

# Today's presenters

Interim CEO and Chief Financial Officer



Magnus Christensen

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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/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 226M<sup>1)</sup>

Market Cap: SEK 528M<sup>2)</sup>

FTE: 9

- 1) Q3 report
- 2) 2021-11-03



### 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	Solid tumors			<b>ESIGN</b> biosciences*	IP: 2034

#### Multiple clinical programs for partnering/out-licensing

Compound	Mechanism	Indication	Phase I	Phase II	Phase III	Exclusivity
Remetinostat	Topical HDAC	MF-CTCL <sup>1)</sup> BCC, SCC				IP: 2034
MIV-711	Cathepsin K inhibitor	OA <sup>2)</sup>				IP: 2034

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

<sup>2)</sup> Osteoarthritis







# Q3 highlights **MEDIVIR** Slide 8

## Q3 Highlights

- Malene Jensen joined Medivir as Vice President Clinical Development
- Positive results from the phase II study with remetinostat against basal cell carcinoma (BCC) were published
- Strengthens the business development potential for remetinostat through a renegotiated multi-party agreement
- Regulatory approval from the British UK Medicines & Healthcare products Regulatory Agency (MHRA) for the upcoming phase 1b/2a combination study with MIV-818 against liver cancer.
- The results from the completed dose escalation part of the phase 1b monotherapy study with MIV-818 were presented at ESMO Congress
- After Q3, the Board of Directors appointed Jens Lindberg as new CEO of Medivir

# Financial highlights **MEDIVIR** Slide 10

## Financial summary Q3

Consolidated Income Statement, summary	Q3		Q1 - Q3		Full year
(SEK m)	2021	2020	2021	2020	2020
Net turnover	0.8	1.1	11.6	12.5	13.9
Other operating income	0.9	15.7	8.9	16.3	27.3
Total income	1.7	16.8	20.5	28.7	41.3
Other external expenses	-9.4	-6.6	-41.2	-37.8	-52.9
Personnel costs	-4.0	-4.9	-15.3	-18.7	-24.9
Depreciations and write-downs	-0.6	-1.1	-2.0	-3.8	-4.4
Other operating expenses	-		-		1.9
Operating profit/loss	-12.3	4.2	-38.0	-31.6	-42.9
Net financial items	-0.5	0.5	-0.2	0.1	0.3
Profit/loss after financial items	-12.8	4.6	-38.3	-31.5	-42.6
Tax	-0.5		-0.6		
Net profit/loss for the period	-13.3	4.6	-38.8	-31.5	-42.6

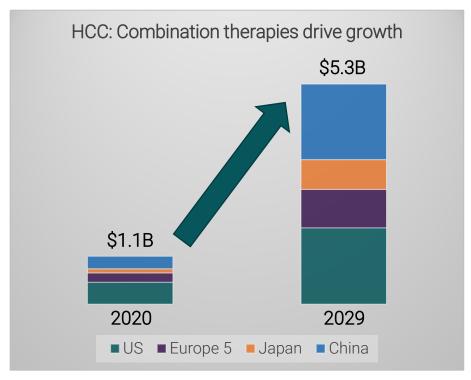
- Net turnover for Q3 2021 was SEK 0.8 million compared to SEK 1.1 million
- Loss for the Q3 2021 was SEK -12.3 million compared to SEK 4.2 million
- Cash flow from operating activities for Q3 2021 was SEK -20.0 million compared to SEK -17.1 million
- Cash balance end of Q3 2021 was SEK 226 million compared to SEK 83 million



# MIV-818 — for the treatment of liver cancer

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# Hepatocellular carcinoma (HCC) is a growing market



Source: GlobalData 2021

- Continued very high unmet medical need in HCC
  - o Despite recent advances in treatment of HCC, there is still a large group of patients that do not respond to or are intolerant to current treatments
- The HCC market growth is driven by;
  - Combination therapies (especially immuno-oncology combinations)
  - More patients receiving therapy when patients are treated in earlier disease stages
- Liver cancer incidence and mortality are increasing and 5-year survival for those with advanced disease is less than 3% (https://seer.cancer.gov/statfacts/html/livibd.htm)

