



**MEDIVIR Q1 CALL**  
**5 MAY 2020**

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# Financial summary

## Summary of the Group's figures

(SEK m)

	Q1		Full Year
	2020	2019	2019
Net turnover	7.3	2.0	8.7
Profit/loss before tax	-23.4	-55.9	-123.3
Cash and cash equivalents at period end	116.6	228.6	134.6

- Net turnover for Q1 2020 was SEK 7 million
- Loss of the quarter Q1 2020 was SEK -23 million
- 13 FTE end of Q1 2020
- Cash position as of March 31, 2020: SEK 117 million
- Market cap as of May 4, 2020: approximately SEK 382 million

# An oncology-focused development company set for growth

## Proprietary nucleotide-prodrug platform

- Multiple opportunities for breakthrough oncology products
- Spearheaded by MIV-818 and MIV-828

## Advanced clinical programs for partnering/out-licensing

- Remetinostat, Birinapant and MIV-711

## The company

- Experienced leadership team and effective organization
- Focus on clinical development and business development

# The nucleotide-prodrug concept: A versatile source of new oncology products

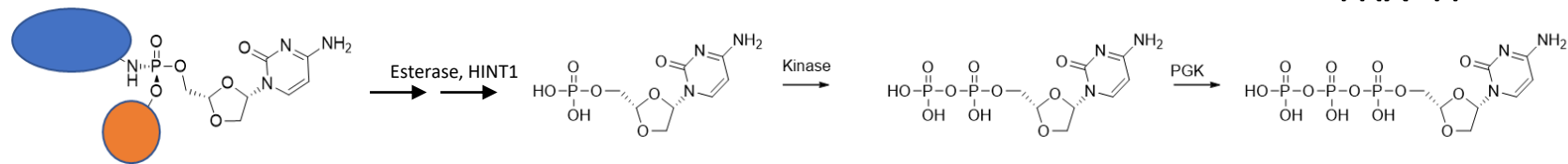
- By combination of “prodrug tail” and a nucleotide, a tunable uptake in target cell/tissue can be achieved.
- Once in the cancer cell, the prodrug is cleaved and an active nucleotide metabolite is formed.
- This concept has the potential to provide oncology products with an improved efficacy/tolerability profile.

Nucleotide prodrug	Indication	Research	Preclinical	Phase I	Exclusivity
MIV-818	HCC				IP : 2035
MIV-828	AML				IP : Est 2039
"MIV-838"	Blood cancer				IP : Est 2040

# MIV-818: A liver-targeted nucleotide

- MIV-818 is an oral prodrug
- Once absorbed from the GI-tract, MIV-818 is transported to the liver
- The prodrug is taken up by liver cancer cells and converted into troxacitabine triphosphate (TRX-TP)
- TRX-TP is incorporated into DNA and causes double-strand DNA breaks and cell death

MIV-818 (prodrug)



