



# MEDIVIR Q4 2021 WEBCAST

FEBRUARY 15, 2022

**MEDIVIR**

# Today's presenters



CEO

- Jens Lindberg
- Joined Medivir 2022
- > 25 years pharma experience with focus in Oncology.
- Has led global product strategy development for late-stage compounds as well as product launch for multiple compounds.
- Experience includes interim CEO role for Sedana Medical AB.
- Medivir ownership; 0 shares & 240.000 warrants



CFO

- Magnus Christensen
- Joined Medivir 2019
- > 20 years experience in finance, including CFO at O'Learys Trademark AB.
- Previous interim CEO at Medivir
- Experience of working in listed-, private equity- and private companies.
- Medivir ownership; 15.000 shares & 172.500 warrants



CSO

- Fredrik Öberg
- Joined Medivir 2011
- > 25 years experience in cancer research from industry and academia
- > 50 scientific articles and holds several patents.
- Adjunct professor at Medical Faculty of Uppsala University
- Medivir ownership; 69.172 shares & 159.010 warrants

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# Today's agenda

1. Highlights since last quarterly report
2. CEO reflections with focus on MIV-818 / fostroxacitabine bralpamide
3. Financial highlights
4. Q/A

# Highlights since last quarterly report

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## Continued progress for lead asset

- Phase 1b/2a study initiated for MIV-818 in combination with either Keytruda® or Lenvima®.
- Biomarker data for MIV-818 monotherapy presented at EASL, supporting proof-of-concept
- MIV-818 awarded INN fostroxacitabine bralpamide, highlighting its unique MoA

## Overall portfolio development

- IGM Biosciences initiated clinical study with birinapant in combination with IGM-8444 (DR5) in patients with solid tumours – milestone MUSD 1.5
- Results from investigator-initiated phase II clinical study of remetinostat in patients with squamous cell carcinoma published

## People development

- Jens Lindberg assumed role of CEO for Medivir
- Recruitment process for permanent CMO initiated

CEO reflections – *with focus on MIV-818/  
fostroxacinabine bralpamide*

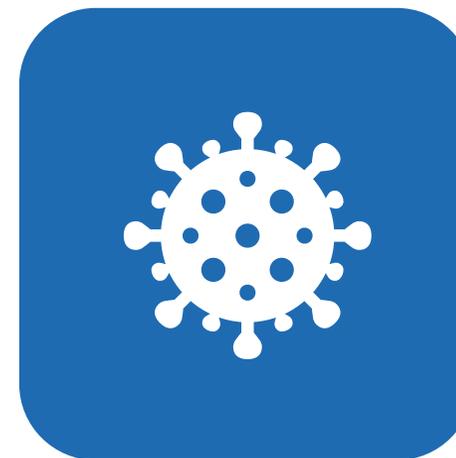
# Three key reasons why I am excited about joining Medivir



**Company in transformation  
with exciting lead asset**



**Experienced &  
engaged team**



**Return to Oncology**

# Medivir – a company with a clear mission & key priorities

Improving life for cancer patients through transformative drugs

1

Accelerate  
product development  
for lead asset MIV-818  
/fostroxacitibine  
bralpamide

