



# ABGSC LIFE SCIENCE SUMMIT VIRTUAL SEMINAR

MAY 25, 2021

**MEDIVIR**  
SCIENCE WORKING WONDERS

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# Executive summary

## Proprietary clinical asset MIV-818

- MIV-818 – A liver directed nucleotide prodrug
- Phase 1b – recommended dose for monotherapy determined
- Phase 1b/2a – upcoming combination study

## Clinical collaboration and recent news

- IGM Biosciences - exclusive licensing agreement for birinapant
- Oversubscribed rights issue and directed issues of SEK 223M, specialist investor HealthInvest new major shareholder in addition to support from major shareholders Linc and Nordea

## Multiple clinical programs for partnering/out-licensing

- Remetinostat and MIV-711

Founded: 1988

Listed: Nasdaq OMX

Location: Stockholm

Cash position: SEK 269M<sup>1)</sup>

Market Cap: SEK 439M<sup>2)</sup>

FTE: 9

1) Q1 report

2) 2021-05-21, (c. EUR 43M)




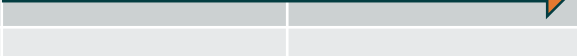
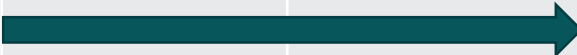
## Focused clinical program

Nucleotide prodrug	Indication	Preclinical	Phase I	Phase II	Exclusivity
MIV-818	Liver cancer				IP : 2035

## Partnered assets in clinical development

Compound	Mechanism	Indication	Phase I	Phase II	Partner	Exclusivity
Birinapant	SMAC mimetic	HNSCC <sup>2)</sup>				IP : 2034

## Multiple clinical programs for partnering/out-licensing

Compound	Mechanism	Indication	Phase I	Phase II	Phase III	Exclusivity
Remetinostat	Topical HDAC	MF-CTCL <sup>1)</sup> BCC, SCC				IP : 2034
						
MIV-711	Cathepsin K inhibitor	OA <sup>3)</sup>				IP : 2034

1) Indications: basal cell carcinoma, squamous cell carcinoma, mycosis fungoides cutaneous T-cell lymphoma (phase III ready)

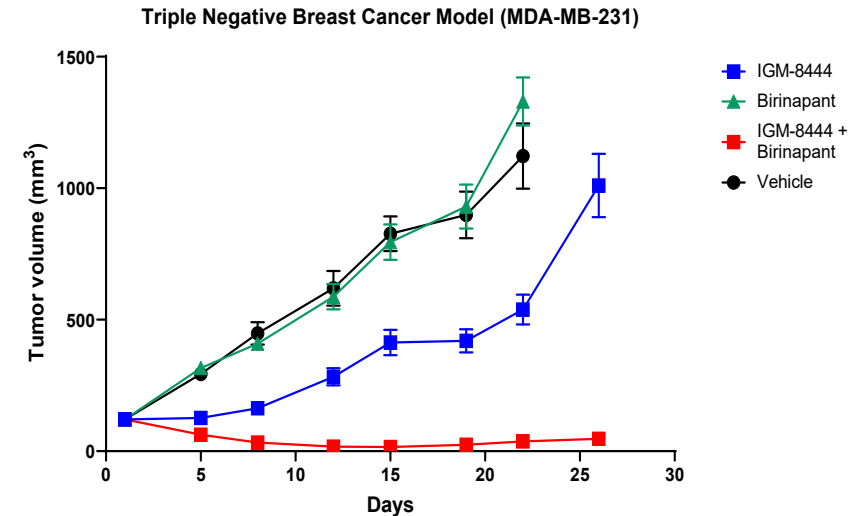
2) Head and neck squamous cell carcinoma

