R&D DAY

STOCKHOLM

MARCH 2, 2020

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Agenda

13.30-14.00	Registration and coffee	
14.00-14.10	Introduction	Dr Uli Hacksell, Medivir
14.10-14.40	Hepatocellular carcinoma (and ihCCA) - unmet needs	Prof Jeff Evans, University of Glasgow
14.40-15.00	The liver cancer therapeutics market	Dr Christina Herder, Medivir
15.00-15.15	Break	
15.15-15.40	The nucleotide prodrug platform and scientific rationale for MIV-818	Dr Fredrik Öberg, Medivir
15.40-16.10	Current status of the development of MIV-818	Dr Karin Tunblad, Medivir
16.10-16.30	Summing up	Dr Uli Hacksell, Medivir
16.30-17.30	Mingel	

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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

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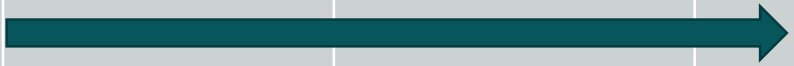
The nucleotide-prodrug platform: A versatile source of new oncology products

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

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Introduction Professor Jeff Evans

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The liver cancer therapeutics market

Dr Christina Herder, Medivir

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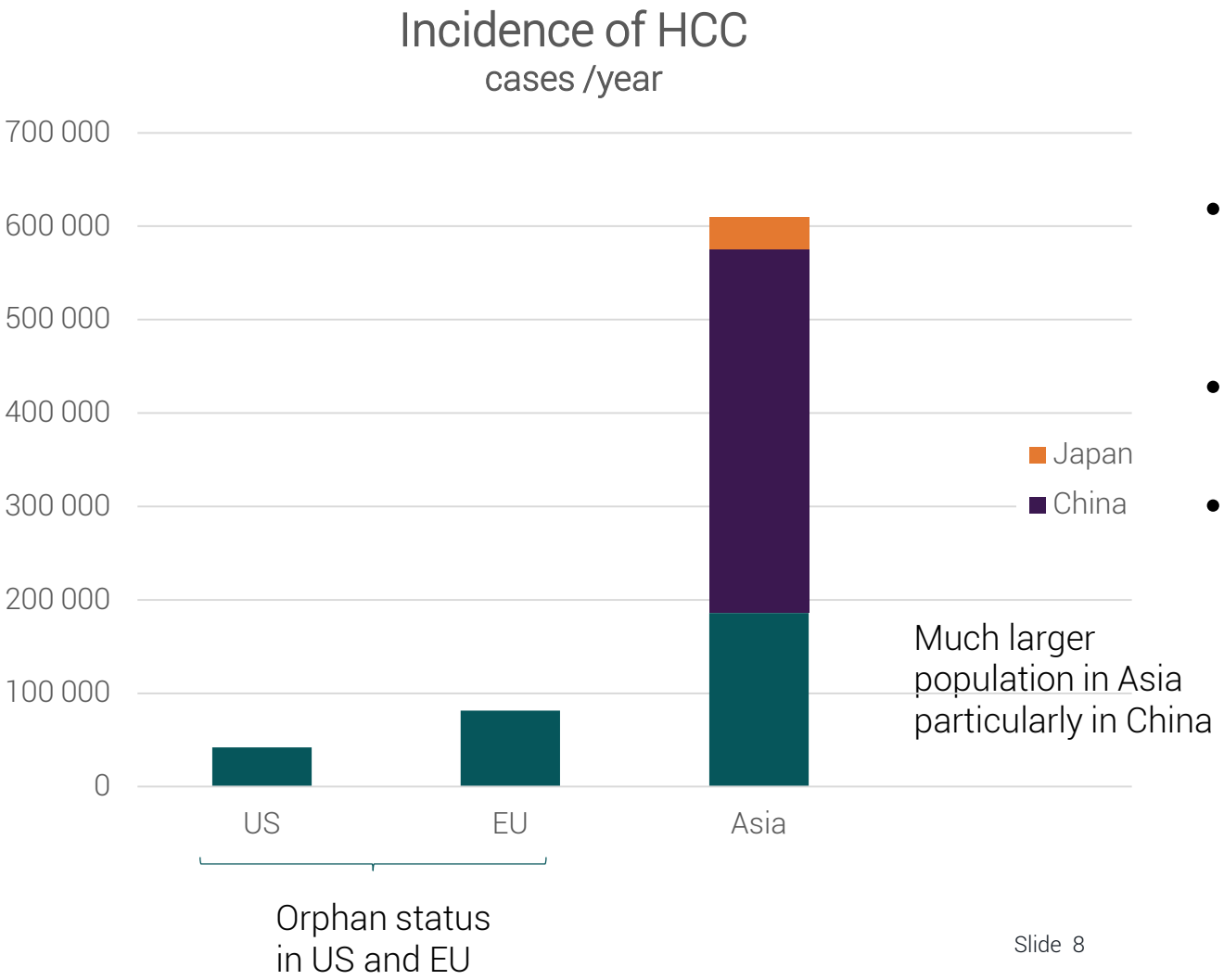
Hepatocellular Carcinoma: Incidence and Mortality



- Current treatment options provide low survival benefits
- Five-year survival rate: 11%
- Third leading cause of cancer-related deaths

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Currently marketed HCC drugs – Only two first-line therapies

Product	Mechanism of action	Approval	Approved in	Line of therapy	Company	Exclusivity
Nexavar *sorafenib*	*Multi Kinase Inhibitor*	2007	US, EU, China	First line	Bayer	US: Q4 2020 EU: Q3 2021
Lenvima *lenvatinib*	*Multi Kinase Inhibitor*	2018	US, EU, China	First line	Eisai	US: Q4 2021 EU: Q4 2026
Stivarga *regorafenib*	*Multi Kinase Inhibitor*	2017	US, EU, China	Second line	Bayer	US: Q1 2031 EU: Q3 2024
Opdivo *nivolumab*	*PD-1 Inhibitor*	2017[1)]	US [2)]	Second line	BMS	US: Q4 2028 EU: Q2 2030
Keytruda *pembrolizumab*	*PD-1 Inhibitor*	2018[1)]	US [2)]	Second line	MSD	US: Q4 2028 EU: Q3 2030
Cabometyx *cabosantinib*	*Multi Kinase Inhibitor*	2019	US, EU	Second line	Exelixis	US: Q3 2026 EU: Q1 2029
Cyramza *ramucirumab*	*Anti-VEGFR2 antibody*	2019	US, EU	Second line	Eli Lilly	US: Q2 2026 EU: Q4 2024

[1)] Accelerated/Conditional approval

[2)] Both Opdivo and Keytruda monotherapies have failed to demonstrate superiority over sorafenib

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Historic development of the HCC market

- Since 2007, Nexavar, a multikinase inhibitor has been dominating as the standard-of-care in first-line setting despite having a rather limited efficacy
- The PD-1 inhibitors, Keytruda and Opdivo were expected to become new monotheraphy first-line options
  - But both Opdivo and Keytruda monotherapies failed to demonstrate superiority over sorafenib in phase III, ended up as second line
- The disappointing results of monotherapy with PD-1 inhibitors may be due to different underlying causes of HCC and thereby genetically heterogeneous cancer forms:
  - viral infections (HBV; HCV, aflatoxins)
  - life-style factor (smoke, tobacco)
  - disease-related (diabetes, obesity)
  - genetic factors (autoimmune hepatitis)

Market is now developing into drug combination treatments

- In late 2019, Roche presented phase 3 results in HCC with their combination of Tecentriq (A PD-L1 inhibitor) and Avastin (An anti-VEGF inhibitor)
  - showed statistically significant and clinically relevant effects on both progression-free survival and overall survival
  - expected to be incorporated into treatment guidelines during 2020, as the two components are already approved for other cancer indications
- Currently there are around ten combination studies ongoing or about to start, all combinations include PD-1 inhibitors, but with different other mechanisms

