



MEDIVIR Q2 2021 WEBCAST

AUGUST 19, 2021

MEDIVIR

Today's presenters

Interim CEO and Chief
Financial Officer



Magnus Christensen

Chief Scientific Officer



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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

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 248M¹⁾

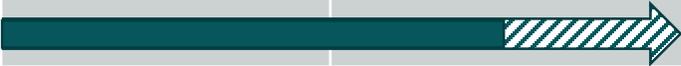
Market Cap: SEK 624M²⁾

FTE: 8

1) Q2 report

2) 2021-08-18

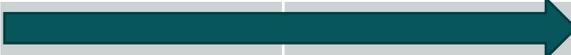
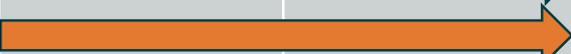
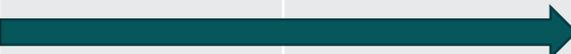
Focused clinical program

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 ²⁾				IP : 2034

Multiple clinical programs for partnering/out-licensing

Compound	Mechanism	Indication	Phase I	Phase II	Phase III	Exclusivity
Remetinostat	Topical HDAC	MF-CTCL ¹⁾ BCC				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 squamous cell carcinoma

3) Osteoarthritis

Financial highlights

Financial summary Q2

Consolidated Income Statement, summary

(SEK m)

	Q2		Q1 - Q2		Full year
	2021	2020	2021	2020	2020
Net turnover	0.9	4.0	10.8	11.4	13.9
Other operating income	0.5	0.6	8.0	0.6	27.3
Total income	1.4	4.6	18.8	11.9	41.3
Other external expenses	-13.1	-10.5	-31.9	-31.2	-52.9
Personnel costs	-5.4	-6.5	-11.2	-13.9	-24.9
Depreciations and write-downs	-0.7	-1.2	-1.4	-2.7	-4.4
Other operating expenses	-	-	-	-	-1.9
Operating profit/loss	-17.8	-13.6	-25.7	-35.8	-42.9
Net financial items	0.4	0.9	0.3	-0.3	0.3
Profit/loss after financial items	-17.4	-12.7	-25.4	-36.1	-42.6
Tax	0.0	-	-0.1	-	-
Net profit/loss for the period	-17.4	-12.7	-25.5	-36.1	-42.6

- Net turnover for Q2 2021 was SEK 0.9 million compared to SEK 4.0 million
- Loss for the Q2 2021 was SEK -17.4 million compared to SEK -12.7 million
- Cash flow from operating activities for Q2 2021 was SEK -21.9 million compared to SEK -23.3 million
- Cash balance end of Q2 2021 was SEK 248 million compared to SEK 95 million