3) Osteoarthritis

# Birinapant outlicensing

# Licensing agreement with IGM Biosciences

- IGM is a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies
- Birinapant is initially intended to be combined with IGM-8444, an IgM antibody targeting Death Receptor 5 (DR5) being developed by IGM, and birinapant has been shown to enhance anti-tumor activity preclinically. Clinical testing of birinapant in combination with IGM-8444 expected to begin this year<sup>1</sup>
- Should birinapant be successfully developed and approved, Medivir is entitled to receive 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



IGM-8444 (5 mg/kg Q2D x 11);  
Birinapant (2.5 mg/kg Q3D x 7)

<sup>1</sup>IGM Biosciences Q1 Report

**MIV-818** — *for the treatment of liver cancer*



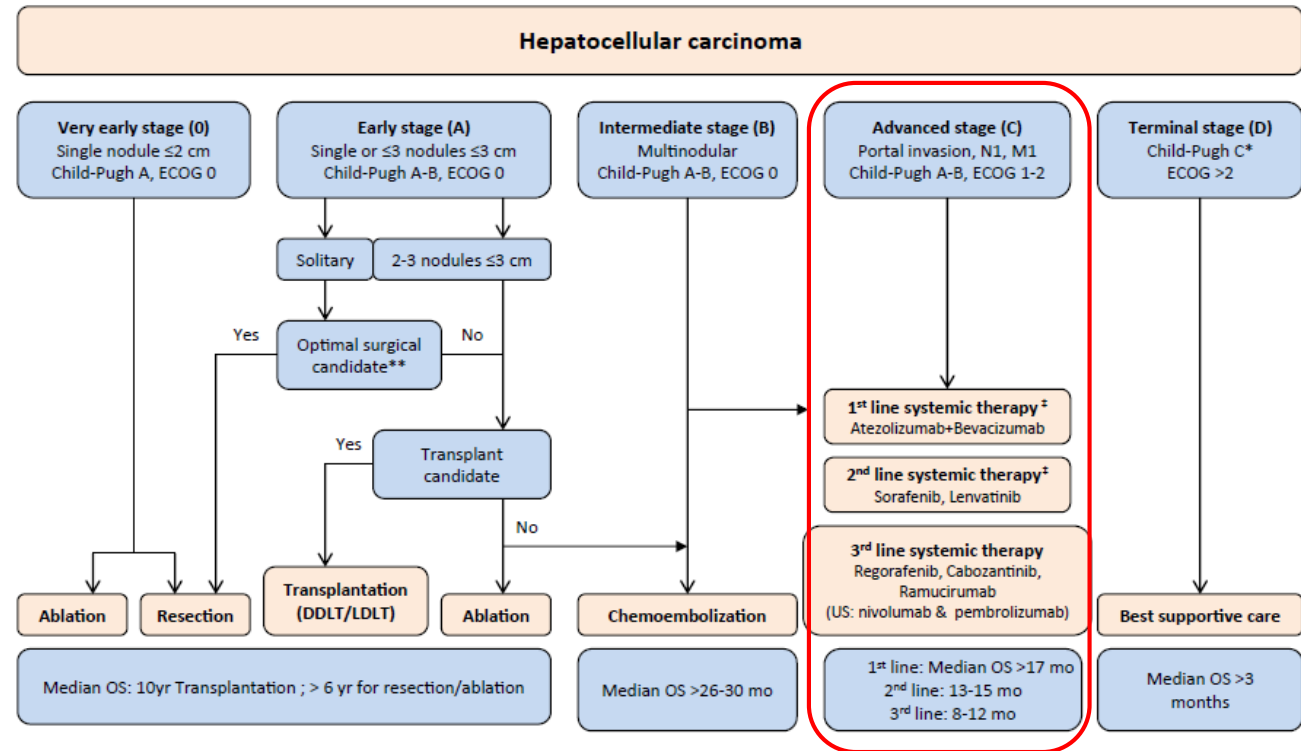
# HCC Epidemiology and current treatments