PD-1	+ MKI
	+ Anti-VEGF
	+ CTLA-4

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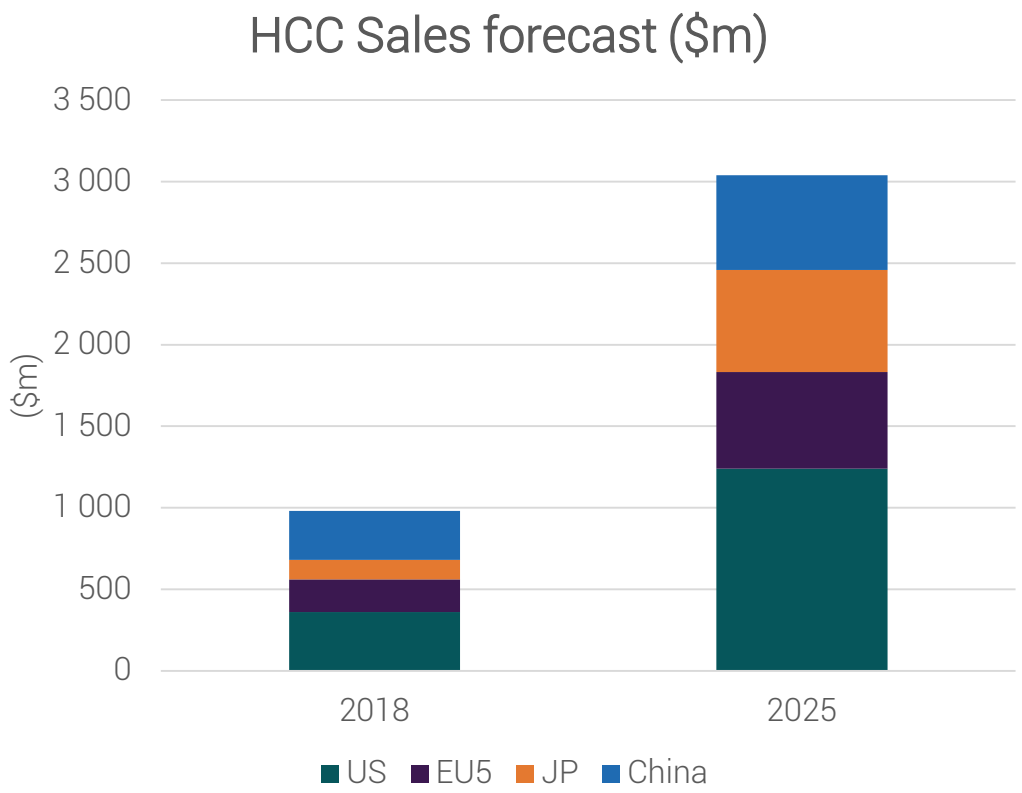
MIV-818 has a unique profile

- Unique profile vs approved HCC drugs, and those in development
- DNA-breaking, small-molecular approach, which selectively reaches all tumour cells irrespective of genetic cause. Normal and slowly dividing cells are not affected
- The efficacy of the orally administered prodrug MIV-818 is directed to the liver providing both efficacy and safety
- Likely to be effective as add-on therapy to other drugs with different mechanisms of action

Global market currently underserved



- Expected to triple within 5 years

Source: Datamonitor (US, EU5, JP), IQVIA (China)

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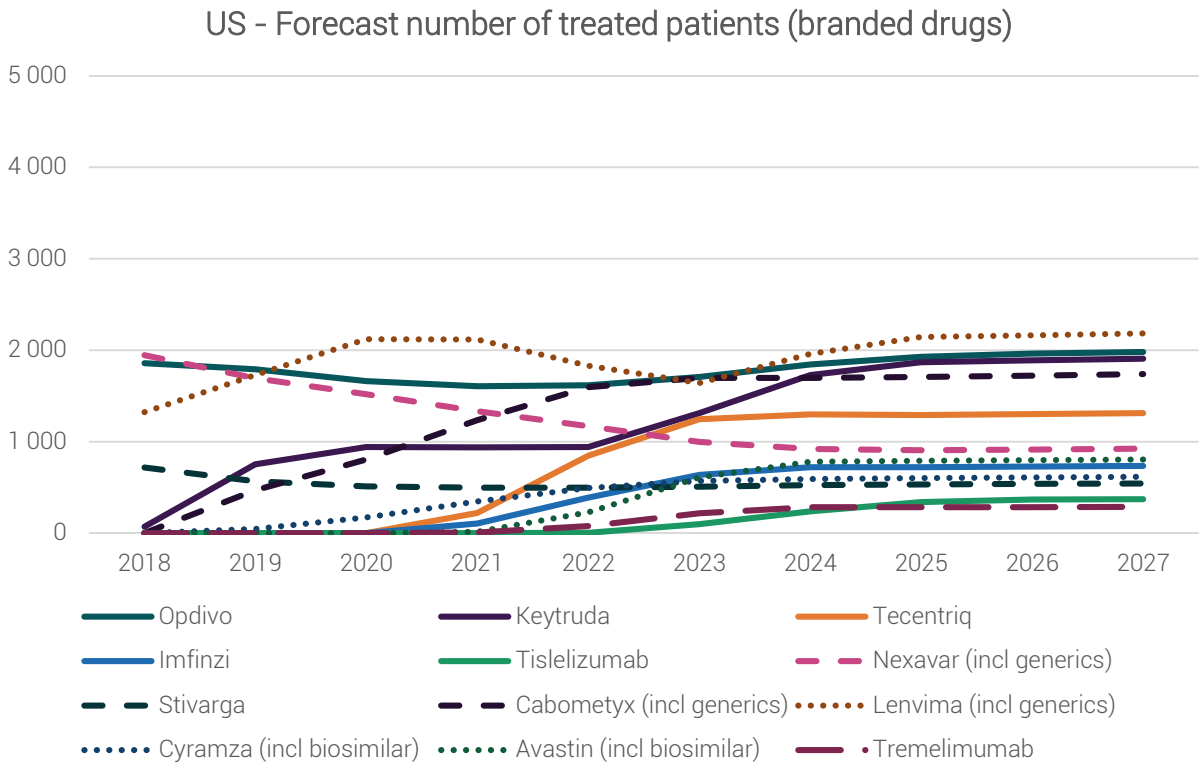
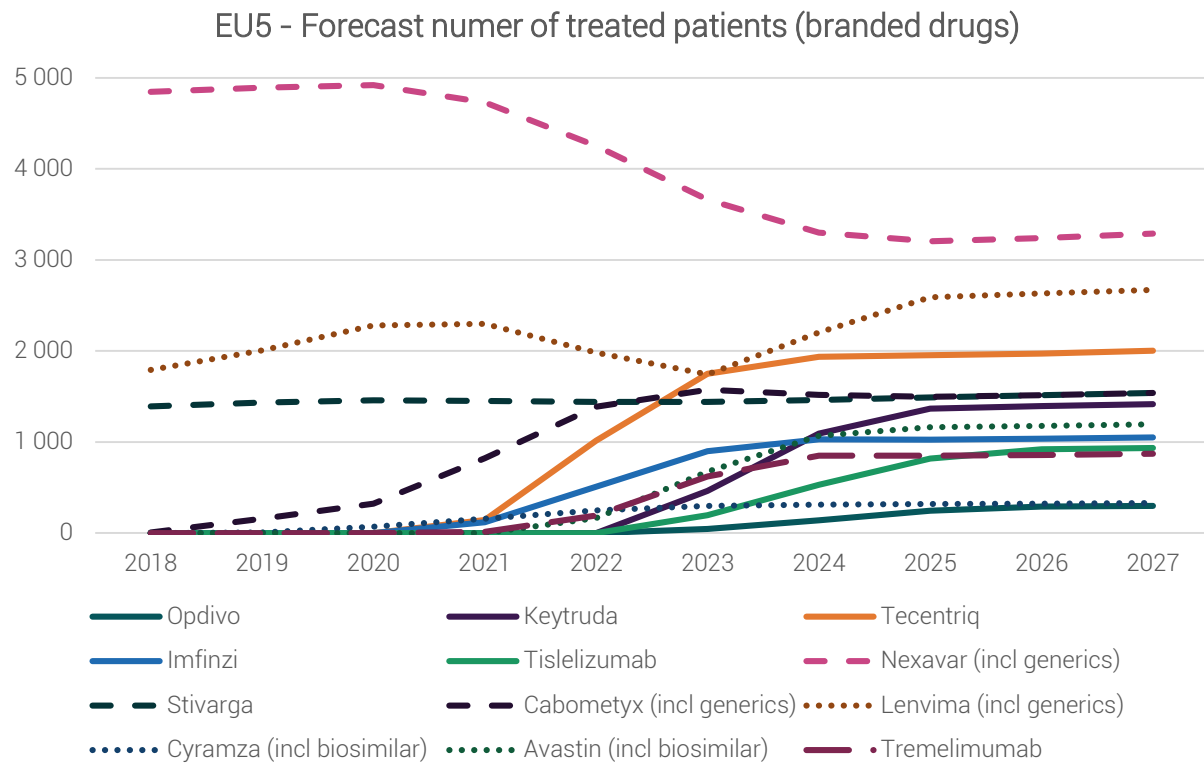
Current standard-of-care will retain position on market – additional add-on therapies will emerge