# MIV-818: A nucleotide-prodrug for primary liver cancer

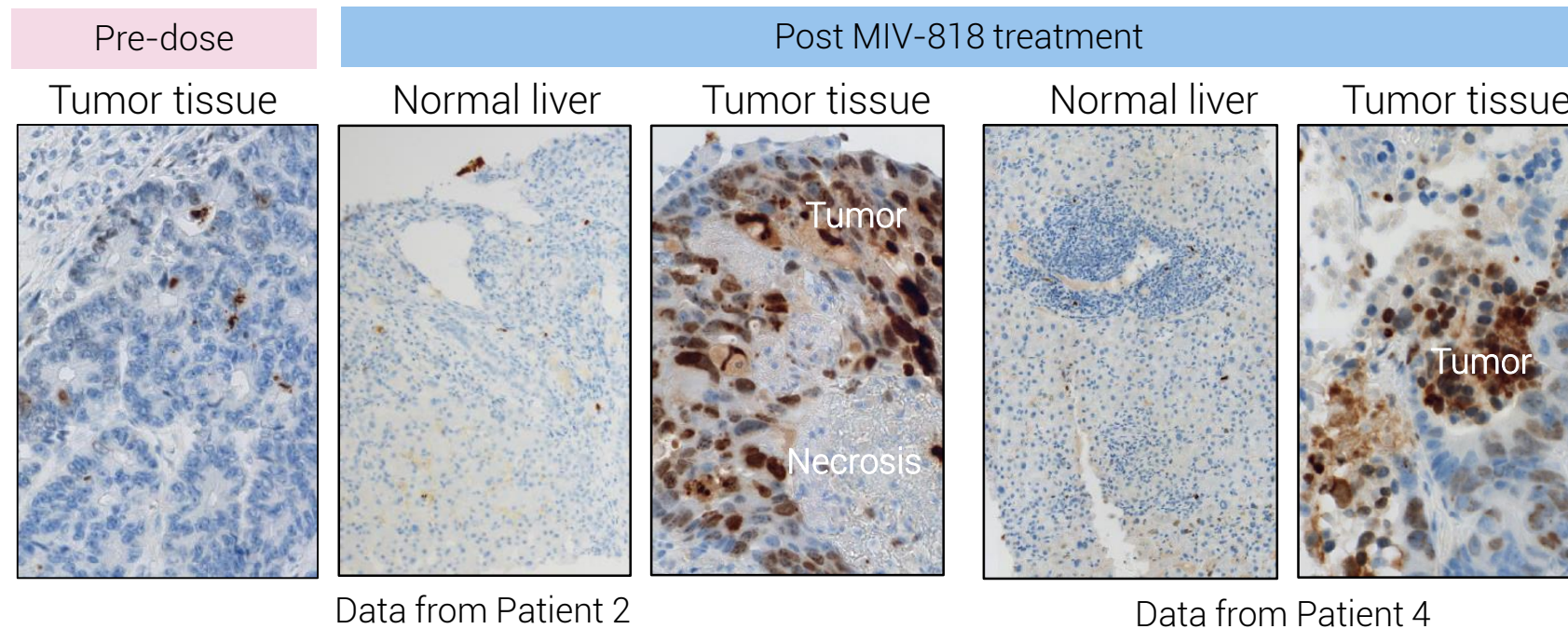
Current treatment options for hepatocellular carcinoma (HCC) provide little benefit. Because of the liver targeting and the mechanism of action, MIV-818 may provide an outstanding efficacy and safety profile. May be ideal as stand alone treatment and/or add-on to standard of care.

HCC is the most common form of primary liver cancer:

- Third leading cause of cancer-related deaths globally
- Orphan disease in western markets, high incidence in Asian markets
- Five year survival: 11%
- Genetically heterogeneous; no good molecularly targeted therapy available

# MIV-818: Selective effect signal in liver cancer in phase Ia

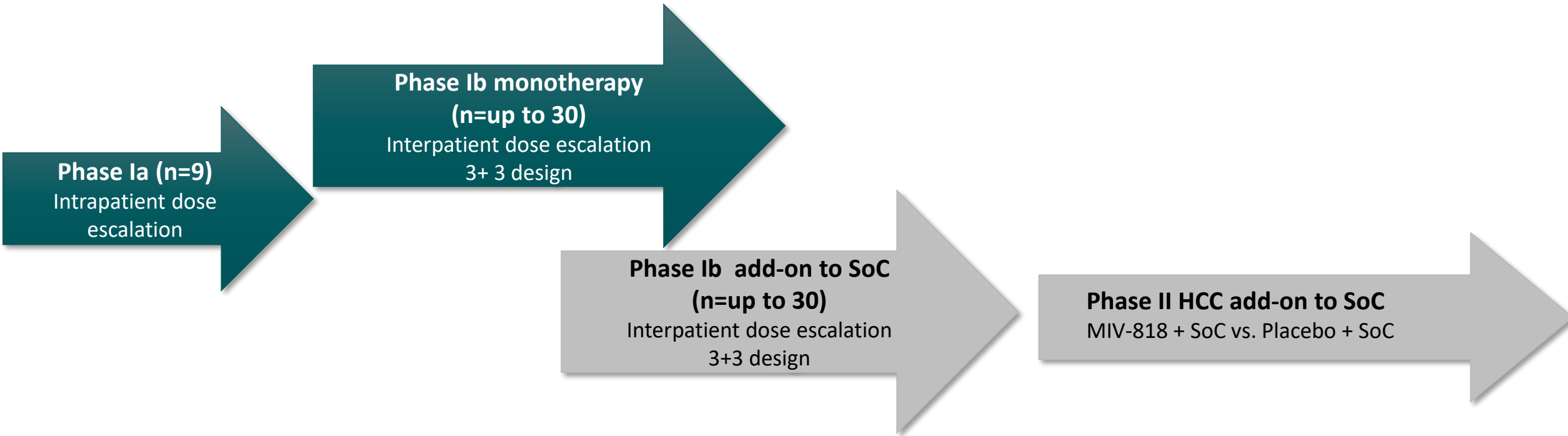
- Clear signs of effect, measured as DNA damage, observed in liver biopsies from tumor tissue in MIV-818 treated patients. Normal liver tissue does not appear to have been affected
- The tumor selective effect is an early proof-of-concept of the intended liver-directed effect in patients
- DNA damage also observed in hypoxic liver cancer regions (not shown)



