CANCERFORSKNING I FRONTLINJE – TEMADAG EPB

STOCKHOLM

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Executive summary

Proprietary clinical asset

- MIV-818 – A liver directed nucleotide prodrug
- In phase Ib clinical development
- Opportunities for breakthrough oncology indications

The company

- Building on an experienced leadership team and effective organization
- Focus on clinical development in unmet oncology indications

Multiple programs for partnering/out-licensing

- Remetinostat, Birinapant and MIV-711

Founded: 1988
Listed: Nasdaq Stockholm
Location: Stockholm
Cash position: c. SEK 95M[1)]
Market Cap: SEK 335M[2)]
FTE: 9

1) Q2 report
2) 2020-09-28

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Focused clinical program

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

Multiple programs for partnering/out-licensing

Compound	Mechanism	Indication	Phase I	Phase II	Phase III	Exclusivity
Remetinostat	Topical HDAC	MF-CTCL[1)] SCC BCC				IP : 2034
Birinapant	SMAC mimetic	HNCC[2)]				IP : 2034
MIV-711	Cathepsin K inhibitor	OA[3)]				IP : 2034

1) Indications: basal cell carcinoma, squamous cell carcinoma, mycosis fungoides cutaneous T-cell lymphoma (phase III ready)
2) Head and neck cancer
3) Osteoarthritis

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Investigator sponsored studies Ongoing studies

MIV-818
Mode of action and preclinical data

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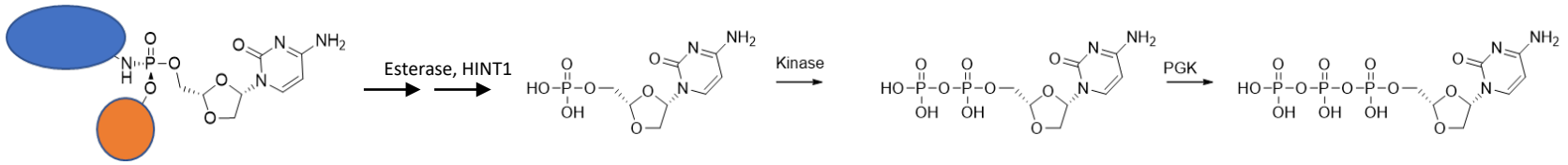
MIV-818: A liver-directed nucleotide

- 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)

TRX-TP



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Troxacitabine - Background

- Developed by Shire Biochem Inc. and SGX pharmaceuticals
- Nucleoside analogue with anticancer activity
- Administration route, intravenous injection
- More than 700 patients have received the drug in phase I/II/III trials
- In a 48 patient phase I/II trial in AML, 5 patients achieved complete response
  - FDA: Fast Track Designation based on the phase I/II data
- Phase II/III in 3rd line AML was initiated in 2005
  - 2006: DSMB recommends to discontinue the trial due to lack of response
  - *i.v.* administration creates a narrow therapeutic window → suboptimal exposure
- Lilly acquires SGX pharmacetuicals, 2008

AML – acute myelogenous leukemia; DSMB – Data safety and monitoring board
Source: 2005 SGX Pharmaceuticals S-1 filing, 2006 DEOXYNUCLEOSIDE ANALOGS IN CANCER THERAPY

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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 a 100-fold higher liver targeting than troxacitabine