- Lenvima taking over 1st line
- Opdivo key in 2nd line

- Lenvima is <u>not</u> expected to take over from Nexavar

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Break

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The nucleotide prodrug platform and scientific rationale for MIV-818

Dr Fredrik Öberg, Medivir

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

- By combination of a “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

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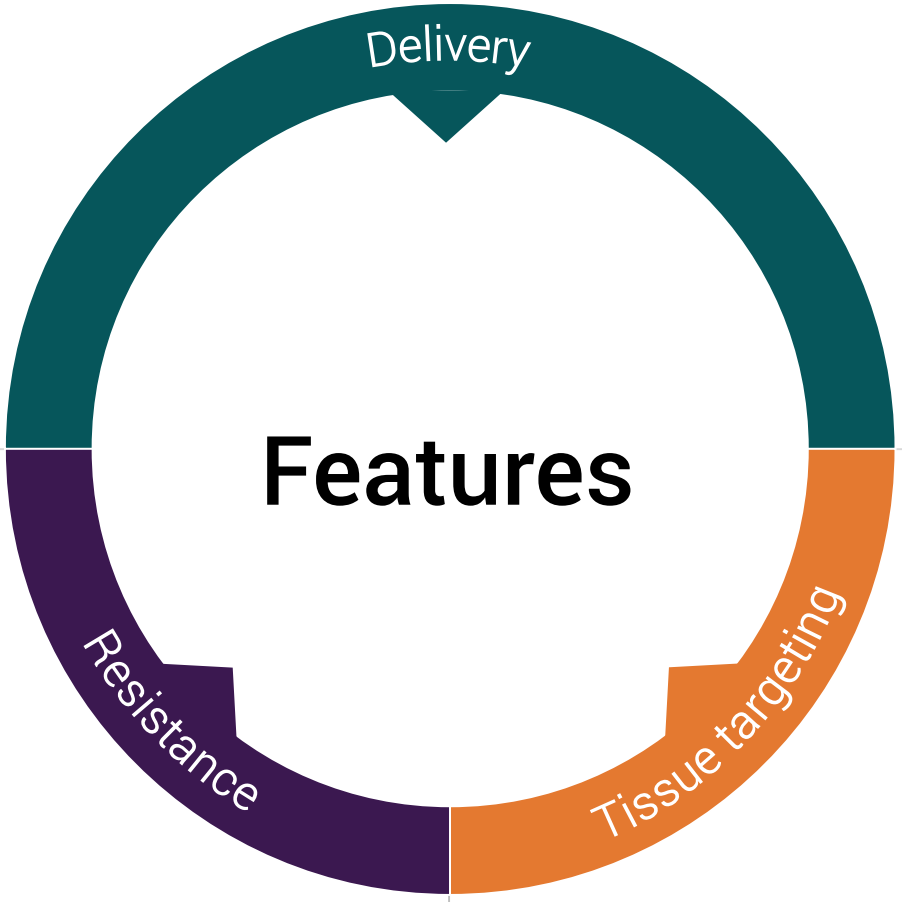
Nucleotide prodrug platform

Delivers NUC-MP

Not reliant on enzyme for 1st step

Rapid generation of active drug

Increased potency



Cell permability and uptake

Increase cell permeability

Possibility to modify uptake

Bypasses resistance

Reduced susceptibility to pharmacologic resistance mechanisms

Tissue targeting

Stability in different tissues can be selectively modified

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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
- 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
- Designed to overcome multiple resistance mechanisms and shows synergy with most approved AML therapeutics
- Shows efficacy in targeting and eradicating 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

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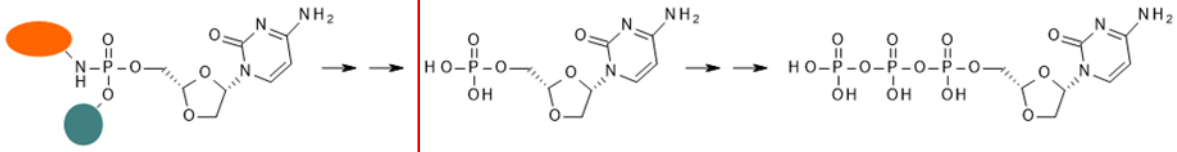
MIV-818 prodrug features

MIV-818 → Monophosphate → Triphosphate



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

Incorporation into DNA during replication

Results in DNA-breaks and cell death

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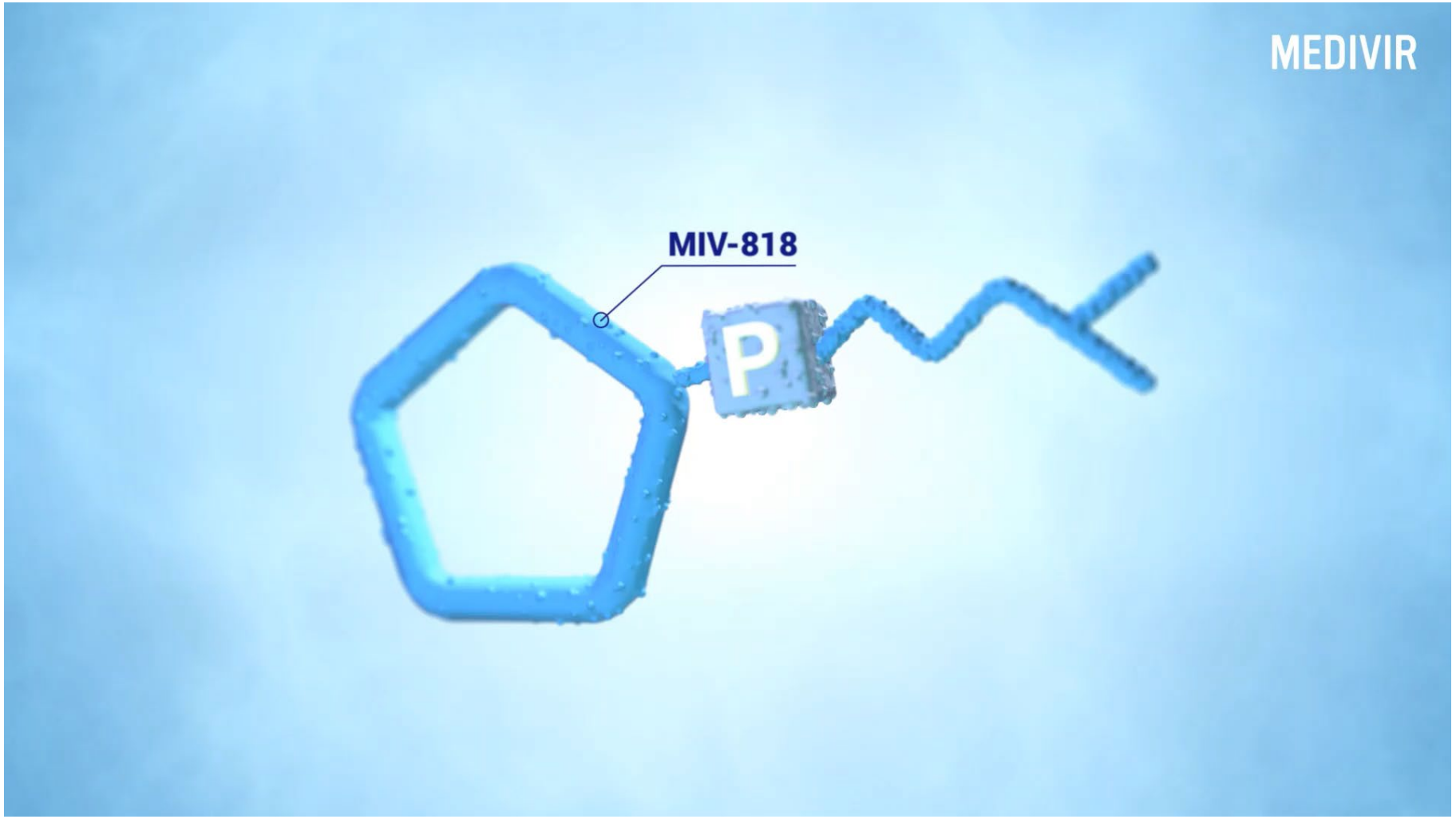
MIV-818: a liver-cancer directed prodrug