Remetinostat revenue share agreement

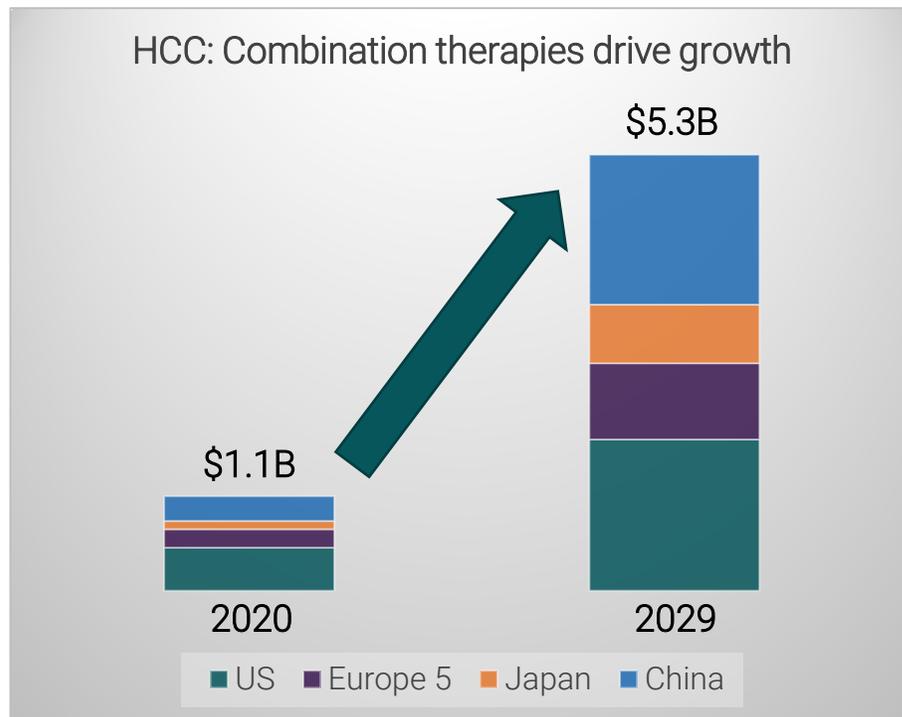
Remetinostat revenue share agreement

- Medivir acquired Remetinostat from TetraLogic in 2016. The original arrangements between Medivir and the Stakeholders included milestone payments with predetermined amounts as well as royalty obligations to the Stakeholders when Medivir develops, markets or out-licenses remetinostat.
- The original agreement has been renegotiated so that the compensation Medivir is obliged to pay in a potential future out-licensing of remetinostat is based solely on the distribution of actual future revenues to Medivir.
- Creates significantly improved conditions for a potential out-licensing or sale in our continued business development efforts related to remetinostat.

MIV-818 — *for the treatment of liver cancer*

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

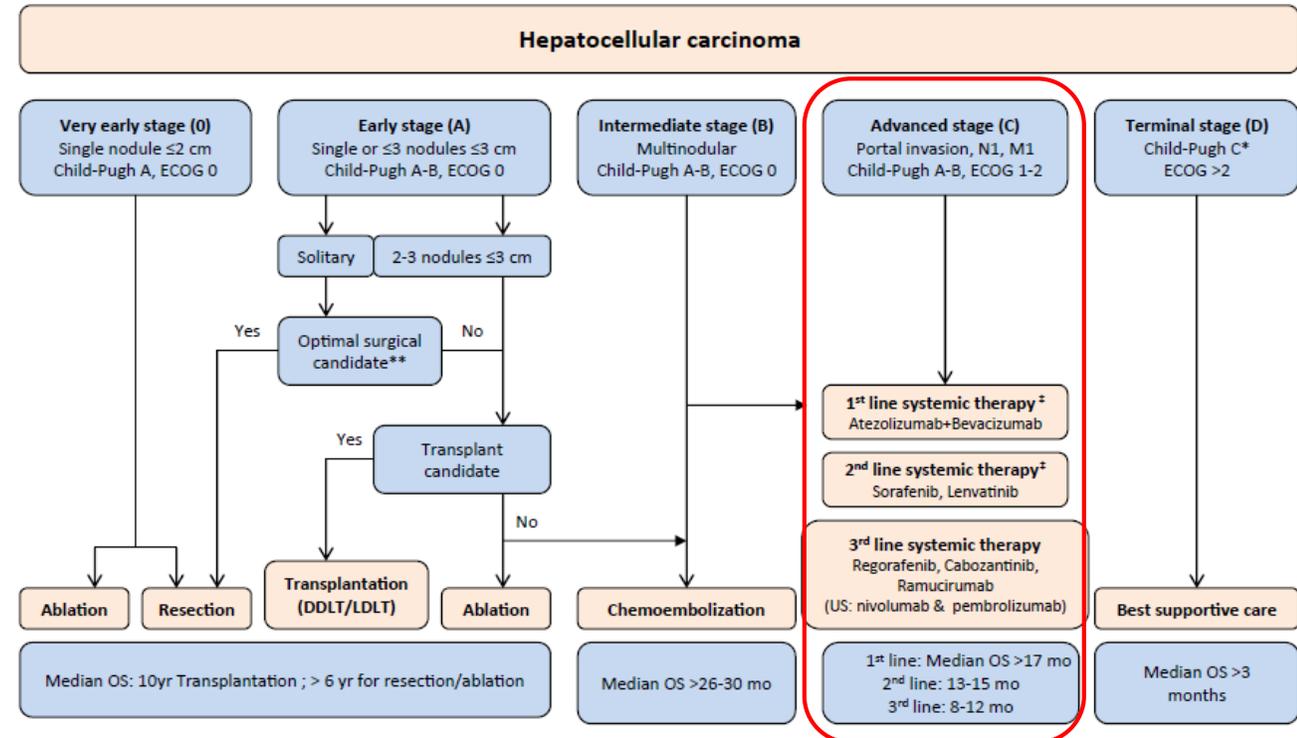
HCC Epidemiology and current treatments

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 has 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