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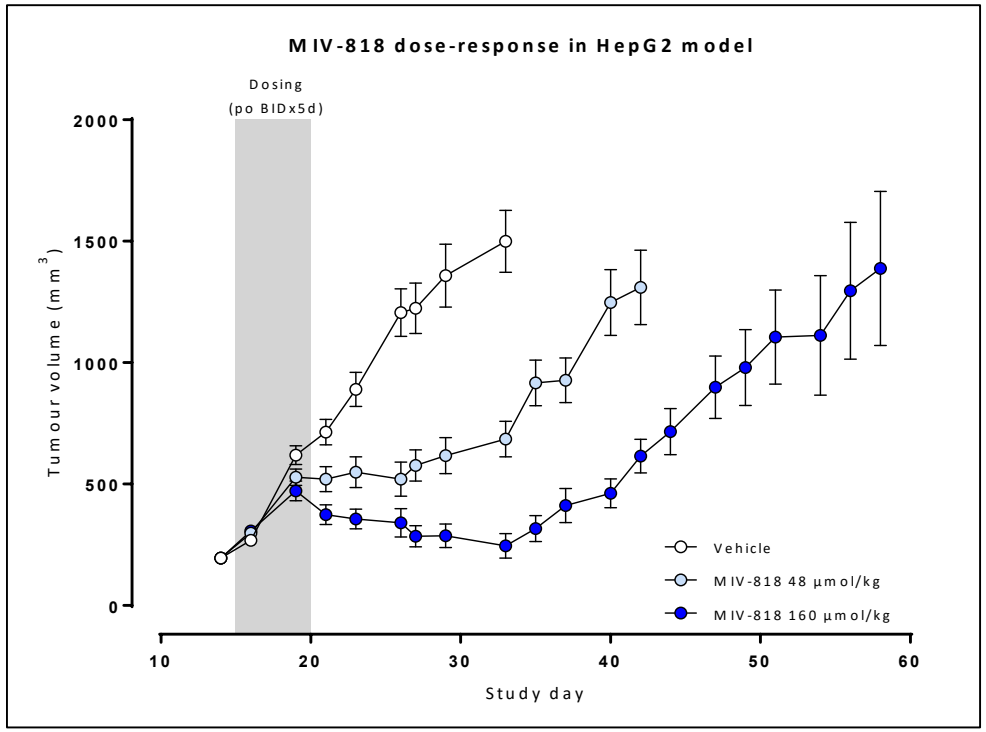
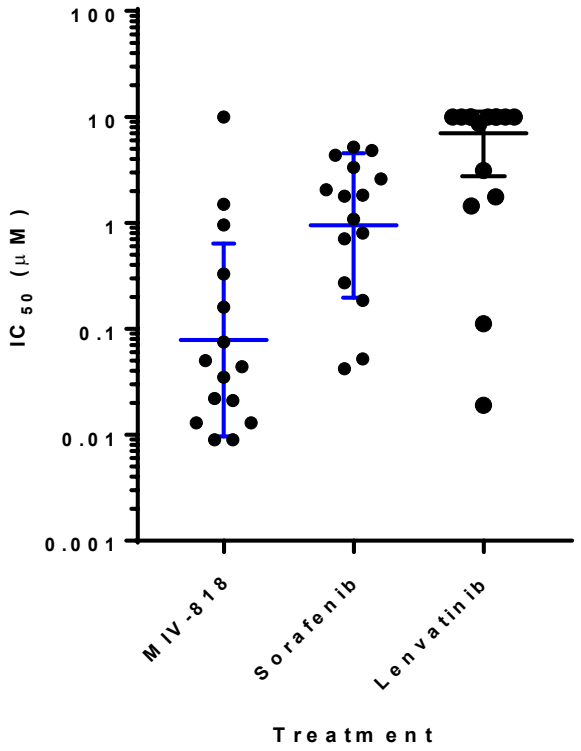
MIV-818 shows efficacy in preclinical HCC models