2

Maximise value of  
assets for partnering  
& out-licensing

3

Inspiring  
place to work &  
an entrepreneurial  
company culture

# Three focus areas in pharmaceutical drug development



**Commercial potential  
& unmet need**



**Differentiation /  
uniqueness**



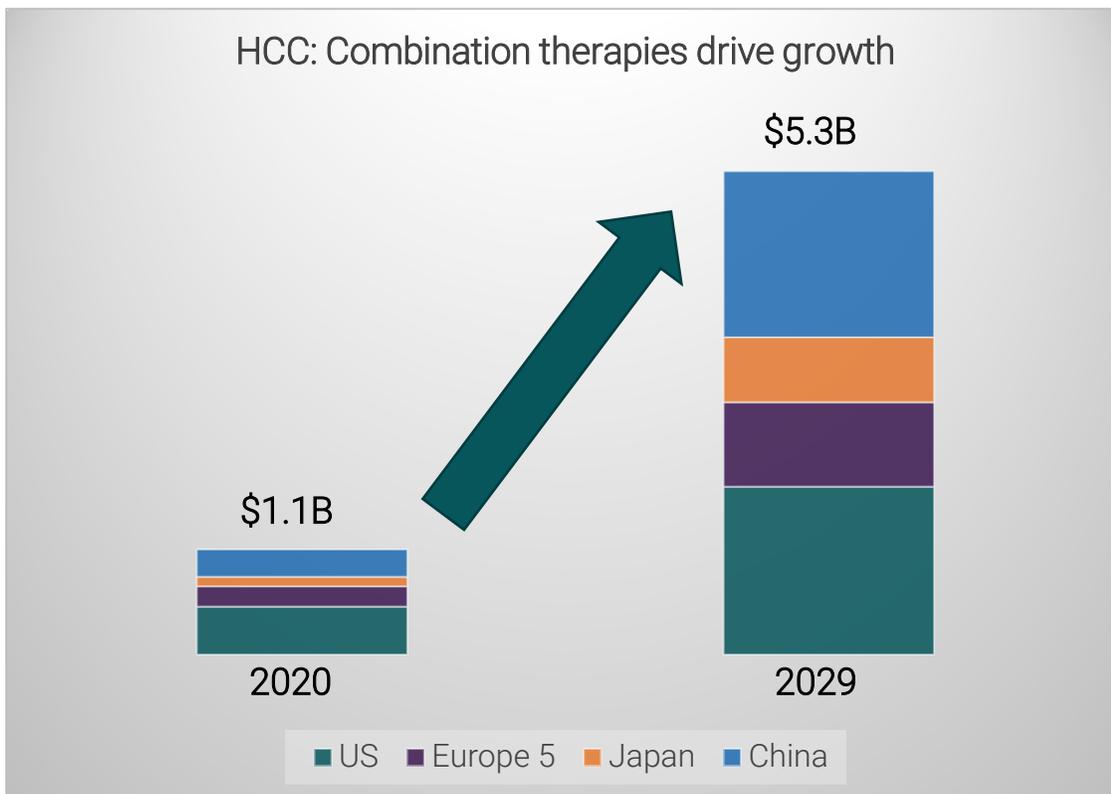
**Technical risk  
minimisation**



# HCC is a significantly growing market with large unmet need

HCC market estimated to grow almost five-fold until 2029

Despite recent advancements, unmet need is still high



- Liver cancer incidence and mortality are increasing and 5-year survival for those with advanced disease is less than 3%<sup>1</sup>
- Liver cancer is the third leading cause of cancer death worldwide<sup>2</sup>
- 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 and patients treated in earlier disease stages

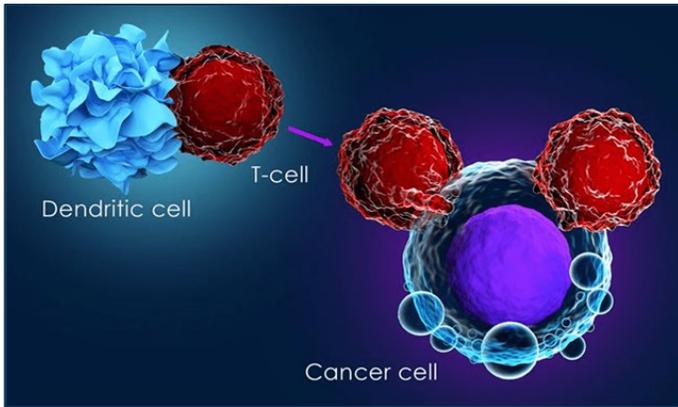
Source: GlobalData 2021

<sup>1</sup>(<https://seer.cancer.gov/statfacts/html/livibd.htm>)

<sup>2</sup> Sayiner M, et al. Digestive Diseases and Sciences. 2019; 64: 910-917

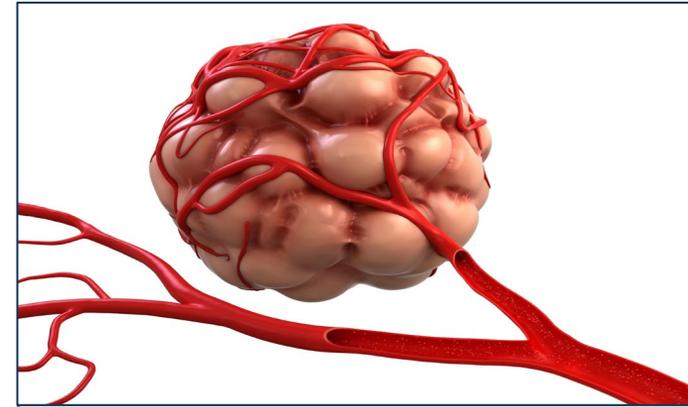
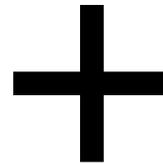