Primary liver cancers: 850,000 cases worldwide annually,

- 90% are hepatocellular carcinoma (HCC)
- Highest incidence in East Asia and Sub-Saharan Africa
- 600,000 deaths worldwide
- 3rd leading cause of cancer-related death
- 5-year survival 18% in US (SEER data)

## Standard treatment

- Tyrosine kinase inhibitors (TKI) main treatment for many years : Sorafenib, lenvatinib, cabozantinib
- **Checkpoint inhibitors** recent additions: pembrolizumab and nivolumab have accelerated approval in US
- Recent approval for **atezolizumab+bevacizumab** for patients with unresectable or metastatic HCC in 1L has changed the treatment landscape



Llovet et al Hepatology vol 73, 2021

# MIV-818: A liver-directed nucleotide prodrug

Liver targeting to deliver high levels of the active metabolite to the liver

MIV-818 has been designed to minimize systemic exposure and limit the toxicity of troxacitabine by primarily targeting liver cells

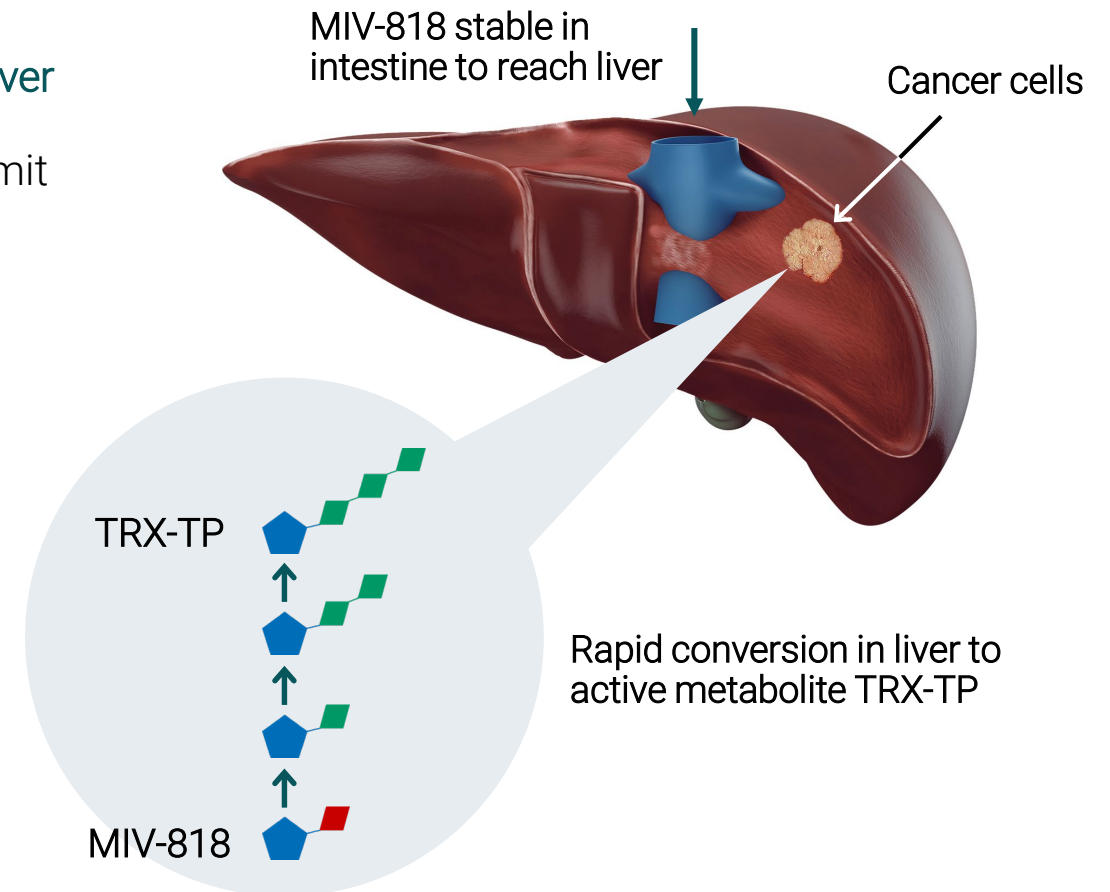
This prodrug technology has been clinically proven to deliver high liver levels of nucleotides in patients with compensated cirrhosis<sup>1</sup>