Inhibition of tumor growth in mouse HCC xenograft models in vivo



Inhibition of patient-derived HCC cell lines in vitro



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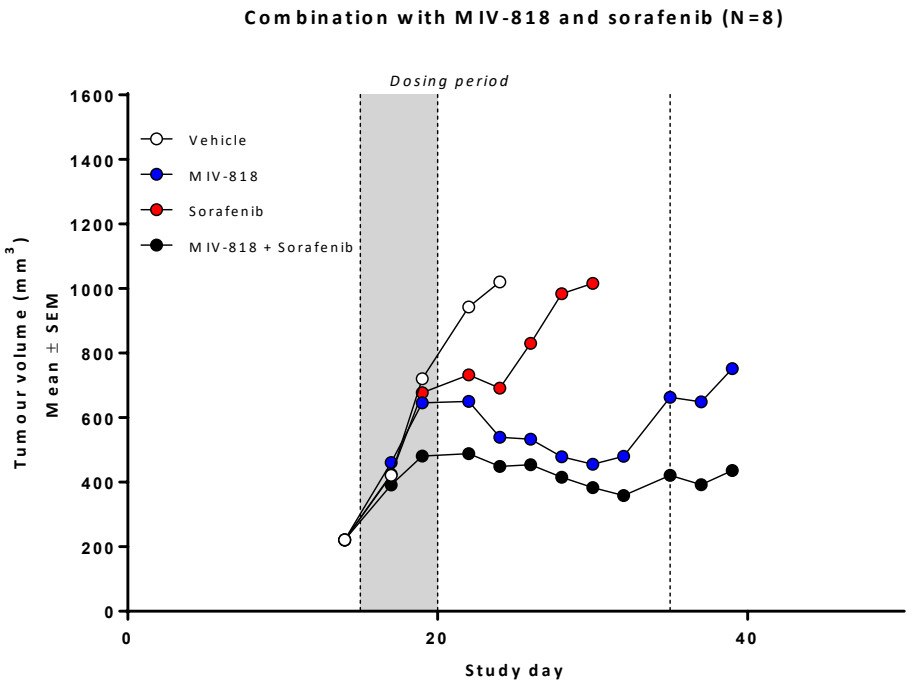
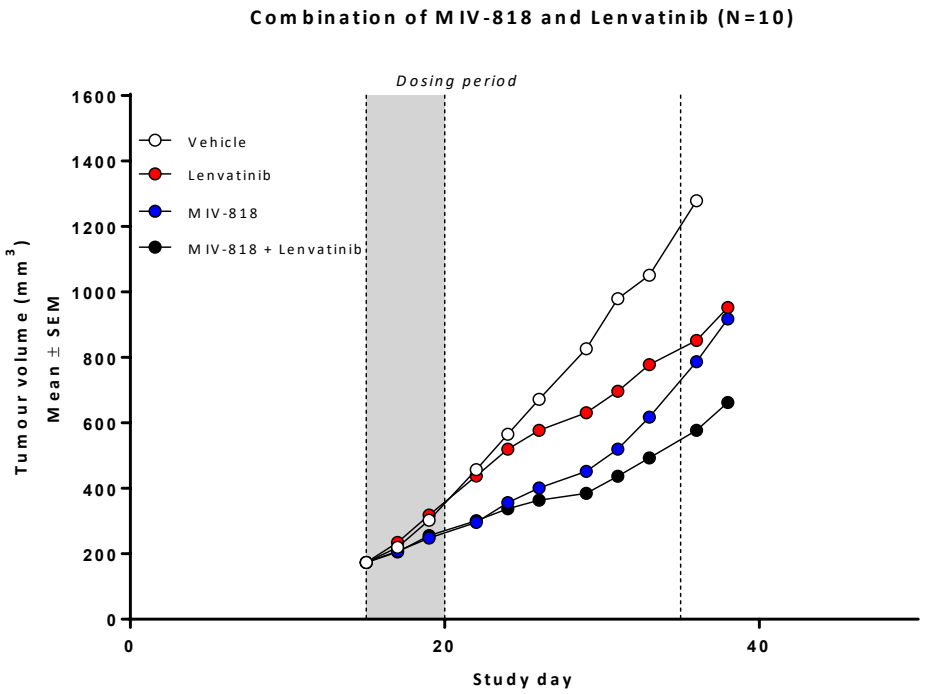
MIV-818: enhanced anti-tumor effect in combination with MKI in preclinical HCC models



Dosing (HepG2 xenograft model):

- MIV-818 100mg/kg BID 5 days
- Lenvatinib 30mg/kg QD 21 days



Dosing (HepG2 xenograft model):

- MIV-818 30mg/kg BID 5 days
- Lenvatinib 3mg/kg QD 21 days

MKI – Multi kinase inhibitor

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Summary

- Preclinical evidence of increased liver targeting with MIV-818 vs *i.v.* troxacitabine
- 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

MIV-818
Clinical development

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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 Hepatocellular carcinoma (HCC), Intra hepatic cholangiocarcinoma (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, plasma PK and PD

