



# REDEYE INVESTMENT CASE GROWTH DAY

JUNE 2, 2021

MEDIVIR

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# Executive summary

## Proprietary clinical asset MIV-818

- MIV-818 – A liver directed nucleotide prodrug
- MIV-818 has received Orphan drug designation by EMA and FDA for the treatment of hepatocellular carcinoma (HCC)
- Phase 1b – recommended dose for monotherapy determined
- Phase 1b/2a – upcoming combination study

## Finance

- Q1 - oversubscribed rights issue and directed issues in total SEK 223M

## Other clinical programs

- IGM Biosciences - exclusive licensing agreement for birinapant
- Remetinostat and MIV-711 for partnering/out-licensing

Founded: 1988

Listed: Nasdaq OMX

Location: Stockholm

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

Market Cap: SEK 468M<sup>2)</sup>

FTE: 9

1) Q1 report

2) 2021-05-31, (c. EUR 46M)

# Clinical programs

## Internal clinical development

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

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

2) Head and neck squamous cell carcinoma




# 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

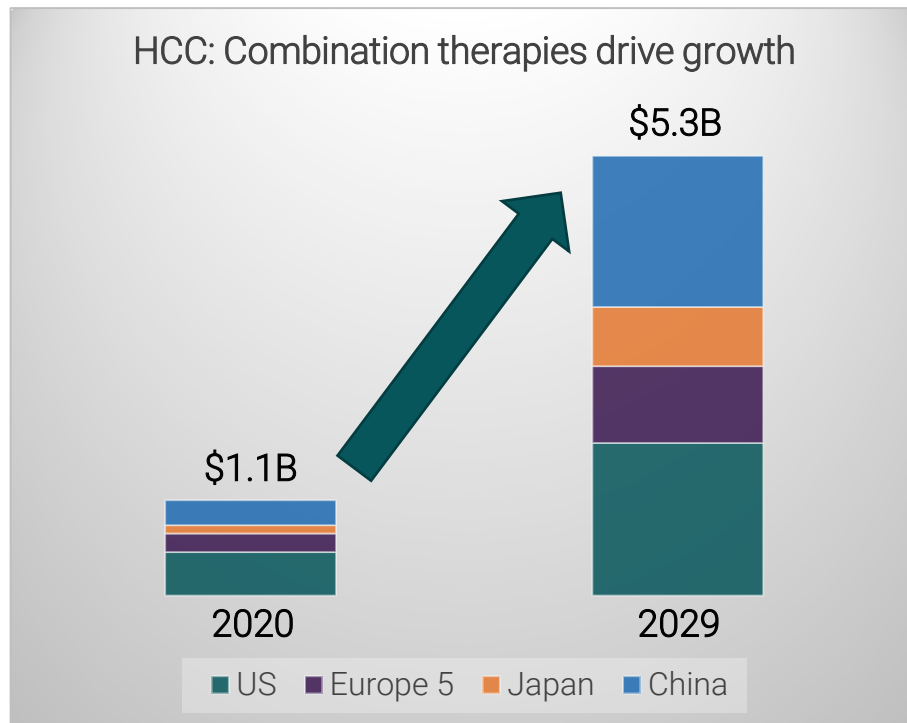
Compound	Mechanism	Indication	Phase I	Phase II	Phase III	Exclusivity
Remetinostat	Topical HDAC	MF-CTCL <sup>1)</sup> BCC, SCC				IP : 2034
MIV-711	Cathepsin K inhibitor	OA <sup>2)</sup>				IP : 2034