Evidence of DNA damage in tumor but not in normal liver tissue



# MIV-818: Clinical development plan in advanced HCC



Unique mechanism of MIV-818 enables add-on treatment to approved therapies

SoC = Standard of Care

# Potential role for MIV-818 in HCC treatment

Early stage disease currently treated with surgery, transplantation or chemo embolization

Drug therapy in advanced disease provides 2-3 months of extended life expectancy:

- 1<sup>st</sup> line therapy; sorafenib or lenvatinib
- 2<sup>nd</sup> line therapy; several immuno-oncology drugs

Role of MIV-818:

- May fill major unmet medical need by providing better efficacy in HCC therapy.
- Provides opportunity for monotherapy and/or add-on to standard-of-care (both 1<sup>st</sup> and 2<sup>nd</sup> line therapy) in patients with advanced stage HCC.

# MIV-828 for acute myeloid leukemia

## Profile of MIV-828

- Nucleotide prodrug given intravenously
- Active metabolite shown to have potent anti-leukemic activity in preclinical in vivo AML models
- Increased activity and reduced susceptibility to pharmacologic resistance mechanisms of prodrugs
- Preclinical activity also demonstrated against T-cell lymphoma

## Opportunity in hematological cancers


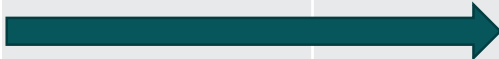
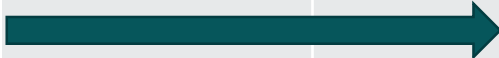


- Better tolerated and more effective agent in patients with relapsed/refractory AML and other hematological cancers
- Overcomes multiple resistance mechanisms and shows synergy with most approved AML therapeutics
- Shows efficacy in targeting AML cancer stem cells

*Acute myeloid leukemia (AML) leads to an overproduction of abnormal immature cells in the bone marrow and prevents development of normal blood cells, which could lead to anemia, bleeding episodes and a high susceptibility for severe infections.*

- Expected new cases 2018: US: ~ 19,500; EU: ~ 43,000; Sweden: ~ 350
- Affects all ages, median age at diagnosis 68 years in the US
- Five-year survival: 50% in younger patients (<60y) and less than 10% in patients > 70y