Patient characteristics:

- Nine patients were enrolled and evaluated: 2 HCC, 1 iCCA and 6 Liver metastatic disease

Sites:

Three sites, 2 in United Kingdom and 1 in Belgium

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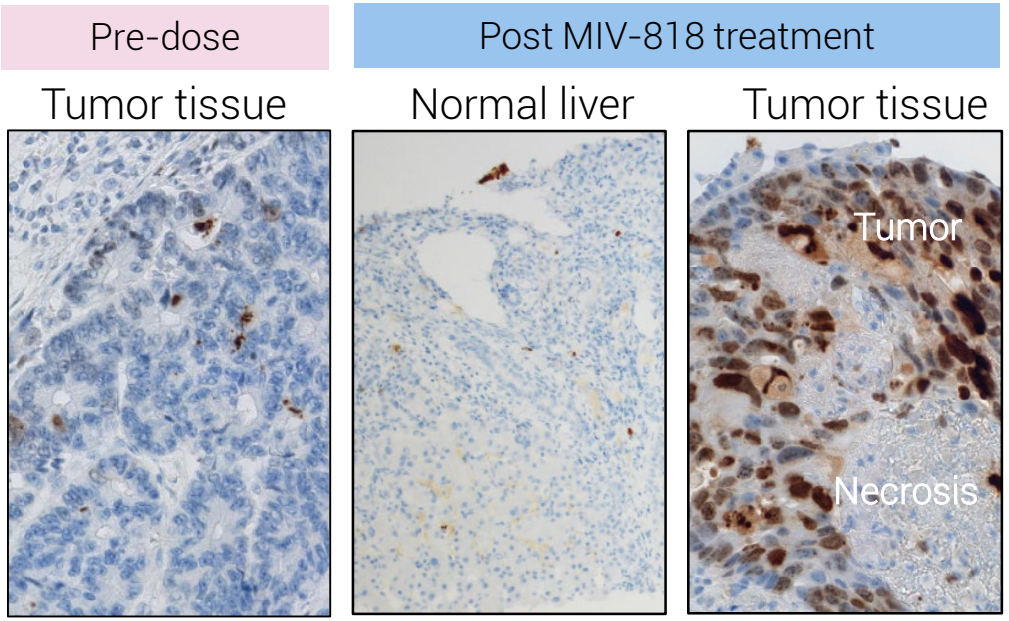
MIV-818: Selective effect signal in liver cancer in phase Ia

- Clear signs of cell death, measured as DNA damage, observed in liver biopsies from tumor tissue in MIV-818 treated patients
- The tumor selective effect is an early proof-of-concept of the intended liver-directed effect in patients



Evidence of DNA damage (brown coloring) in tumor but not in normal liver tissue

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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 in this heavily pre-treated population

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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
Part A will be conducted as a monotherapy and Part B as add-on to SoC
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

SoC = Standard of Care

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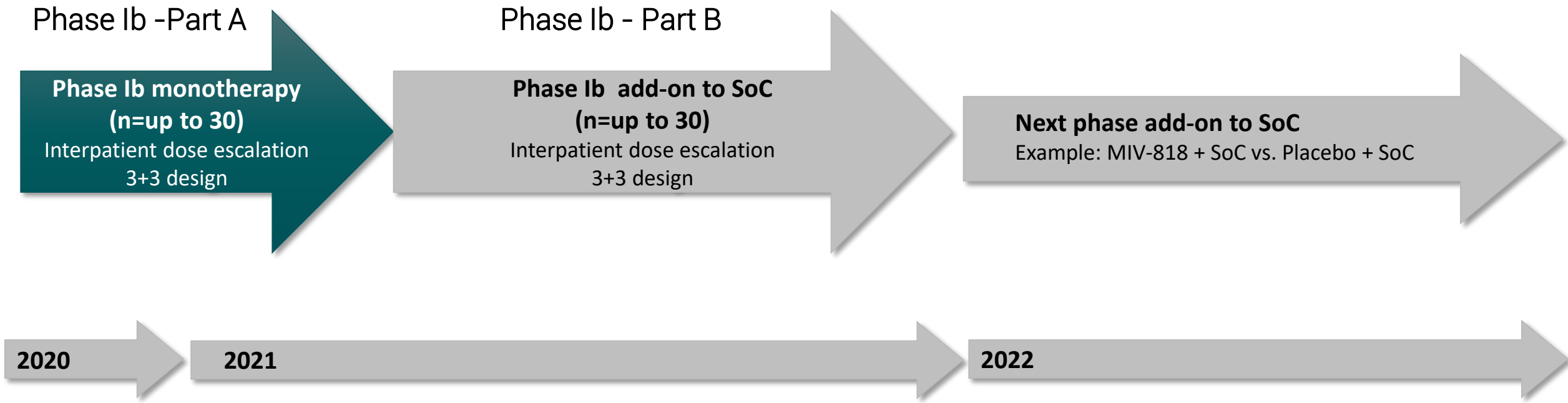
MIV-818: Clinical development plan in advanced liver cancer