# Current pipeline of new HCC therapies consists of a variation of combination trials with two key mechanisms of actions



## Stimulation of immune system

- Keytruda (PD-1)
- Tezentriq (PD-L1)
- Opdivo (PD-1)
- Imfinzi (PD-L1)
- Yervoy (CTLA-4)
- Tremelimumab (CTLA-4)



## Blocking blood supply to tumor\*

- Avastin
- Nexavar
- Lenvima
- Stivarga
- Cometriq/Cabometyx

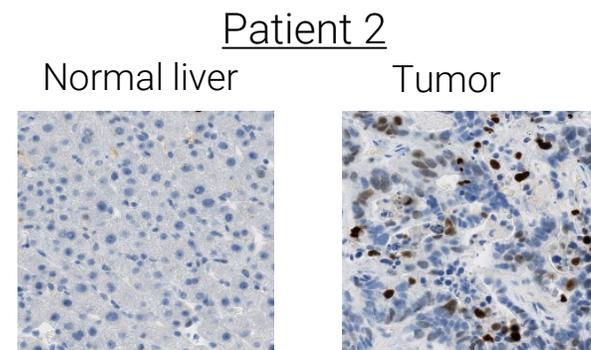
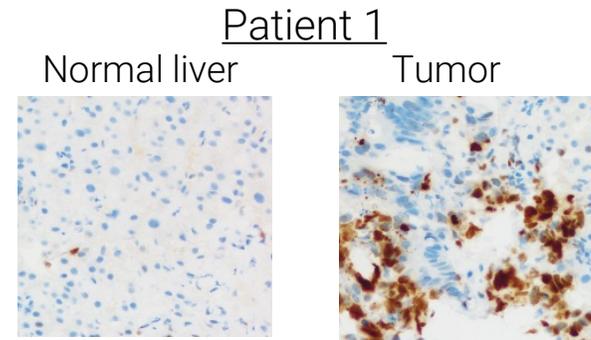
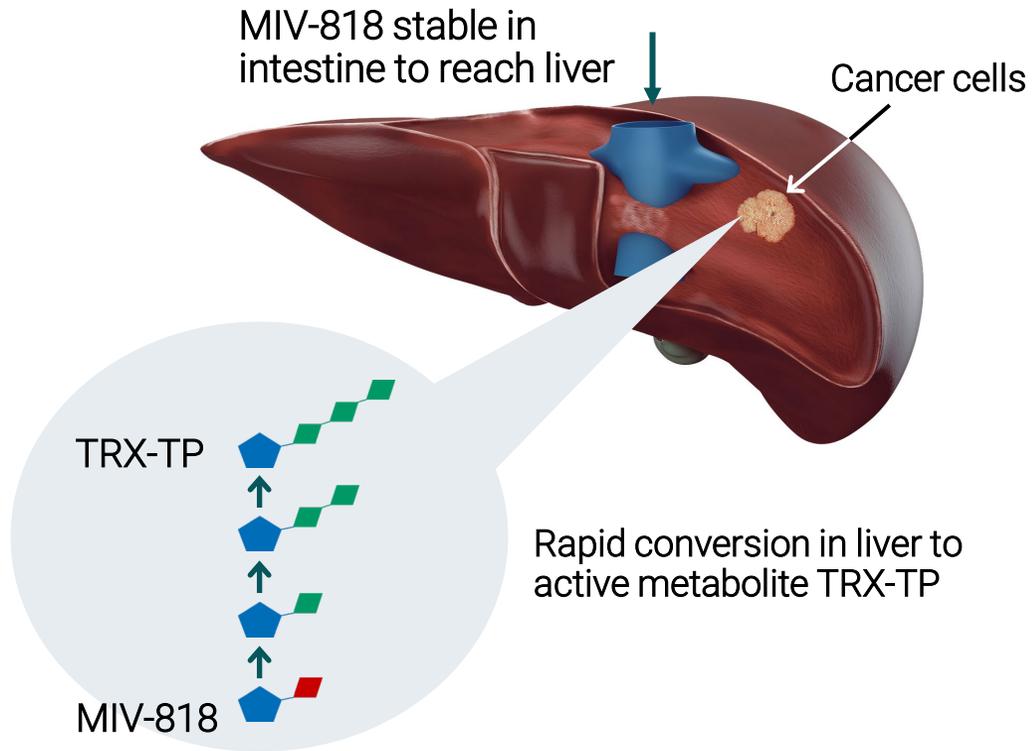
\*Some of these drugs are multifunctional and have additional functions