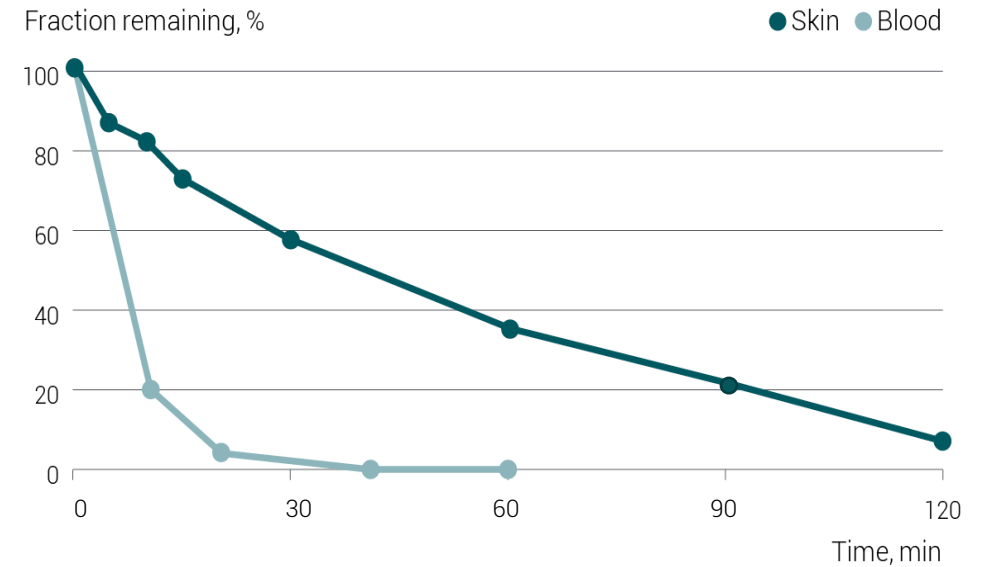
# Three advanced clinical-stage assets for partnering

- The phase III ready remetinostat – a topical HDAC inhibitor for cutaneous T-cell lymphoma (MF-CTCL) and potentially basal cell carcinoma (BCC) and squamous cell carcinoma (SCC).
- The bivalent SMAC mimetic birinapant – currently in one combination study: head and neck cancer (HNC) with radiation.
- The cathepsin K inhibitor MIV-711 for osteoarthritis (OA) - has the potential to be the first disease modifying OA medicine.

Nucleotide prodrug	Indication	Phase I	Phase II	Phase III	Exclusivity
Remetinostat	MF-CTCL				IP : 2034
	BCC				
	SCC				
Birinapant	HNC				IP : 2034
MIV-711	Osteoarthritis				IP : 2034

# Remetinostat for MF-CTCL

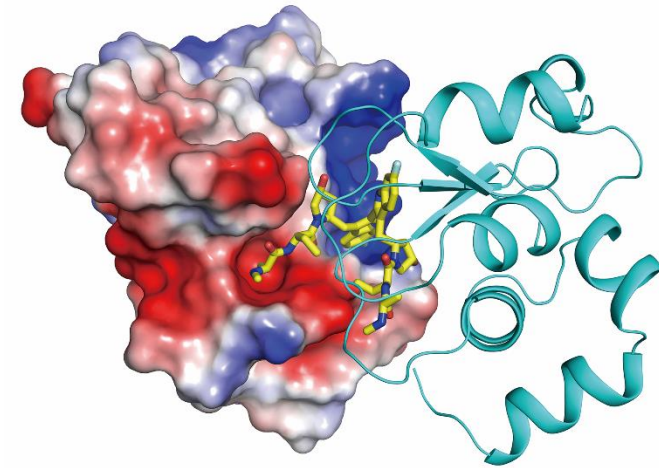
- Formulated as gel for topical administration
- Strong phase II efficacy and safety data
- US-orphan drug designation for MF-CTCL
- EOP2 discussions with FDA clarified that:
  - One placebo-controlled phase III study sufficient for approval
  - Co-primary endpoint required to define lesion effect
  - Pruritus as key secondary endpoint
- Interim analysis of ongoing phase II BCC study reported (at SID 2019) to proceed very well
- A phase II study in SCC initiated in December 2019



Remetinostat is much more stable in skin compared to blood.

# Birinapant for solid tumors

- Birinapant enables tumor cell death and augments the immune system. Has great potential to improve cancer therapy in combination with other treatments
- Ongoing phase I study in head and neck cancer in combination with radiation
- Phase II combination study with Merck's Keytruda® in MSS colorectal cancer was discontinued in December 2019 because of futility



Birinapant antagonises cIAP-1 and cIAP-2

# MIV-711 for osteoarthritis (OA), the most common form of joint disease

Successful placebo controlled phase II study of MIV-711 in OA:

- MIV-711 showed significant effects on joint structure (bone and cartilage) after 26 weeks.
- Trends favoured MIV-711 over placebo on knee pain and function.
- Safety and tolerability profile supportive of further development.

OA affects around 240 million worldwide

No disease-modifying medicine approved for OA

The FDA open to consider data on structural endpoints – correlation with pain will be required