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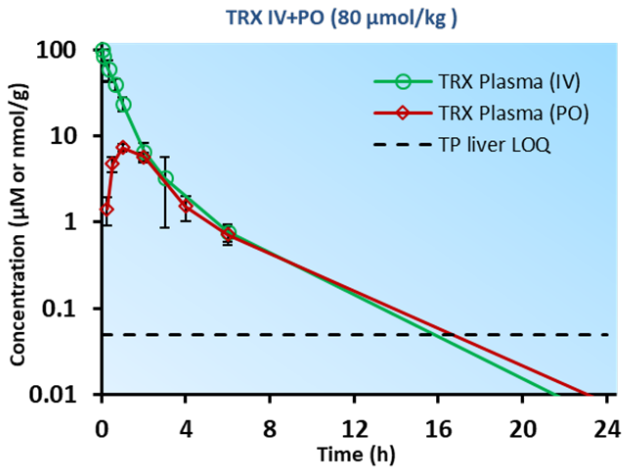
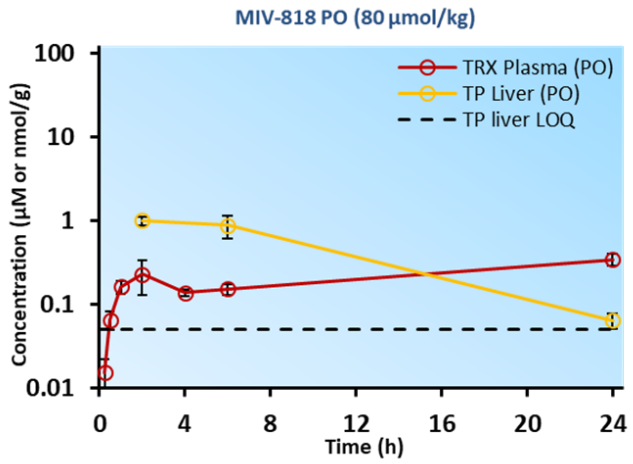
Preclinical evidence for MIV-818 liver targeting

Compound	Route	Dose (µmol/kg)	Liver TRX-TP/Plasma TRX (AUC ratio)
Troxacitabine (TRX)	*iv*	80	<0.016
MIV-818	*oral*	80	1.9





- MIV-818 exhibited substantial liver targeting by preferential formation of the active TRX-TP metabolite in liver of rats
- MIV-818 shows a100-fold higher liver targeting than troxacitabine

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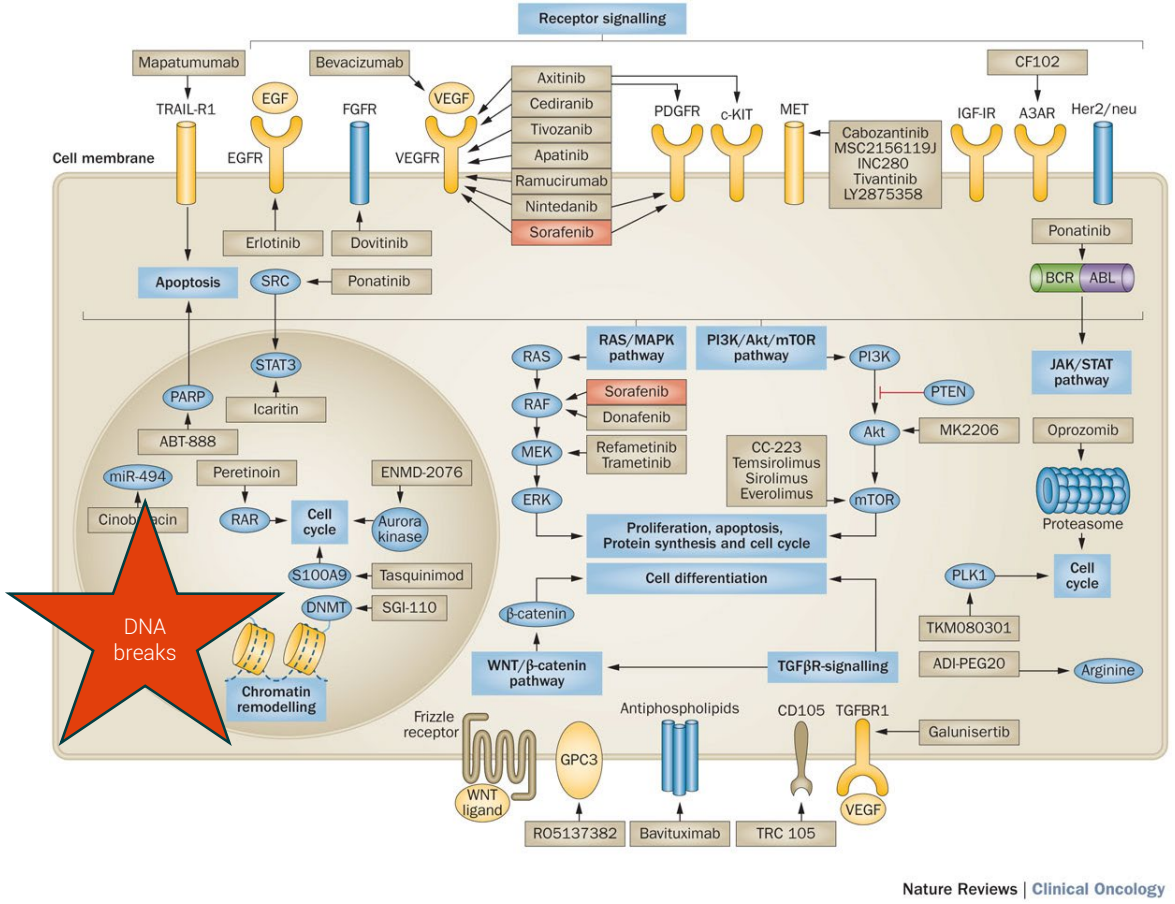
MIV-818: unique mechanism of action

- 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



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

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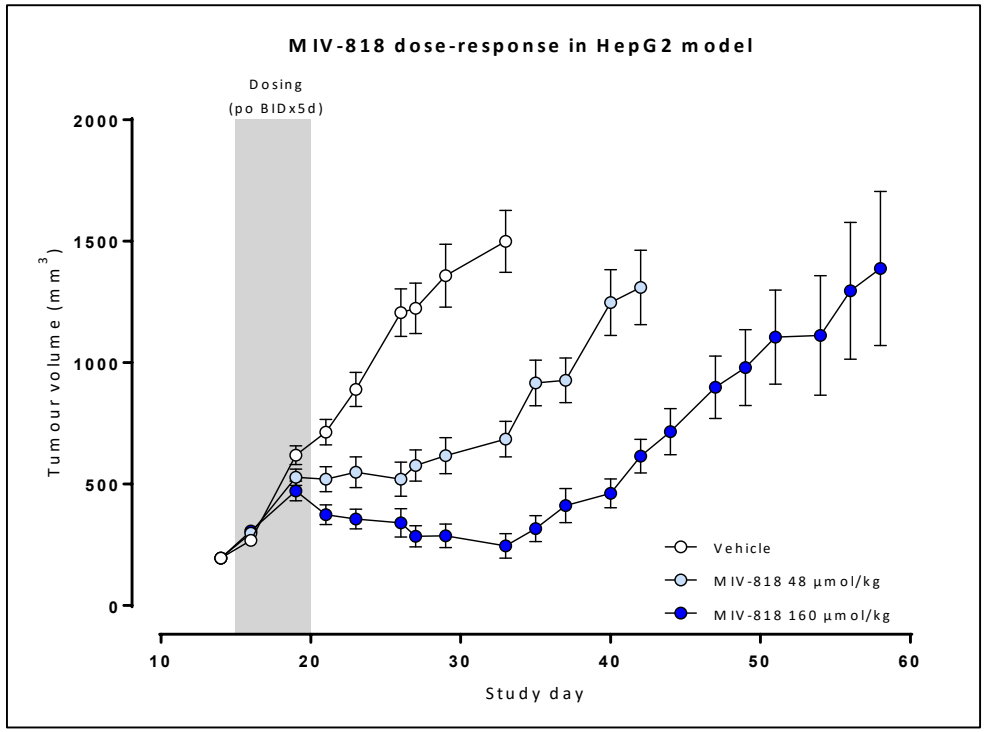
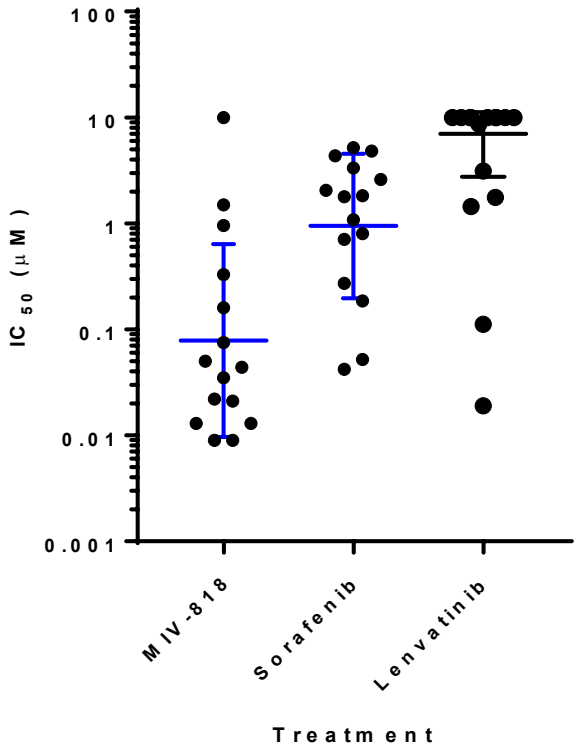
MIV-818 shows efficacy in preclinical HCC models