# Differentiated mechanism designed to have a targeted, tumor selective action in the liver

Designed to reach the liver & minimise systemic exposure

DNA-damage in tumour tissue but not in normal liver tissue\*



MIV-818 induced effect observed across different types of liver cancer

\*PD marker gH2AX (% positive cells/brown stain) shows MIV-818 induced DNA-damage in tumor cells and not normal liver tissue

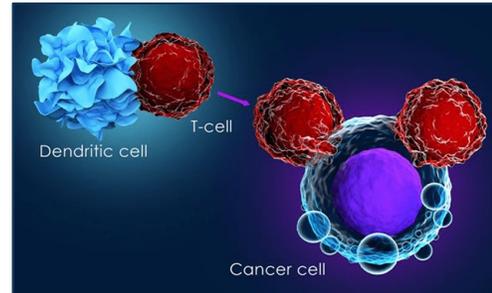


# A new, unique tool in HCC inhibiting DNA replication with strong potential for combinations

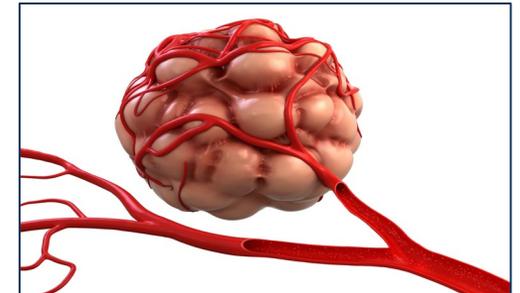
MIV-818 + stimulation of immune system (PD-1)

MIV-818 + blocking blood supply to tumor (TKI)

MIV-818 /  
fostroxacitabine  
bralpamide



MIV-818 /  
fostroxacitabine  
bralpamide



“MIV-818 induces DNA damage and tumor cell death, potentially leading to increased tumor antigen presentation and increased immune response”

“TKI’s induce lack of oxygen in tumours leading to increased PGK1\* expression and most importantly higher levels of MIV-818 active metabolite”

\*Phosphoglycerate kinase 1 – hypoxia inducible gene



# MIV-818 = fostroxacitabine bralpamide

No need for 1<sup>st</sup> phosphorylation providing increased potency & avoidance of resistance mechanisms with potential for a more optimal dose

The mechanism of action, inhibition of cancer cells DNA-replication and induction of DNA-damage & cell death is well established in cancer therapy

This type of pro drug has already successfully proven its targeted, clinical efficacy in the liver within anti-HCV treatment

Tried & tested mechanism of action minimizing technical risk

# MIV-818 – A unique, first-in-class potential treatment for primary liver cancer

## Commercial potential & unmet need



Significant unmet need; MIV-818 complementing, not replacing, existing therapies

## Differentiation / uniqueness



Unique MoA that selectively targets cancer in the liver with strong potential for combinations

