



# ÅRSSTÄMMA 2020

MEDIVIR

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# 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

# Achieved milestones 2019

MIV-818: POC in phase Ia

Q2 2019 ✓

New organization in place

Q3 2019 ✓

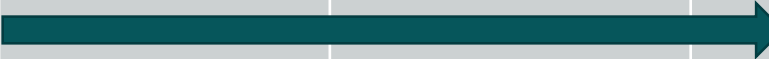
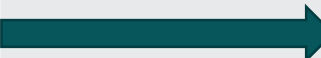

Birinapant Head & Neck cancer phase I study started

Q4 2019 ✓

Birinapant/Keytruda<sup>®</sup>: phase II futility analysis

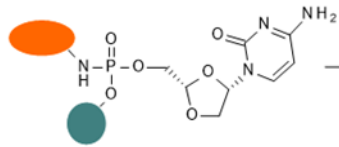
Q4 2019 ✓

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

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

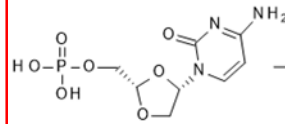
# MIV-818 prodrug features

MIV-818

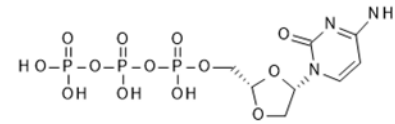


- Stable in GI-tract
- Stable in blood
- Increased potency in HCC
- Increased cell permeability
- Rapid conversion in liver to active TRX-TP