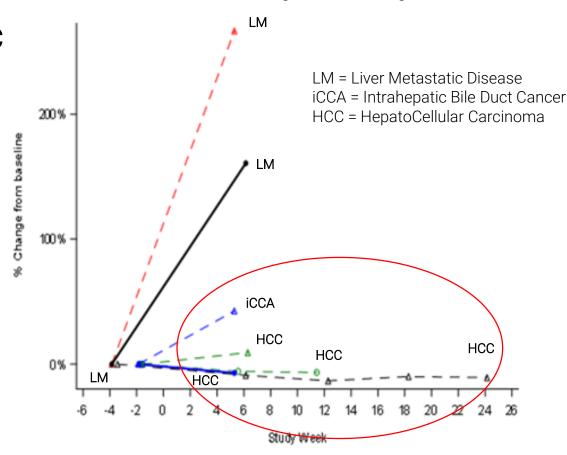


#### Phase 1b monotherapy results presented at ESMO

Phase 1b change in liver target lesions\*

#### Supports continued development of MIV-818 in HCC

- Decreases in blood cell counts were the most common side effects, these resolved quickly
- In phase 1b four patients out of seven with primary liver cancer (e.g. HCC, iCCA) had stable disease as best overall response; one stayed on treatment for eight months
- Liver biopsy data has demonstrated delivery of MIV-818 to the liver, and a selective effect of MIV-818 on cancer cells vs normal liver tissue, across different types of cancer



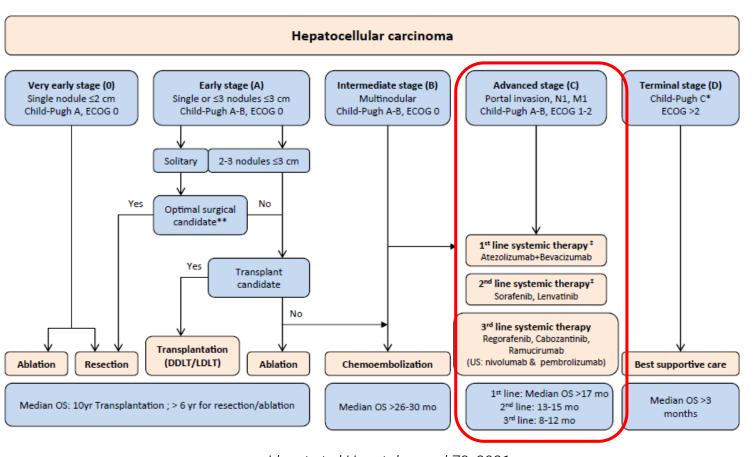
\*Out of 10 enrolled patients, one did not complete safety follow up and one lacked independent radiologist assessment



#### HCC Epidemiology and current treatments

Primary liver cancers: 850,000 cases worldwide annually

- 90% are hepatocellular carcinoma (HCC)
- 3rd leading cause of cancer-related death, with 600,000 deaths wordwide



Llovet et al Hepatology vol 73, 2021



### MIV-818 – A new unique tool in HCC

Current development pipeline of new HCC-therapies consists of a variation of combination trials with two main mechanisms of actions

