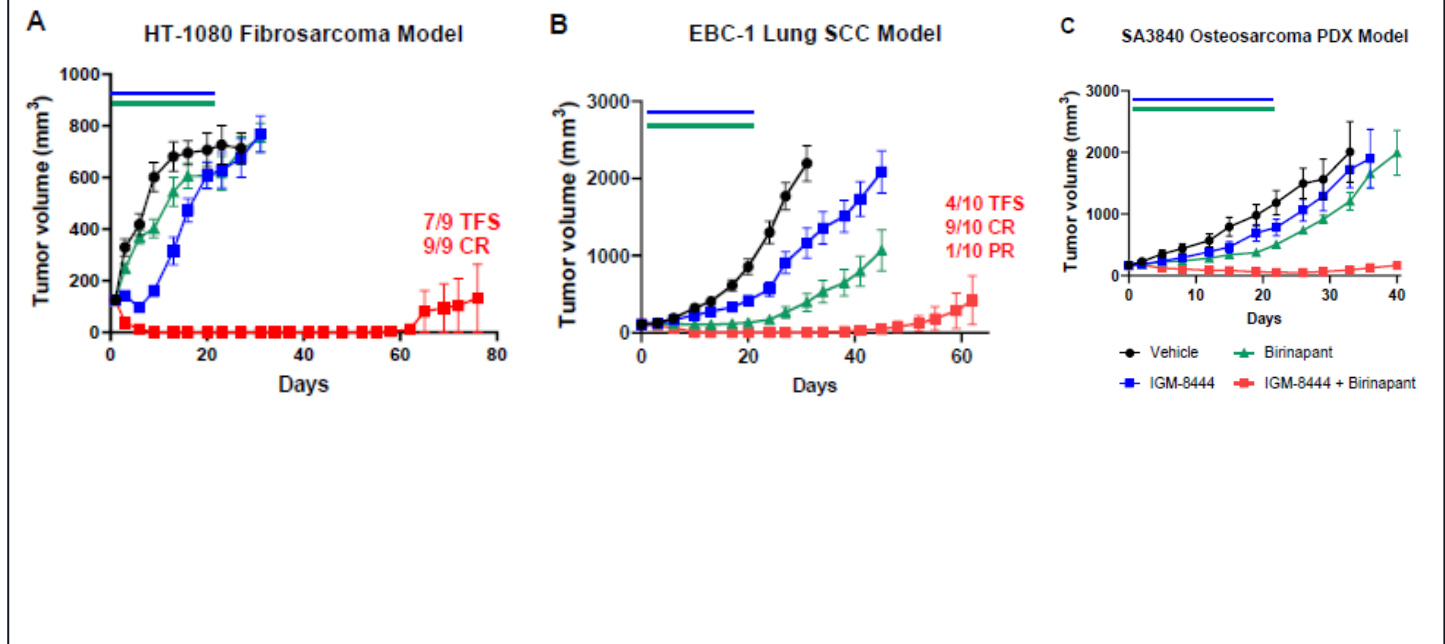
Projects developed by Medivir
 Projects developed by external partner

Birinapant – Licensing agreement with IGM Biosciences

Continued clinical momentum in 2022

- Birinapant + IGM-8444, a DR5 agonist, now in phase 1 in patients with solid tumors¹
- The first dose escalation cohort cleared with no DLTs to date, currently enrolling second 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

Strong synergistic cytotoxicity across multiple solid tumor indications²



¹Open-label, Multicenter, phase I Study with IGM-8444 in combination with Birinapant (IGM-9427) in patients with solid tumors will be in two stages: a dose-escalation stage and an expansion stage (NCT04553692)

²Wang, Beatrice T. et al, Poster no. 1068, 2022 AACR meeting, New Orleans, April 8-13

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)

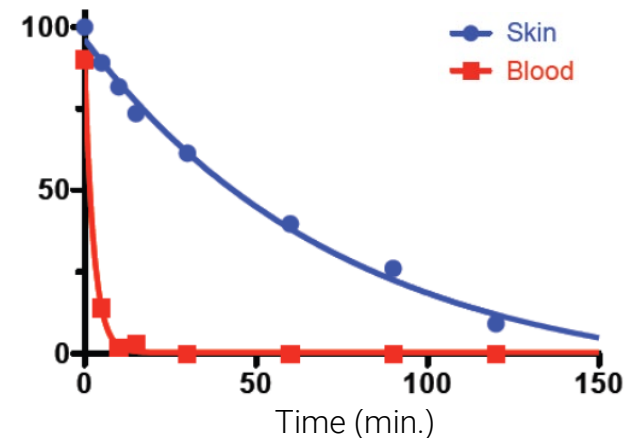
- Open label phase II study (25 patients, Stanford ISS) results showed 70% ORR