Unique mechanism of action of MIV-818 makes it attractive to be combined with many targeted and non-targeted drugs

MIV-818 is an orally administered nucleotide prodrug of the active metabolite troxacitabine triphosphate (TRX-TP)

When incorporated into DNA, TRX-TP causes double strand DNA breaks and cell death

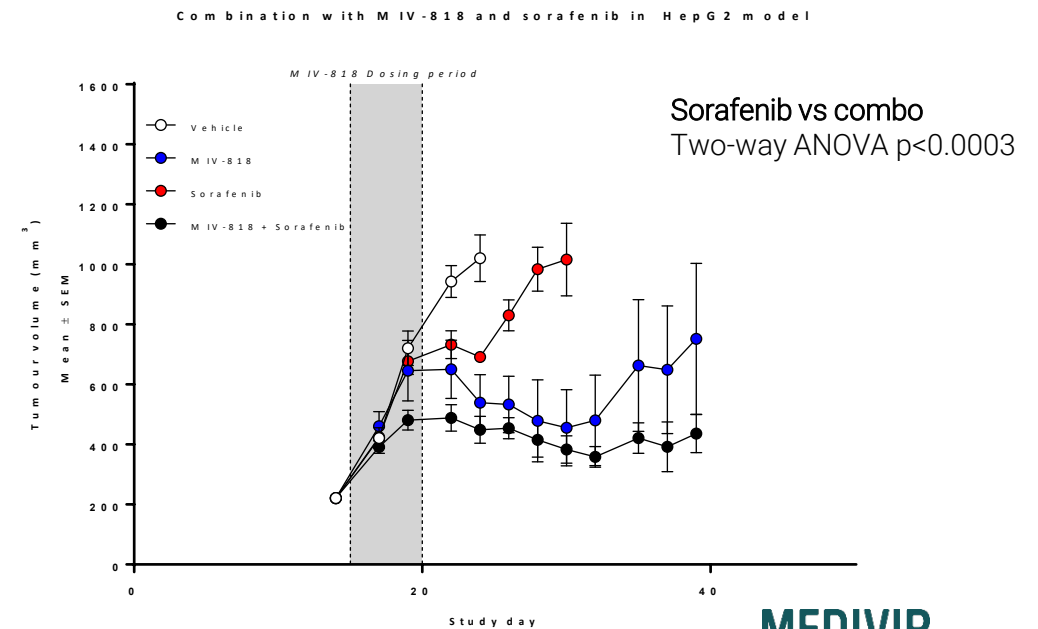
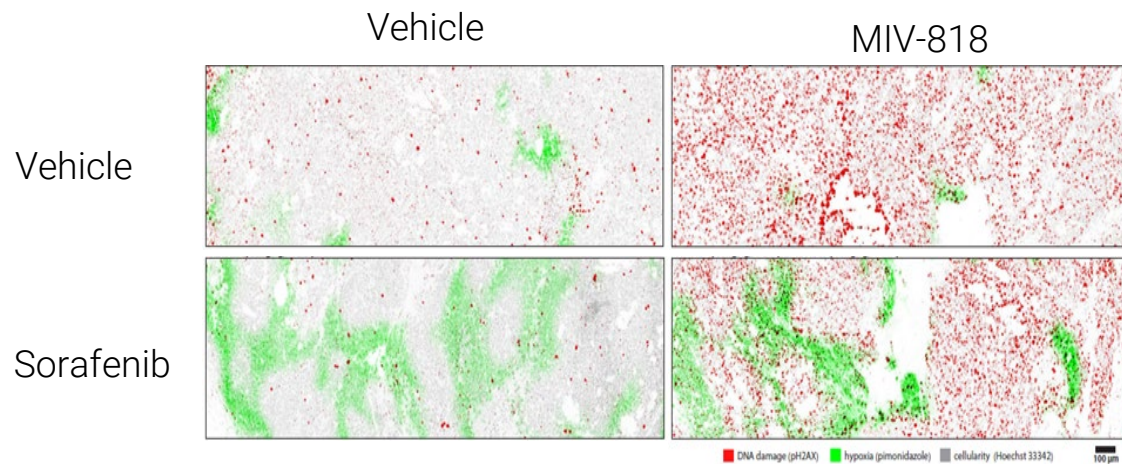
<sup>1</sup>Babuis et al., Antimicrob Agents Chemother. 2018, doi: 10.1128/AAC.02587-17