Stimulation of immune system

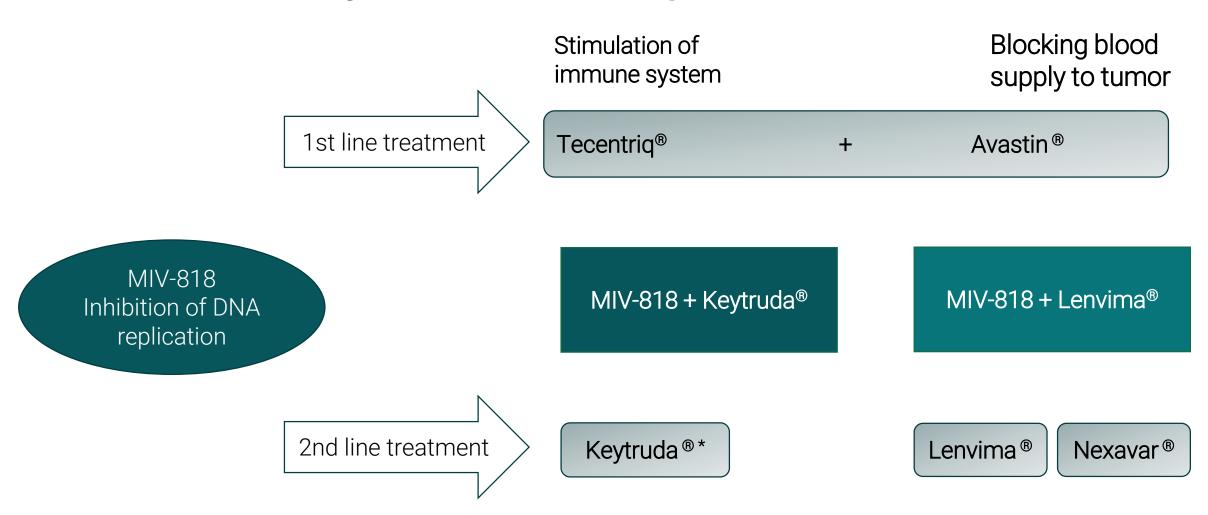
Marketed drugs (aPD1/PD-L1): Keytruda<sup>®</sup> Opdivo<sup>®</sup> Tecentrig<sup>®</sup> Blocking blood supply to tumor\*

#### Marketed drugs:

Lenvima® (Tyrosine Kinase) Nexavar® (Tyrosine Kinase) Avastin® (anti-Vascular Endothelial Growth Factor)



# MIV-818 - aiming to be the new improved second line treatment

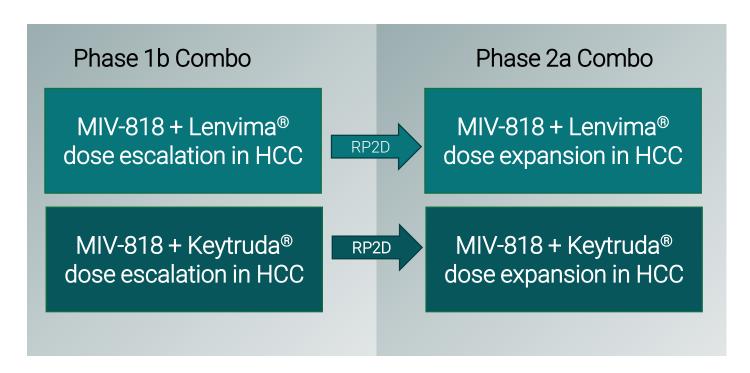




## Upcoming phase 1b/2a combination study in 2nd line HCC

#### Patient population to be studied

- advanced inoperable HCC
- progressed on or intolerant of first line standard therapy for HCC
- candidates for Keytruda<sup>®</sup> or Lenvima<sup>®</sup> treatment



#### On track to initiate the combination study in 2021 as planned

Combination study with MIV-818 has been approved in UK, where additional sites will be opened, and we also plan to open sites in Spain and South Korea



# MIV-818 – Key advantages

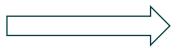
Once daily oral dosing

Targeting the liver

Bypasses resistance through the pro-drug approach

Unique Mechanism of Action









Patient convenience

Tumor selective for liver cancer

Increased efficacy

Attractive for combinations



# Upcoming milestones 2021

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### **Upcoming milestones 2021**

MIV-818: First patient in combination study expected to be enrolled 2021

Birinapant: IGM plan to start a combination study with birinapant and IGM-8444 2021