Inhibition of tumor growth in mouse HCC xenograft models in vivo



Inhibition of patient-derived HCC cell lines in vitro



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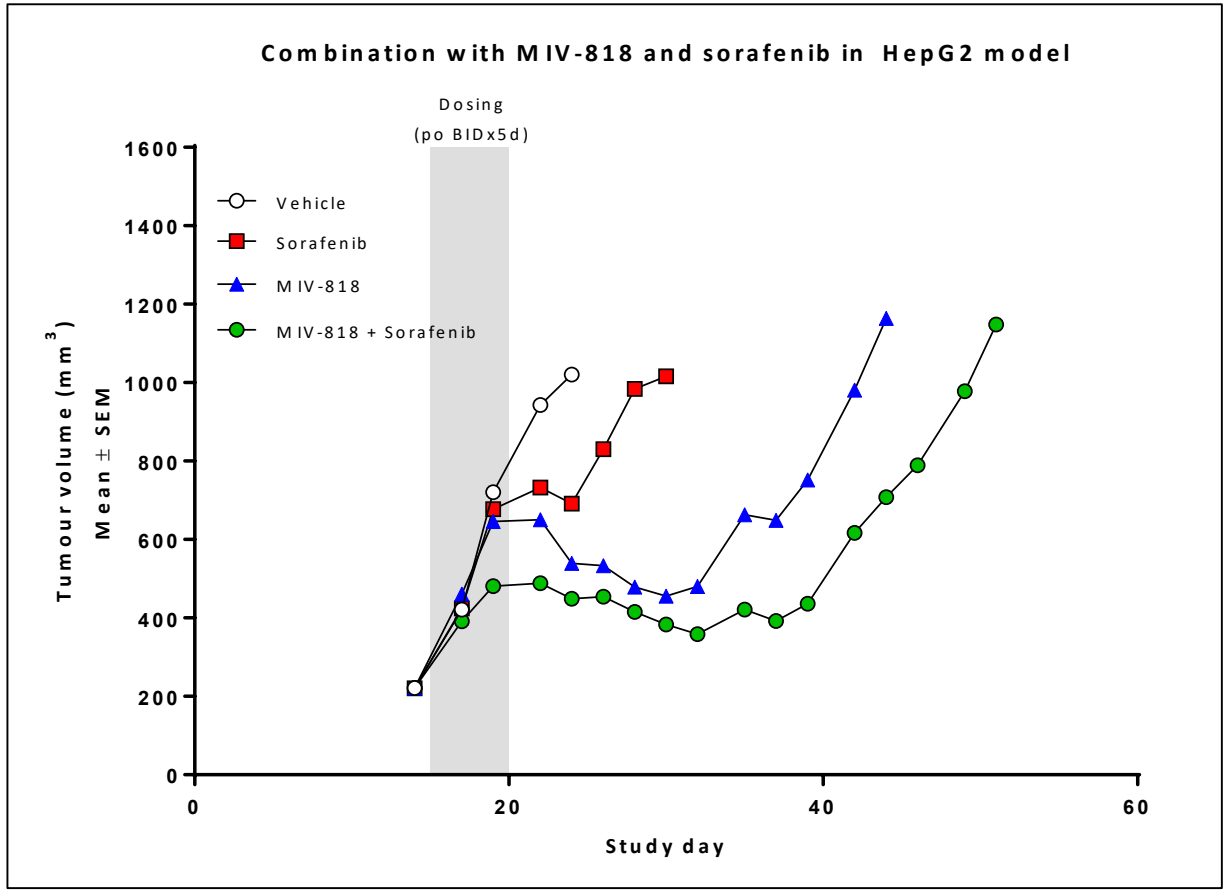
MIV-818: enhanced anti-tumor effect in combination with sorafenib in preclinical HCC models



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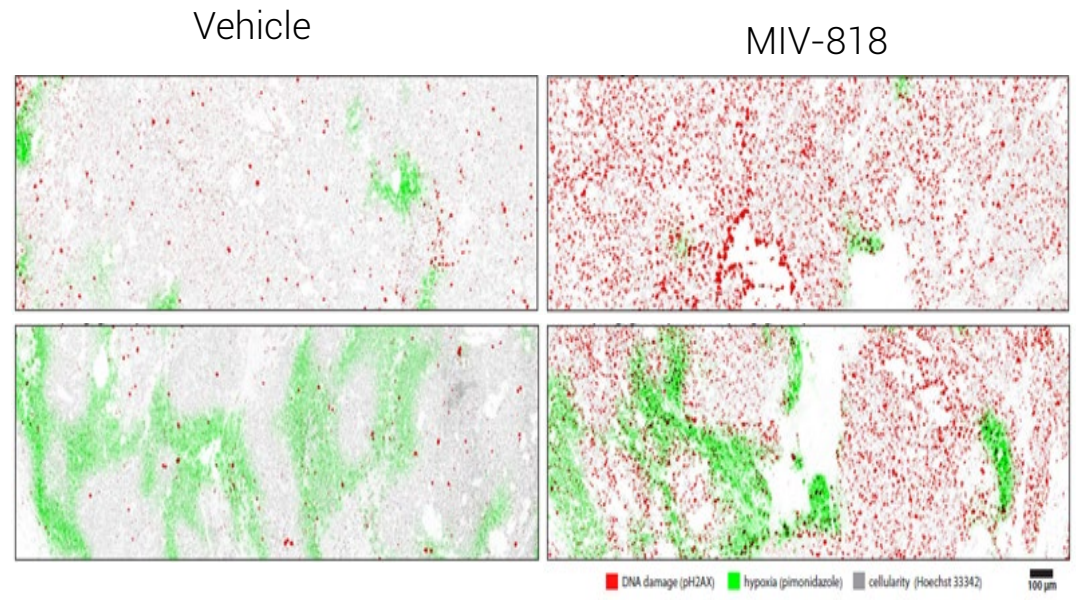
MIV-818: enhanced anti-tumor effect in combination with sorafenib in preclinical HCC models

- MIV-818 induces DNA-damage, as measured by pH2AX in tumor sections (red staining)
- Treatment with Sorafenib leads to an increase in hypoxia in the tumor (green staining) as a result of anti-angiogenic activity
- MIV-818 induced DNA-damage is observed in hypoxic regions of the tumor