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

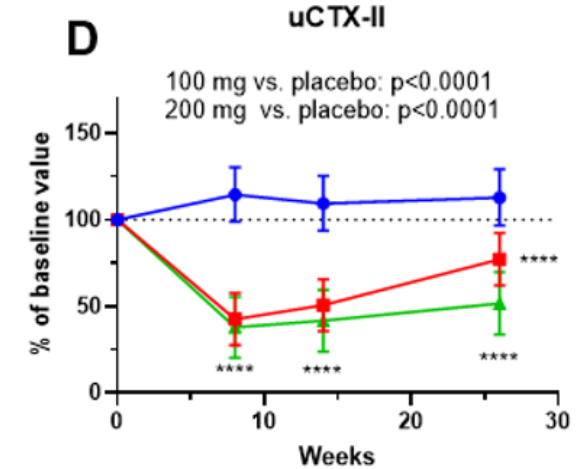
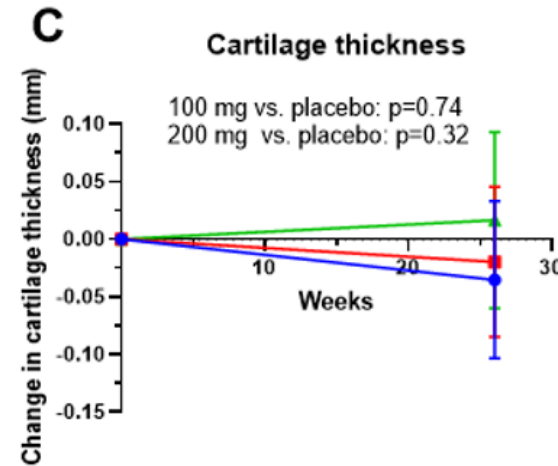
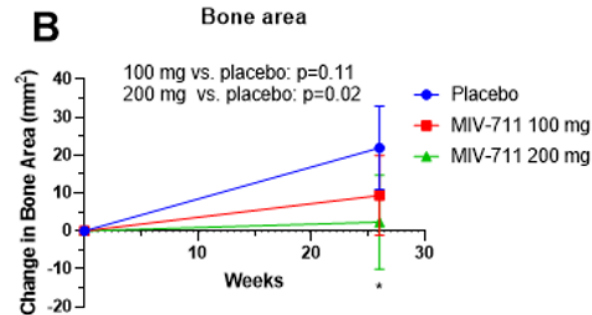
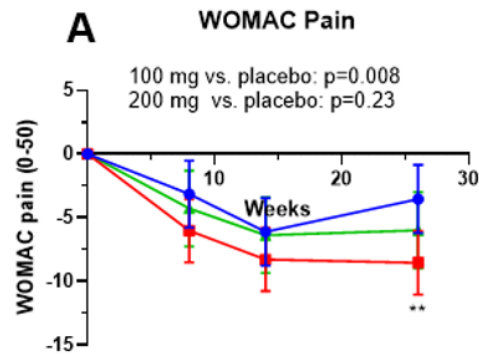
MIV-711 – In a subgroup with predominantly unilateral knee pain, significant reduction in OA pain was found, with concurrent beneficial structural effects

Significant reduction in OA pain for 100 mg, numerical trend for 200 mg

Significant difference in bone area for 200 mg, numerical trend for 100 mg

No significant difference in cartilage thickness, only numerical trend

Significant reduction in cartilage degradation biomarker in both groups



The data strengthens the hypothesis for positive effects on both pain & joint structure and provides guidance for future clinical trials²

¹Bihlet et al, *Clinical and Experimental Rheumatology*, published online 28 February 2022

²Yazici et al *Osteoarthritis and Cartilage* 2021

Looking ahead

Financial summary Q4, 2021

Consolidated Income Statement, summary

(SEK m)

	Q4		Q1 - Q4	
	2021	2020	2021	2020
Net turnover	13.9	1.5	25.5	13.9
Other operating income	1.3	9.2	10.2	27.3
Total income	15.3	10.7	35.7	41.3
Other external expenses	-32.0	-15.1	-73.3	-52.9
Personnel costs	-6.1	-6.2	-21.4	-24.9
Depreciations and write-downs	-0.6	-0.7	-2.6	-4.4
Other operating expenses	-0.6	-	-0.6	-1.9
Operating profit/loss	-24.1	-11.3	-62.1	-42.9
Net financial items	-0.3	0.1	-0.5	0.3
Profit/loss after financial items	-24.3	-11.2	-62.6	-42.6
Tax	0.0	-	-0.5	-
Net profit/loss for the period	-24.3	-11.2	-63.1	-42.6

Cash balance end of Q4 2021 was SEK 221 million compared to SEK 70 million previous year, according to plan

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

Recent progress across product portfolio

Potential future key events

Accelerating fostrox

- Phase 1b monotherapy data presented at ESMO & additional proof-of-concept data at EASL
- Decision to continue development as combination therapy & phase 1b/2a combo study initiated with Keytruda® or Lenvima®
- Initiation of clinical trial centers in Spain and South Korea with ~45% of planned centers in South Korea

- 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 first IGM-8444 + birinapant combination dose escalation cohort cleared with no DLTs.
- Re-negotiated deal for remetinostat improving Business Development potential
- Subgroup analysis of phase II study with MIV-711 showing significantly reduced osteoarthritis-related pain.

- 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



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