Monophosphate



Triphosphate

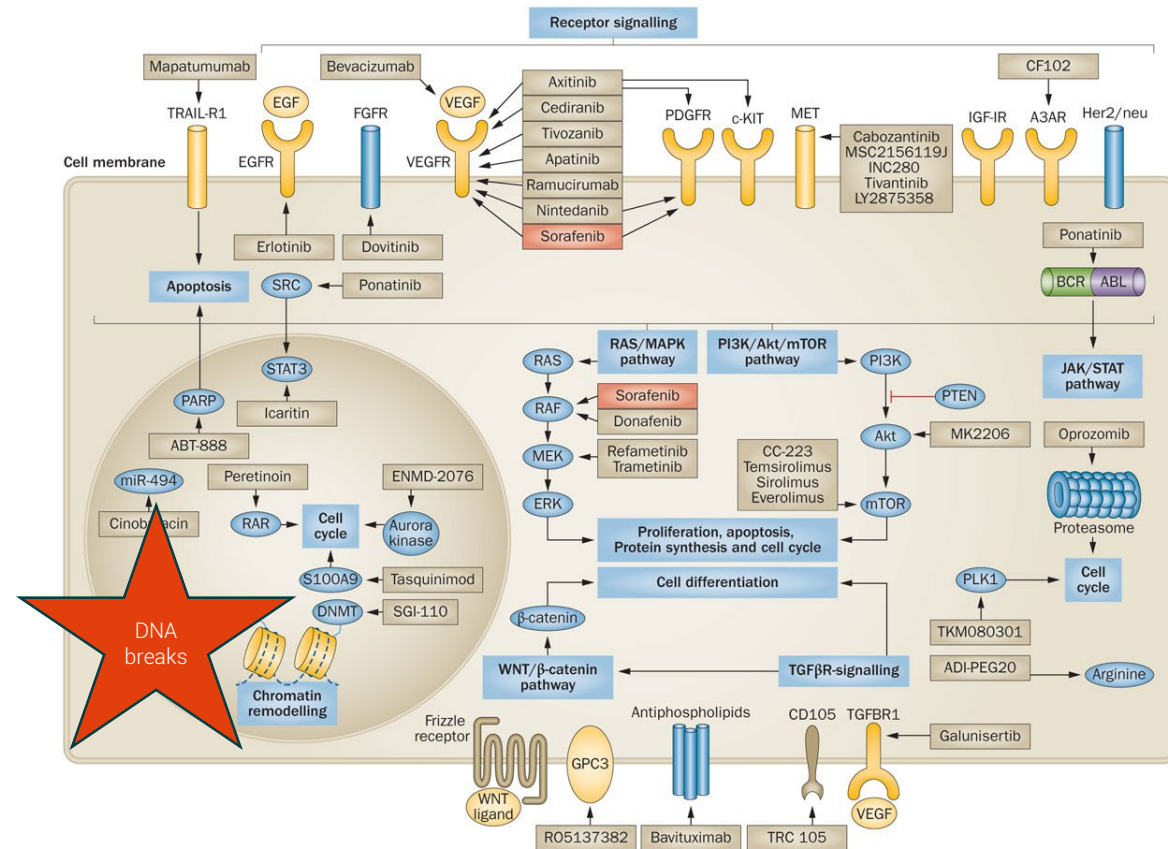


↓  
Incorporation into DNA  
during replication

↓  
Results in DNA-  
breaks and cell death

# MIV-818: unique mechanism of action

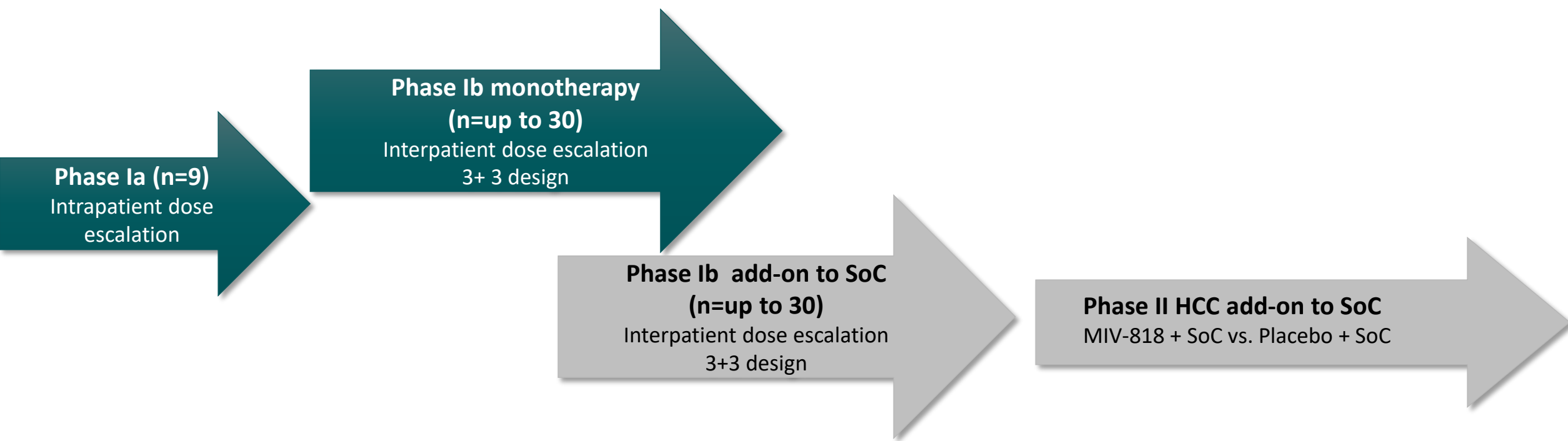
- By incorporation into DNA replication MIV-818 causes DNA breaks resulting in cell death
- Mechanism independent of molecularly targeted therapies
- Unlikely to be impacted by resistance mechanisms to **molecularly** targeted therapies
- MIV-818 also shows favourable combination effect in preclinical models in vitro with:
  - Multi-kinase inhibitors (anti-angiogenesis)
  - Check-point (anti-PD1) inhibition
  - Multiple DNA damage repair inhibitors



Nature Reviews | Clinical Oncology

Adapted from Llovet, J. M. *et al.* (2015) *Nat. Rev. Clin. Oncol.* doi:10.1038/nrclinonc.2015.103