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



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Summary

- The nucleotide prodrug platform provides Medivir with an efficient way to generate a pipeline of new medicines to follow MIV-818
- MIV-818 has demonstrated efficacy in multiple preclinical HCC models
  - Pharmacodynamic markers for DNA-damage e.g. phosphorylation of histone 2AX (pH2AX)
  - Evidence of activity in hypoxic regions of tumor, commonly hard to treat
- The unique mechanism-of-action allows for:
  - Less impact of resistance to other therapies being used
  - Potential to combine effectively with current and future therapies

Current status of the development of MIV-818

Dr Karin Tunblad, Medivir

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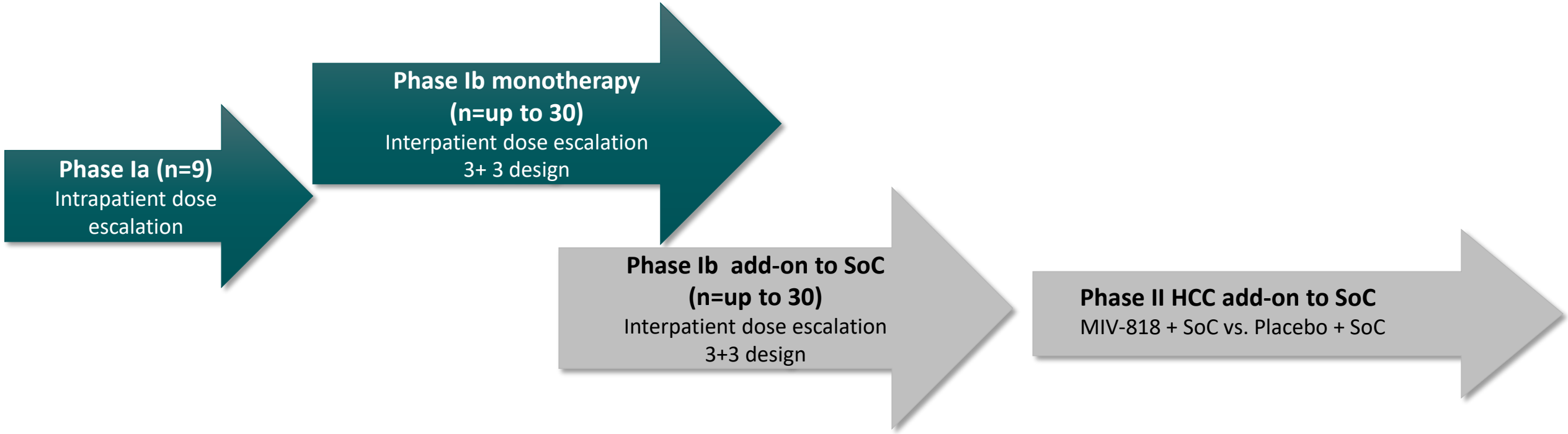
MIV-818: Clinical development plan in advanced HCC



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

SoC = Standard of Care

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MIV-818: Phase Ia objectives

Primary objectives

- To assess safety and tolerability of escalating doses of MIV-818 in patients with HCC, iCCA, or metastatic liver disease and to establish the phase Ib start dose

Key secondary and exploratory objectives

- To evaluate the overall response rate (ORR) based on RECIST v1.1 in patients treated with escalating doses of MIV-818
- To determine the plasma PK profile of MIV-818 and its metabolites
- To assess the pharmacodynamic effects of MIV-818 on biomarkers, e.g. markers of DNA damage

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MIV-818: Phase Ia design and study conduct

Design:

Intrapatient dose-escalation study

Dose: 3 -70 mg, 3 – 5 days per week

Measurement:

Tumor evaluation: every 6 weeks by CT scan

Safety assessments throughout the study

Blood sampling for pharmacokinetics

Liver biopsy collection for biomarker analysis

Sites:

Three sites, 2 in United Kingdom and 1 in Belgium

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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

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Grading of adverse events (AEs)

CTCAE (The Common Terminology Criteria for Adverse Events) scale, version 5.0

- Standardized criteria for the classification of adverse events of drugs used in cancer therapy
- Uses a range of grades from 1 to 5

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Mild	Moderate	Severe or medically significant but not immediately life-threatening	Life-threatening consequences	Death
Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.	Minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL.	Hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL	Urgent intervention indicated.	Death related to AE

ADL= Activities of Daily Living

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MIV-818: Phase Ia adverse events

Adverse event	Gr 3, No of patients	Gr 4, No of patients
Anemia	3	0
Neutropenia	1	2
Neutropenic sepsis	1	0
Thromocytopenia	1	1
Bilirubin elevated	1	0
Liver enzyme elevation	1	0
Hyponatrimia	1	0
Pulmonary embolism	2	0
Pain (eye, bone, liver biopsy)	2	0
Spinal cord compression	1	0
Oesophageal bleeding & vomiting	1	0

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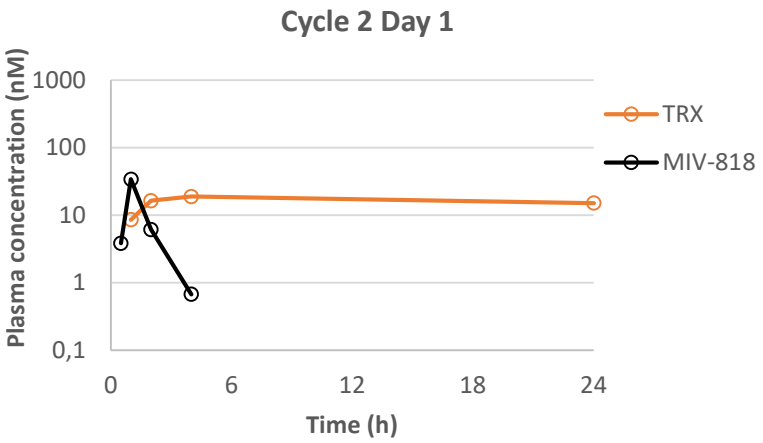
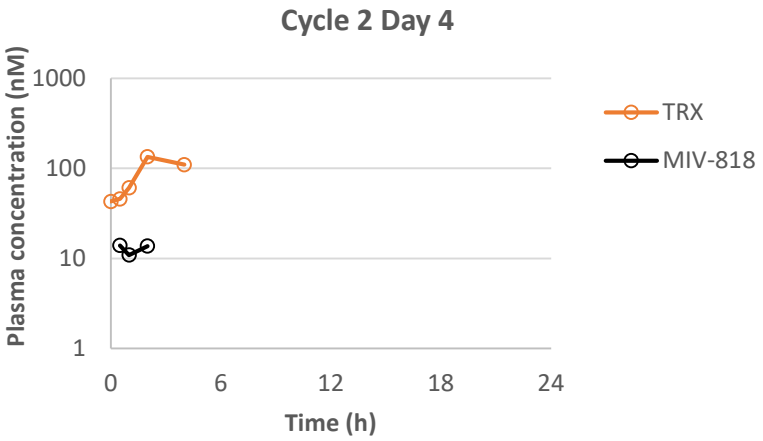
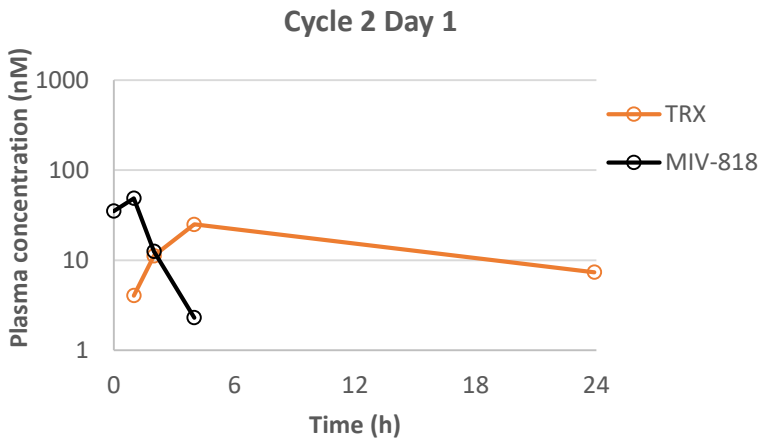
MIV-818: Phase Ia pharmacokinetics