# Scientific rationale for MIV-818 + TKI combination

- Tyrosine kinase inhibitors (TKIs), e.g. sorafenib, lenvatinib, cabozantinib, regorafenib, inhibit angiogenesis and induce tumour hypoxia
- Expression of Phosphoglycerate Kinase 1 (PGK1), the enzyme that phosphorylates TRX-DP to the active metabolite TRX-TP, is induced by hypoxia. In vitro studies have shown higher active metabolite (TRX-TP) in hypoxic cells

DNA damage (pH2AX) and hypoxia in mouse HCC tumor model HepG2



# Scientific rationale for MIV-818 + anti-PD1 combinations

- HCC typically has low prevalence of tissue tumor mutational burden high (tTMB-H) and microsatellite instability-high (MSI-H), predictors of aPD1 response<sup>1</sup>
- Through its mechanism of action MIV-818 induces DNA damage and tumour cell death, potentially leading to increased tumour antigen presentation and/or increased immunogenicity
- Preclinical data has demonstrated an impact on the tumour micro-environment (cytokine profile, increased IL-2 expression, increased PBMC-mediated cell killing), and tumour growth inhibition in an *in vivo* model, which are consistent with an enhanced efficacy of a MIV-818 combination with aPD1
- We plan to present preclinical data on MIV-818 and aPD1 at a coming scientific conference

<sup>1</sup>Alexandrov et al Nature. 2013,(500):415-21, Cortes-Ciriano et al Nat Commun. 2017 (8):15180, Hause et al Nat Med. 2016 (11):1342-1350