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

2) Osteoarthritis

# MIV-818: Focus on Hepatocellular Carcinoma (HCC)

## Rapid market growth



- 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

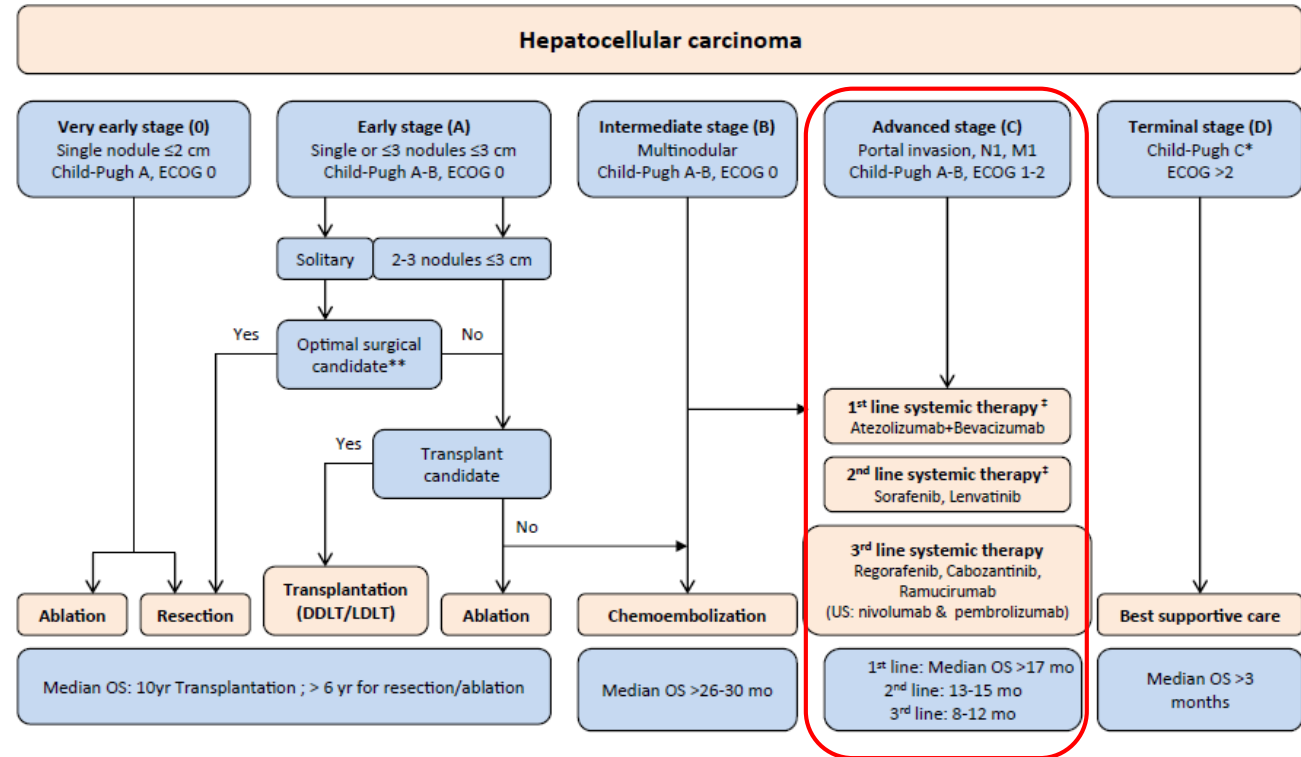
# HCC Epidemiology and current treatments

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

## 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 advanced HCC in 1L has changed the treatment landscape
- Additional combinations of checkpoint inhibitors and TKIs in late phase clinical development, e.g. **pembrolizumab+lenvatinib**