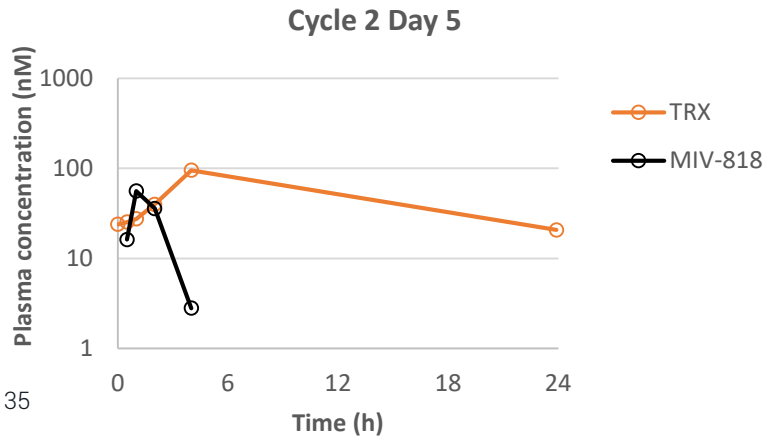
Patient 5 HCC 4 x 60 mg





Patient 7 Liver metastatic disease 5 x 50 mg





(Preliminary data)

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MIV-818: Phase Ia biomarker data

Patient	Diagnosis	Dose (C2)	% tumor cells	Pretreatment tumor pH2AX	C2 Tumor pH2AX	C2 Normal Liver pH2AX
1	Liver metastatic disease[1]	1x10 mg	n/a	n/a	n/a	n/a
2	Liver metastatic disease	3x20 mg	60%	0,2%	20-56%	<1%
3	Intrahepatic cholangiocarcinoma	3x30 mg	80%	n/a	14-17%	1.6%
4	Liver metastatic disease	4x40 mg	70%	n/a	37-52%	<1%
5	Hepatocellular Carcinoma[2]	4x60 mg	n/a	n/a	n/a	n/a
6	Liver metastatic disease	5x30 mg	80%	n/a	0-11%	0%
7	Liver metastatic disease	5x50 mg	80%	n/a	0.2-2.8%	n/a[4]
8	Liver metastatic disease	5x60 mg	60%	n/a	4-43%	<1%
9	Hepatocellular Carcinoma[3]	5X60 mg	n/a	n/a	n/a	n/a

[1] No biopsy (discontinuation on C2)
[2] 100% tumour cell necrosis
[3] No biopsy (discontinued after C1)
[4] No non-neoplastic liver, only striated muscle and fat tissue

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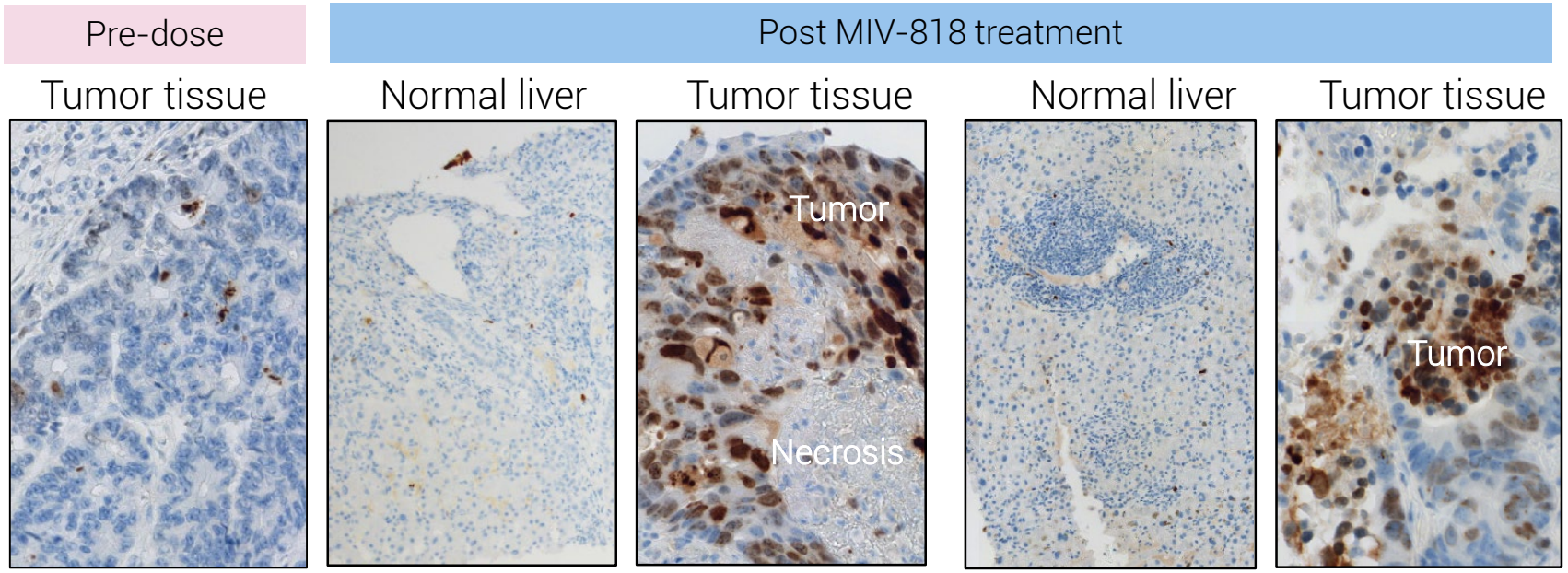
MIV-818: Selective effect signal in liver cancer in phase Ia

- 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

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Response evaluation criteria in solid tumors, RECIST 1.1[1]

- Both tumor shrinkage (objective response) and time to the development of disease progression are important endpoints in cancer clinical trials
- RECIST evaluation is based on CT scans
- Up to 5 tumor target lesions selected for evaluation of tumor response

RECIST criteria defines 4 types of responses:

Complete response (CR):	Disappearance of all target lesions
Partial response (PR):	At least 30% decrease in the sum of diameters of target lesions from baseline
Stable disease (SD):	Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD
Progressive disease (PD):	At least 20% increase in the sum of diameters of target lesions from the lowest observed value

[1]Eisenhauer 2009

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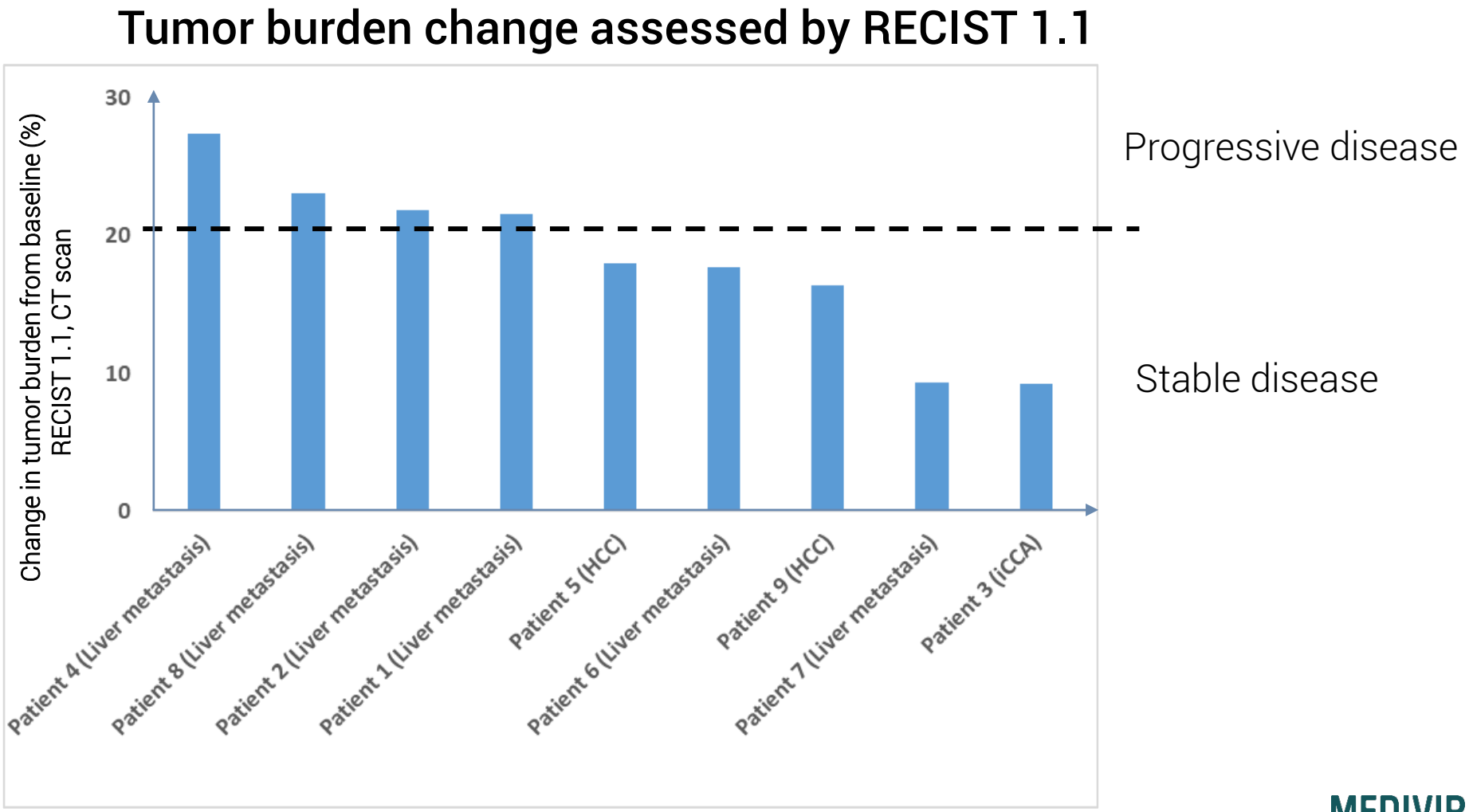
MIV-818: Phase Ia change in liver tumor burden after treatment