# MIV-818: Clinical development plan in advanced HCC



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

SoC = Standard of Care



# MIV-818: Phase Ia demography

## Patient characteristics:

Nine patients were enrolled and evaluated

8 males and 1 female

57 years (median), range 50-84

All patients non-hispanic white

## Disease:

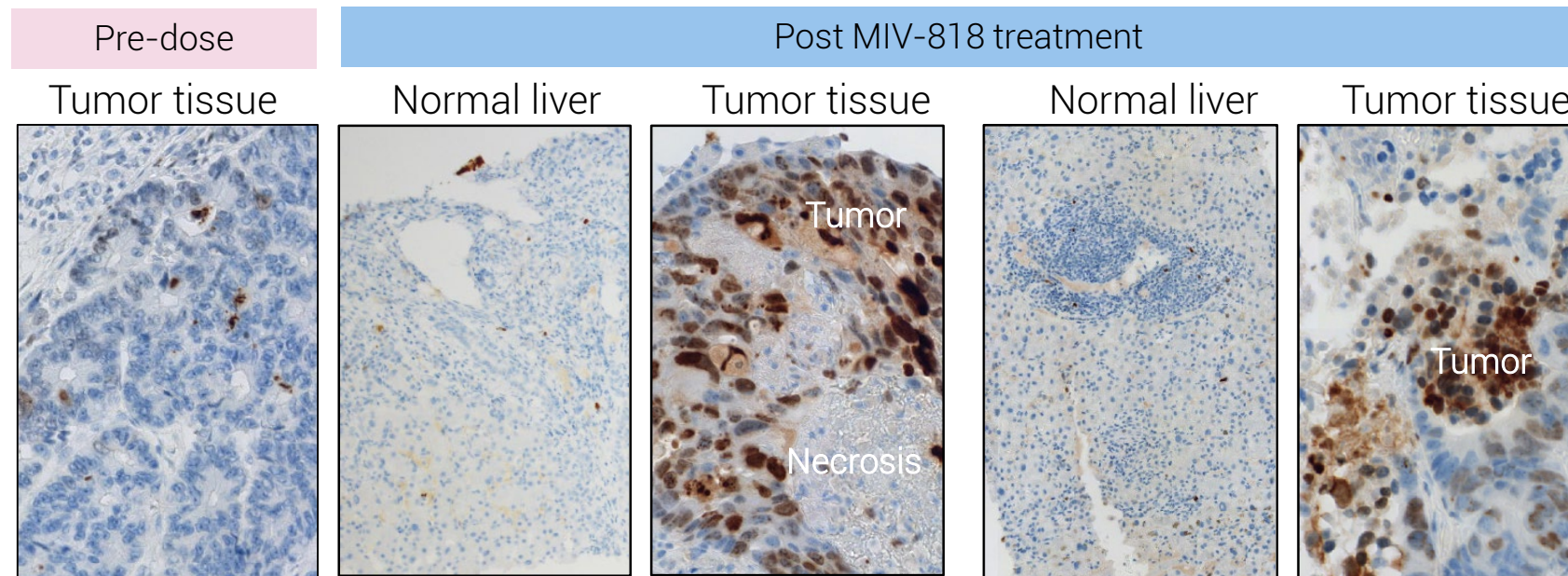
Hepatocellular carcinoma: 2

Intra hepatic cholangiocarcinoma: 1

Liver metastatic disease: 6

# 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)



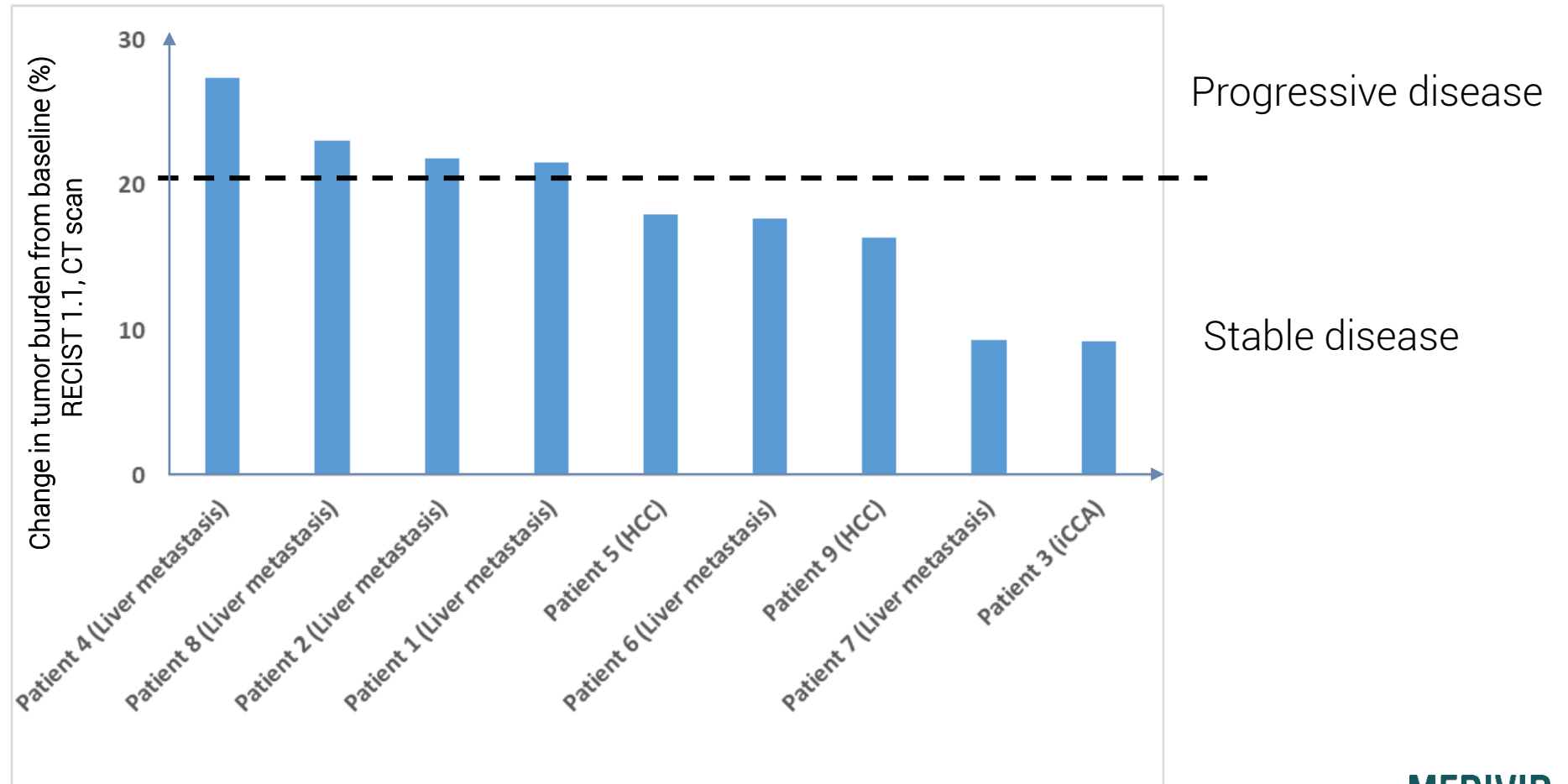
Data from Patient 2

Data from Patient 4

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

# MIV-818: Phase Ia change in liver tumor burden after treatment

## Tumor burden change assessed by RECIST 1.1



# MIV-818: Conclusions from phase Ia

- Adverse events were generally mild and the few severe adverse events were reversible
- Only low levels of MIV-818 and acceptable exposure to troxacitabine were observed in blood after two treatment cycles
- Liver biopsies showed selective DNA damage in tumor tissue and minimal or no impact of MIV-818 in healthy liver tissue
- Five out of nine patients achieved stable disease after MIV-818 treatment

# MIV-818: Phase Ib study conduct and objectives

## Study conduct:

Classic 3+3 dose escalation study in HCC, iCCA and liver metastatic disease patients  
Start dose 5x40 mg per 21-day cycle  
Six sites: 4 sites in United Kingdom and 2 in Belgium

## Objectives:

Primary: Establish the phase II dose based on safety and tolerability  
Secondary: Efficacy evaluated by RECIST 1.1, pharmacokinetics and pharmacodynamics

# Partnering opportunities in our clinical portfolio

While we internally are focussing on MIV-818, we are seeking to develop our other clinical assets through partnerships.

*Our clinical pipeline aimed for partnering*

Compound	Mechanism	Indication	Phase I	Phase II	Phase III	Exclusivity
Remetinostat	Topical HDAC	MF-CTCL	→			IP : 2034
		BCC	→			
		SCC	→			
Birinapant	SMAC mimetic	HNC	→			IP : 2034
MIV-711	Cath K inhibitor	OA	→			IP : 2034

# Corporate information

## Summary of the Group's figures

(SEK m)

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