SoC = Standard of Care

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The liver cancer therapeutics market

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Potential target populations

	US	5EU	7MM/8MM
Intrahepatic CCA (iCCA)			
Diagnosed incident cases	5,000	5,500	12,500[1]
Diagnosed prevalent cases	7,000	8,000	18,000[1]
HCC			
Diagnosed incident cases	28,000	43,000	105,000[1]
Diagnosed prevalent cases	38,000	59,000	155,000[1]
Colorectal cancer			
Diagnosed incident cases	140,000	250,000	875,000[2]
Diagnosed prevalent cases	480,000	765,000	2,800,000[2]

- iCCA and HCC are indications with cancer in the liver
- iCCA and HCC are orphan indications
- Company has received orphan designation for HCC in the US and EU

- One of the most common sites for metastasis in metastatic colorectal cancer is the liver

[1] 7MM = Seven Major Markets (US, UK, Germany, France, Italy, Spain, Japan)
[2] 8MM = US, France, Germany, Spain, Italy, UK, Japan, China
Source: DRG (Decision Resources Group), GlobalData, Datamonitor

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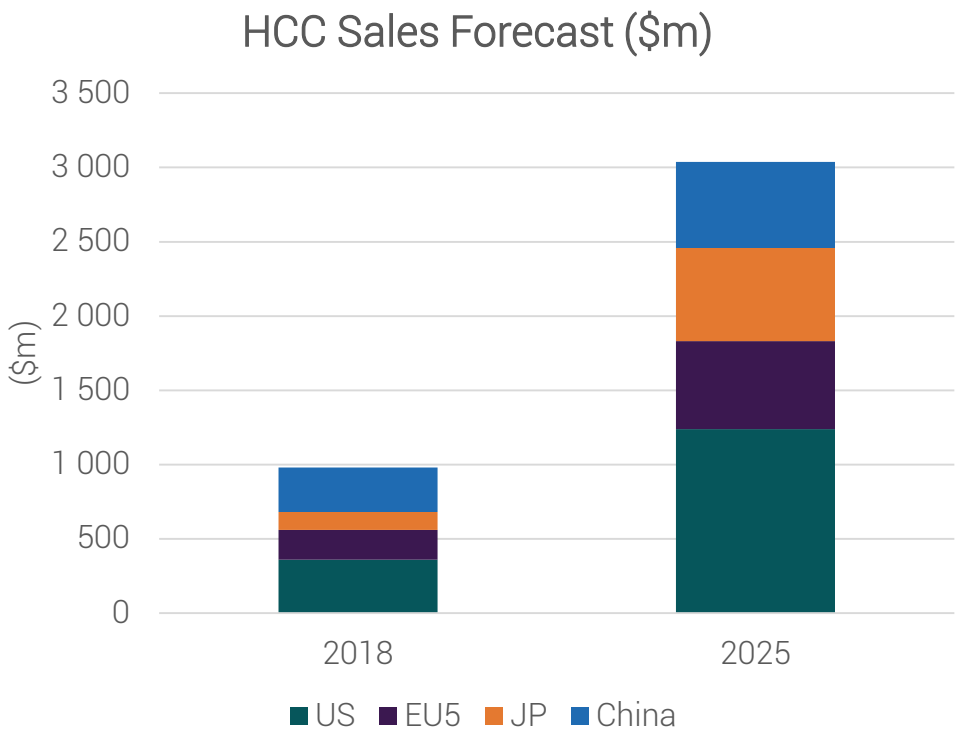
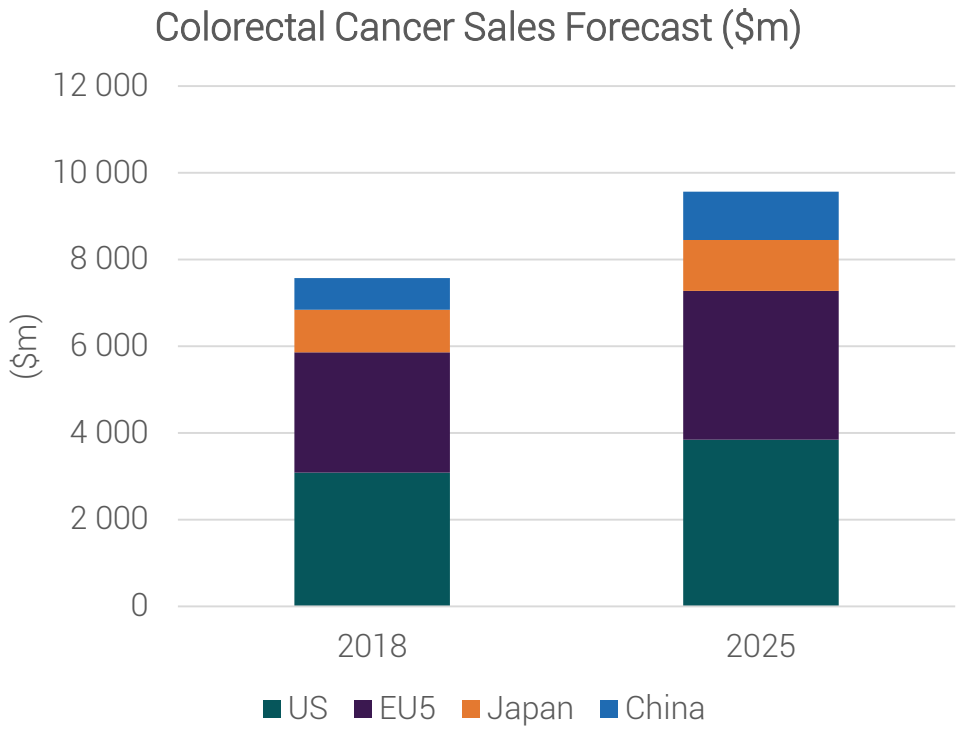
Global market for HCC and Colorectal cancer





- HCC sales in 8 major markets are estimated to USD 3Bn in 2025
- Colorectal cancer markets sales in 8 major markets estimated to ca USD 9.5Bn in 2025

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

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MIV-818 has a unique profile

- Unique profile vs approved drugs in iCCA, HCC and CRC
- DNA-breaking, small-molecular approach, which selectively reaches all tumour cells irrespective of genetic cause.
- 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

Other assets

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Multiple programs for partnering/out-licensing

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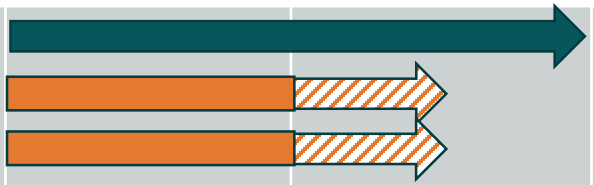
Remetinostat	Topical HDAC	MF-CTCL[1)] SCC BCC				IP : 2034
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Partnering deals executed in 2020

- Preclinical research deal with Tango Therapeutics
- Entered into a license agreement for Chinese rights with Yuanmai Biotech with our product Xerclear® for labial herpes
- Option agreement with a biotech company for an undisclosed preclinical research project

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Proprietary clinical asset

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- In phase Ib clinical development,
- Data from part A expected in Q1-2021

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[2)] 2020-09-28

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