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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

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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

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MIV-818: drug product and substance production

Drug substance

- GMP material has been produced in large scale at a large European contract manufacture
- Efficient synthesis in final optimization from commercially available starting materials
- Commercial grade material will be used in phase II
- Optimized process will enable production at competitive price at commercial scale

Drug product

- Long shelf-life at room temperature

Current situation around intellectual property

Composition of matter claims & HCC treatment claims

WO2016/030335	*20 year expiry: 24 August 2035*
Granted/allowed:	*US, EU (incl Switzerland, Turkey, Balkans) Australia Hong Kong Indonesia Israel Japan Mexico Russia South Africa Taiwan*
Pending	*Brazil Canada China Egypt India Malaysia New Zealand Singapore South Korea Thailand Vietnam*

Combination with sorafenib & analogues

WO2017/151044	*20 year expiry: 28 February 2037*
Granted	*US*
Pending	*Australia Brazil Canada China EU Hong Kong India Indonesia Japan Malaysia South Korea Russia South Africa*

Combination with PD(L)1 monoclonals

PCT/SE2020/050175	*20 year expiry: 17 February 2040*
Pending	*world-wide*

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Summing up

Dr Uli Hacksell, 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

Partnering strategy

After Medivir's strategic redirection during 2019, we are looking for partners to be able to continue development of our clinical and preclinical assets in the portfolio

If there is an Unmet Medical Need for Patients
there is a potential business opportunity,
even if we are unable to continue the development

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Partnering opportunitites 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

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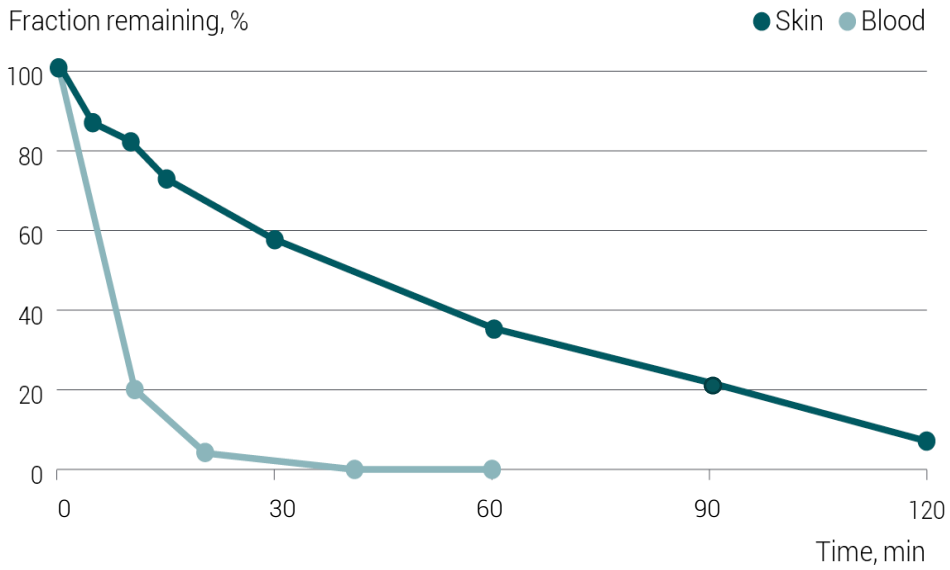
Remetinostat for MF-CTCL

- 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.

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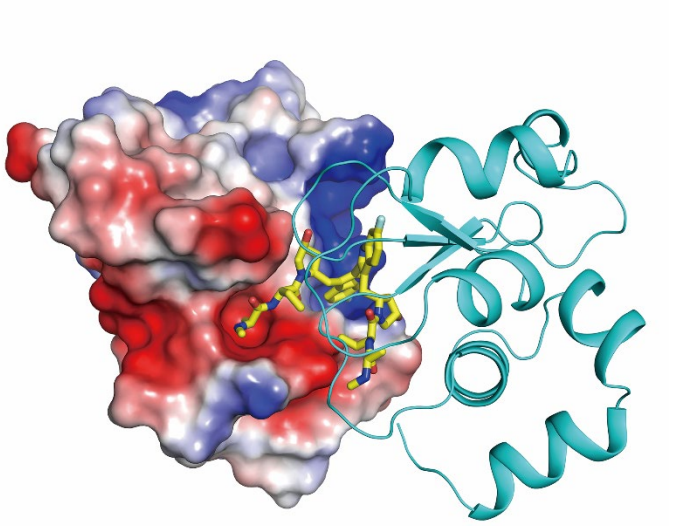
Birinapant for solid tumors

- 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



Birinipant antagonises cIAP-1 and cIAP-2

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

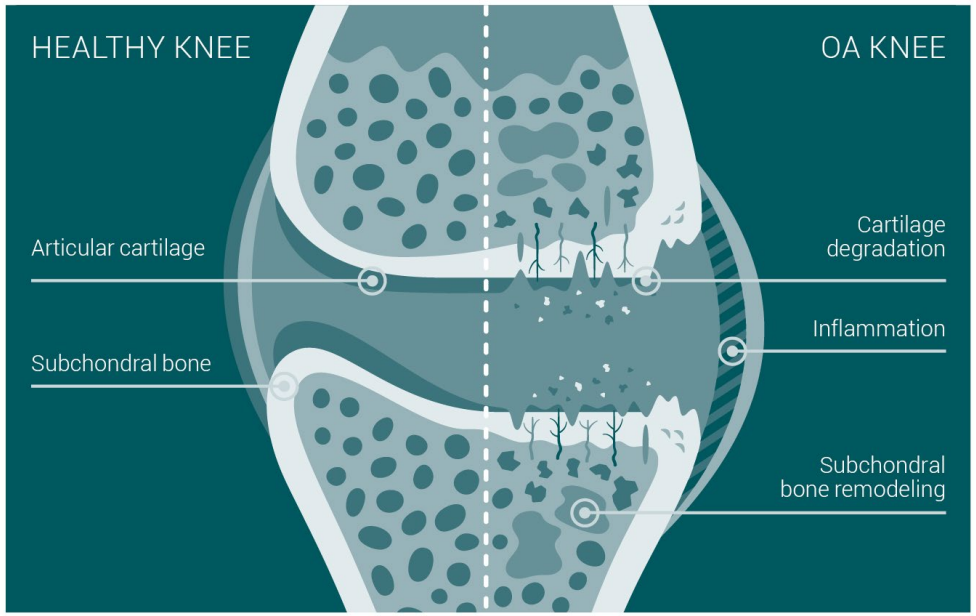
Successful placebo controlled phase II study of MIV-711 in OA:

- 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



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Other partnering opportunitites

- We are currently looking for "new homes" for all preclinical projects that were paused in connection with our strategic redirection:
  - One of the assets have entered into an option deal with a biotech company

- As disclosed last Monday, we have also entered into a license agreement for Chinese rights with Yuanmai Biotech with our product Xerclear® for labial herpes

Q&A

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