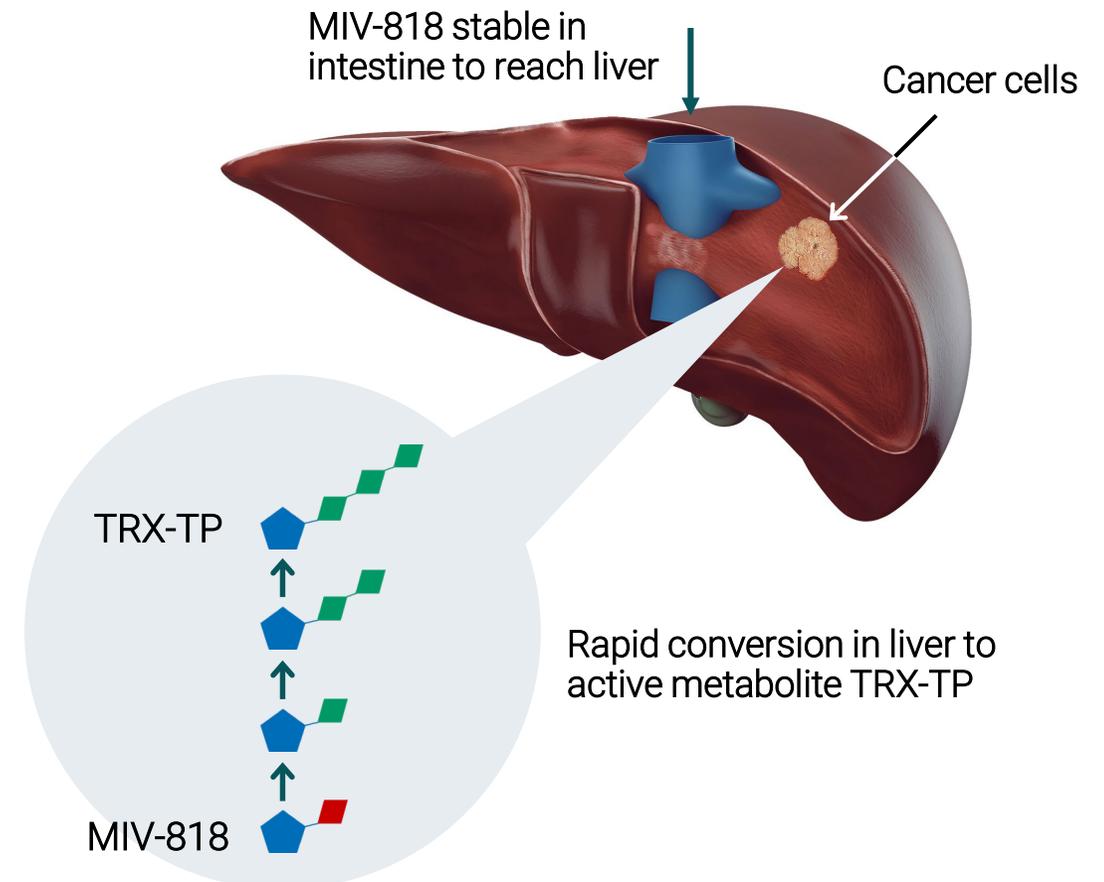
Liver targeting to deliver high levels of the active metabolite to the liver

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

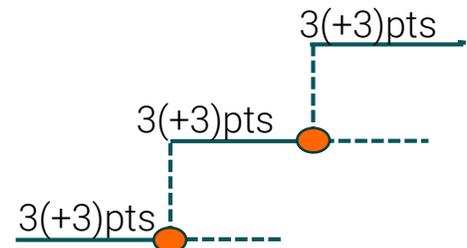
MIV-818 + Lenvatinib
dose escalation in HCC

MIV-818 + Pembrolizumab
dose escalation in HCC

MIV-818 + Lenvatinib
dose expansion in HCC

MIV-818 + Pembrolizumab
dose expansion in HCC

Completed



2021

2022

2023

MIV-818 summary

We continue to advance the MIV-818 clinical development programme

- The 1b monotherapy study, which enrolled late stage patients with HCC, iCCA and metastatic liver disease, has been completed. The recommended phase 2 monotherapy dose (RPD2) was 40 mg
- We will present phase 1b monotherapy data at the ESMO Congress 16-21 September 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, and the study is planned to be conducted in Europe and Asia

Other assets

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 ¹⁾ BCC, SCC				IP : 2034
MIV-711	Cathepsin K inhibitor	OA ²⁾				IP : 2034

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

2) Osteoarthritis

Upcoming milestones, H2 2021

MIV-818: Data from phase 1b monotherapy ESMO	Q3 2021
MIV-818: First patient in combination study expected to be enrolled	H2 2021
Birinapant: IGM plan to start a combination study with birinapant and IGM-8444	H2 2021

Q/A