*Llovet et al Hepatology vol 73, 2021*



# MIV-818: An orally delivered liver-directed nucleotide prodrug

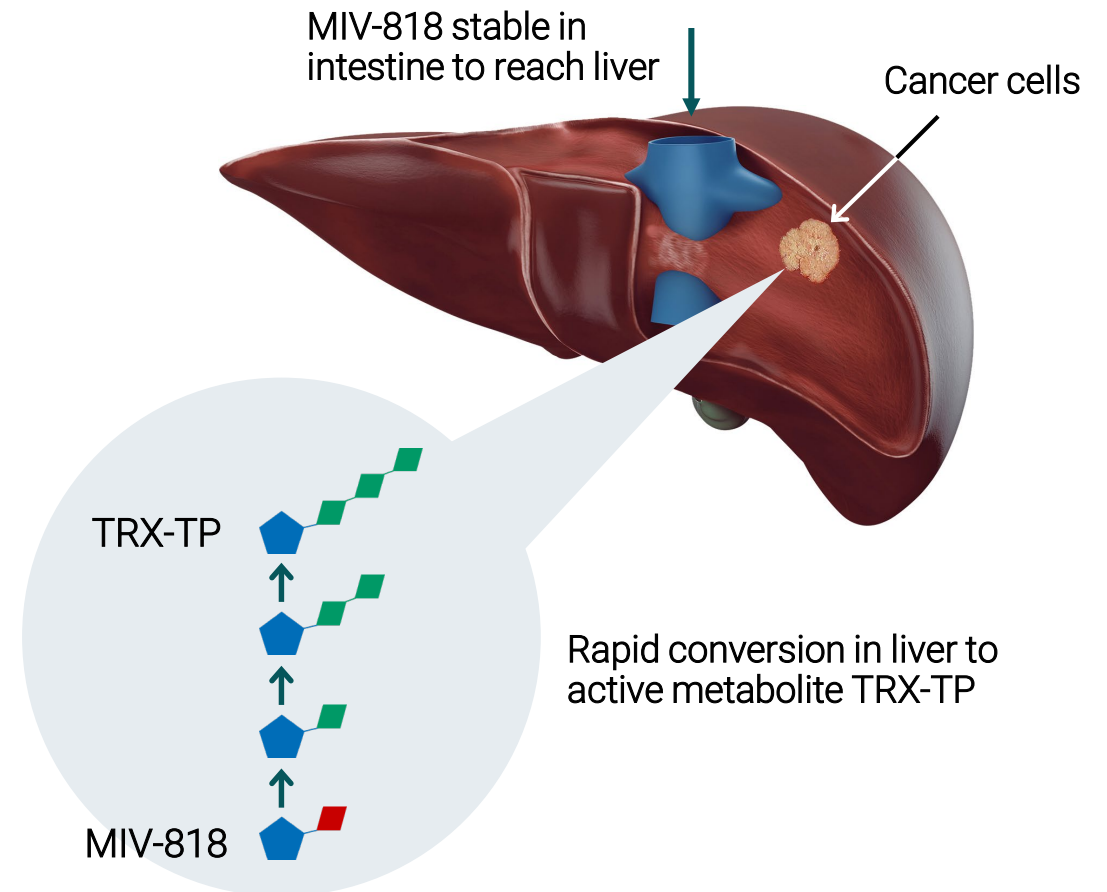
Liver targeting to deliver high levels of the active metabolite to the liver

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

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

**Tyrosine kinase inhibitors (TKI):** Inhibit angiogenesis and induce tumor hypoxia and the enzyme (PGK1) that phosphorylates TRX-DP to the active metabolite TRX-TP, is induced by hypoxia. Potentially resulting in higher TRX-TP levels.

**Checkpoint inhibitors (aPD1/aPD-L1):** When incorporated into DNA, troxacitabine triphosphate (TRX-TP) induces DNA damage and tumor cell death, potentially leading to increased tumor antigen presentation and/or increased immunogenicity





# 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

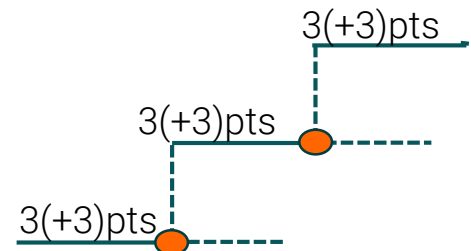
3+3 dose escalation

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

# 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, and we expect to present phase 1b monotherapy data at scientific conference second half of 2021
- Combination study will be two parallel streams in combination with the two main classes of standard treatment, lenvatinib (TKI) or pembrolizumab (aPD1) in HCC patients who have progressed on, or are intolerant of, first line standard therapy
- On track to start enrollment of patients for combination study second half of 2021