# Next studies: Combination with two parallel streams in HCC

Phase 1a

Phase 1b Mono

Phase 1b Combo

Phase 2a Combo

Single patient  
Inpatient dose  
escalation

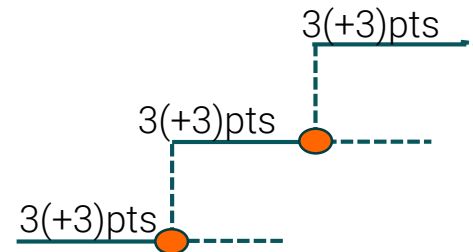
3+3 dose escalation

MIV-818 + Lenvatinib  
dose escalation in HCC

MIV-818 + Pembrolizumab  
dose escalation in HCC

MIV-818 + Lenvatinib  
dose expansion in HCC

MIV-818 + Pembrolizumab  
dose expansion in HCC

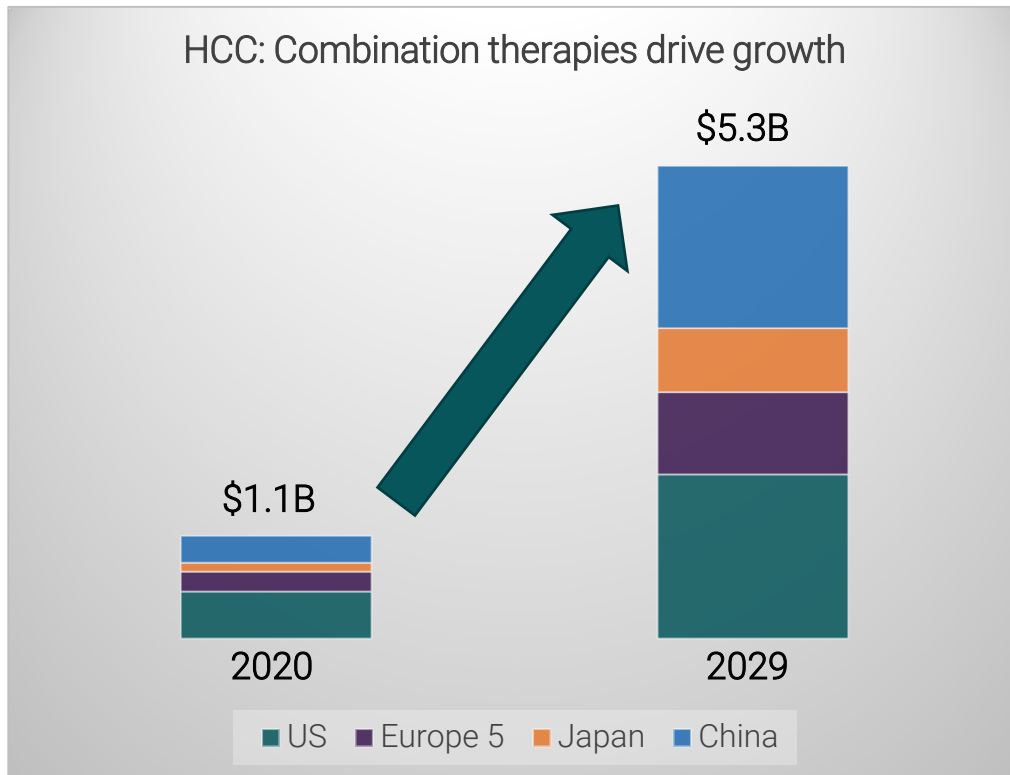


2021

2022

2023

# Rapid market growth for Hepatocellular Carcinoma (HCC)



- HCC is associated with Non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH), and NAFLD and NASH is increasing in the US and globally.
- Liver cancer incidence and mortality are increasing in the US, and 5-year survival for those with advanced disease is less than 3%
- New combination therapies (especially immuno-oncology combinations) are expected to drive the market growth in HCC

# MIV-818 summary

We continue to advance the MIV-818 clinical development programme

- Last patient recruited to phase 1b monotherapy, and has completed the safety follow-up period
- Expect to present phase 1b monotherapy data at scientific conference second half of 2021
- Combination study expected to be two parallel streams in combination with lenvatinib or pembrolizumab
- On track to start enrollment of patients for combination study second half of 2021

# Other assets





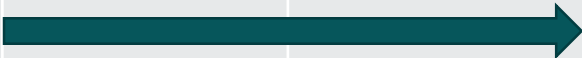
# Two clinical programs for partnering/out-licensing

## Remetinostat

- MF-CTCL Phase II (60 patients) data showed 40% ORR, and reduced pruritus in 80% of patients
- BCC Phase II data (30 patients, Stanford ISS) showed 70% ORR
- SCC Phase II data (4 patients, Stanford ISS) showed 100% ORR

## MIV-711

- Medivir has conducted a phase II study showing positive effects in both bone and cartilage in joints in osteoarthritis patients after only six months of treatment with MIV-711

Compound	Mechanism	Indication	Phase I	Phase II	Phase III	Exclusivity
Remetinostat	Topical HDAC	MF-CTCL <sup>1)</sup> BCC, SCC				IP : 2034
MIV-711	Cathepsin K inhibitor	OA <sup>2)</sup>				IP : 2034

1) Indications: basal cell carcinoma, squamous cell carcinoma, mycosis fungoides cutaneous T-cell lymphoma (phase III ready)

2) Osteoarthritis

Q/A