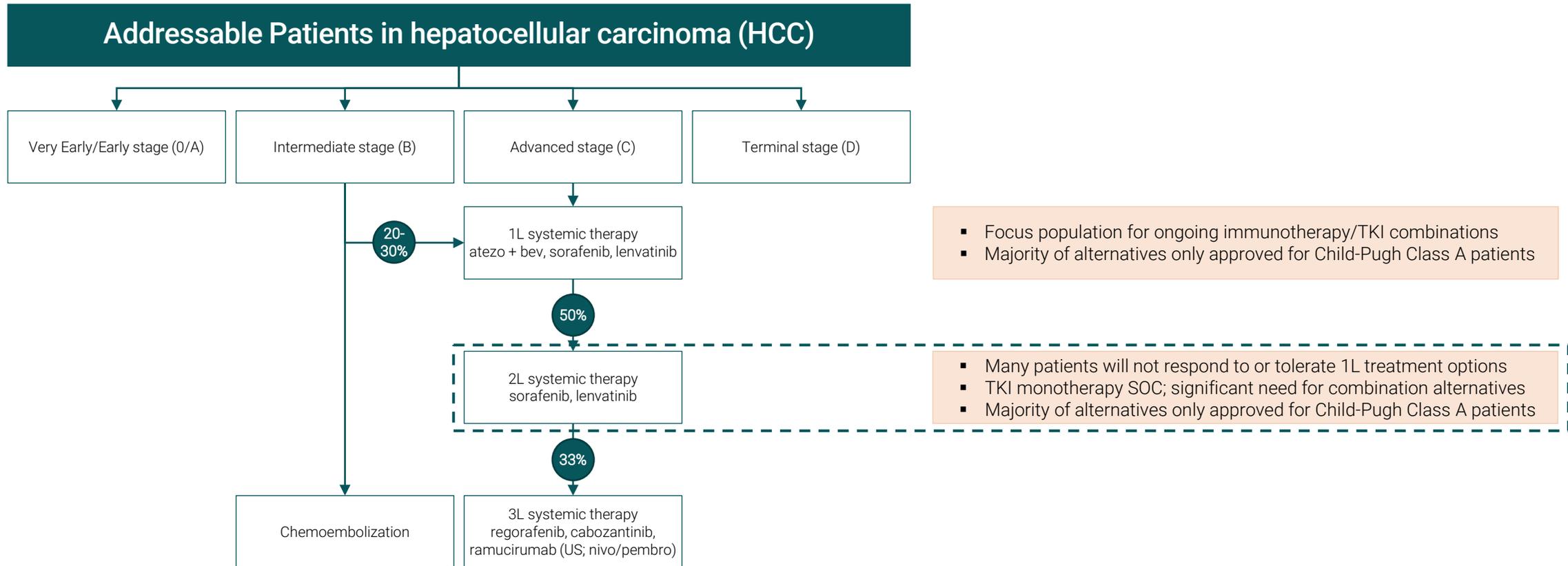
## Technical risk minimisation



Induction of DNA-damage & cell death already well established in cancer, confirmed by recent phase 1 data



# MIV-818 – Planned first market entry in 2L HCC, displacing TKI monotherapy

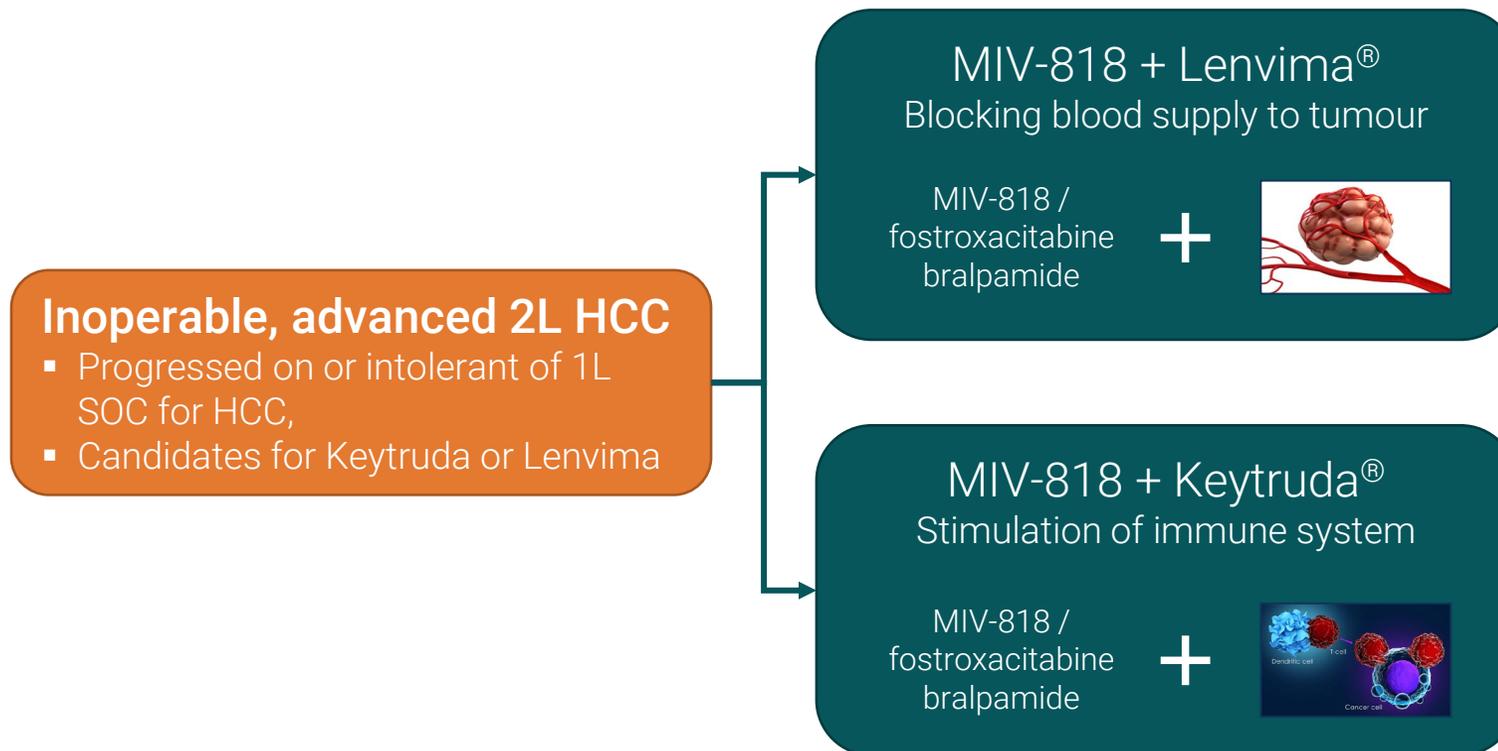




# Initial focus on 2L advanced HCC identifying the best possible combination(s)

Phase Ib/2a study to position MIV-818 as preferred combination option in 2L

Rationale for study design



- Unique, complementary mechanism of action
- 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
- Patients progressing on 1L atezo/bev combination eligible for inclusion in both arms

# Clinical Program Overview

## 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 |         |          |         | 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><br>BCC, SCC |         |          |           | IP : 2034   |
| MIV-711      | Cathepsin K inhibitor | OA <sup>2)</sup>                  |         |          |           | IP : 2034   |

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

2) Osteoarthritis

# Financial highlights Q4

# Financial summary Q4, 2021

## Consolidated Income Statement, summary

(SEK m)

|  | Q4           |              | Q1 - Q4      |              |
|--|--------------|--------------|--------------|--------------|
|  | 2021         | 2020         | 2021         | 2020         |
| Net turnover                             | 13.9         | 1.5          | 25.5         | 13.9         |
| Other operating income                   | 1.3          | 9.2          | 10.2         | 27.3         |
| <b>Total income</b>                      | <b>15.3</b>  | <b>10.7</b>  | <b>35.7</b>  | <b>41.3</b>  |
| Other external expenses                  | -32.0        | -15.1        | -73.3        | -52.9        |
| Personnel costs                          | -6.1         | -6.2         | -21.4        | -24.9        |
| Depreciations and write-downs            | -0.6         | -0.7         | -2.6         | -4.4         |
| Other operating expenses                 | -0.6         | -            | -0.6         | -1.9         |
| <b>Operating profit/loss</b>             | <b>-24.1</b> | <b>-11.3</b> | <b>-62.1</b> | <b>-42.9</b> |
| Net financial items                      | -0.3         | 0.1          | -0.5         | 0.3          |
| <b>Profit/loss after financial items</b> | <b>-24.3</b> | <b>-11.2</b> | <b>-62.6</b> | <b>-42.6</b> |
| Tax                                      | 0.0          | -            | -0.5         | -            |
| <b>Net profit/loss for the period</b>    | <b>-24.3</b> | <b>-11.2</b> | <b>-63.1</b> | <b>-42.6</b> |

- Net turnover for Q4 2021 was SEK 13.9 million compared to SEK 1.5 million.
- Operating loss for the Q4 2021 was SEK -24.1 million compared to SEK -11.3 million
- Cash flow from operating activities for Q4 2021 was SEK -5.4 million compared to SEK -1.0 million
- Cash balance end of Q4 2021 was SEK 221 million compared to SEK 70 million

# Highlights since last quarterly report

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Q/A

## Upcoming activity

- Erik Penser Bank Healthcare Day – February 24 at 15.50