



HANDELSBANKEN HEALTHY HOUR

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MEDIVIR

Today's presenters

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Executive summary

Medivir and recent events

Proprietary clinical asset MIV-818

- MIV-818 – Once daily orally dosed liver directed nucleotide prodrug
- Unique mechanism of action in the HCC space, makes it attractive to combine with other therapies

Recent events

- Strengthens the business development potential for remetinostat through a renegotiated multi-party agreement
- Supporting clinical data from the phase 1b monotherapy presented at EMSO
- Jens Lindberg appointed new CEO for Medivir
- Birinapant clinical study initiated by IGM Biosciences – milestone MUSD 1.5

Founded: 1988

Listed: Nasdaq OMX

Location: Stockholm

Cash position: SEK 226M¹⁾

Market Cap: SEK 628M²⁾

FTE: 9



1) Q3 report

2) 2021-11-19






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 (IGM-9427)	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 ¹⁾ BCC				IP : 2034
						
MIV-711	Cathepsin K inhibitor	Osteoarthritis				IP : 2034

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

Partnerships

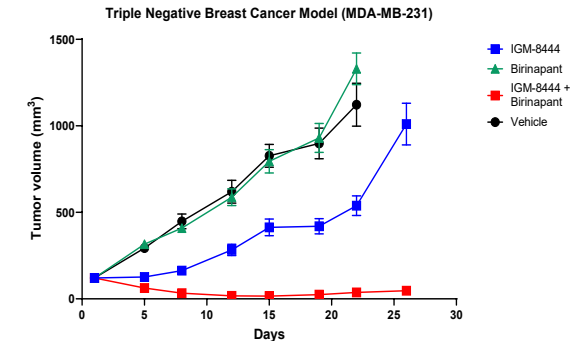
Delivering on our partnering strategy

Asset	Date	Partner(s)	Type of deal	Potential future revenues
Xerclear ¹⁾	Feb 2020	SYB	Outlicensing	Royalties
Malt1	Feb 2020	Rheos Medicines	Option	Option fee
USP-1	March 2020	Tango Therapeutics	Outlicensing	Milestones and royalties
Birinapant	Dec 2020	Tetralogic	Re-negotiated to enable an outlicensing deal	
Birinapant	Jan 2021	IGM Biosciences	Outlicensing	Milestones and royalties
USP-7	Feb 2021	Ubiquigent		Revenue share
Remetinostat	August 2021	Several stakeholders	Re-negotiated to enable an outlicensing deal	

1) Medivir receives royalties on Xerclear[®]/(Zoviduo[®]) European sales from Glaxosmithkline

Birinapant - Licensing agreement with IGM Biosciences

- IGM is a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies
- Birinapant will initially be combined with IGM-8444, a Death Receptor 5 (DR5) agonist being developed by IGM, which has demonstrated synergistic anti-tumor activity without added toxicity in several preclinical models
- Clinical testing of birinapant (IGM-9427) in combination with IGM-8444 has started
- Should birinapant be successfully developed and approved, Medivir is entitled to receive development, regulatory and sales milestone payments up to a total of approximately USD 350 million plus tiered royalties from the mid-single digits up to mid-teens on net sales

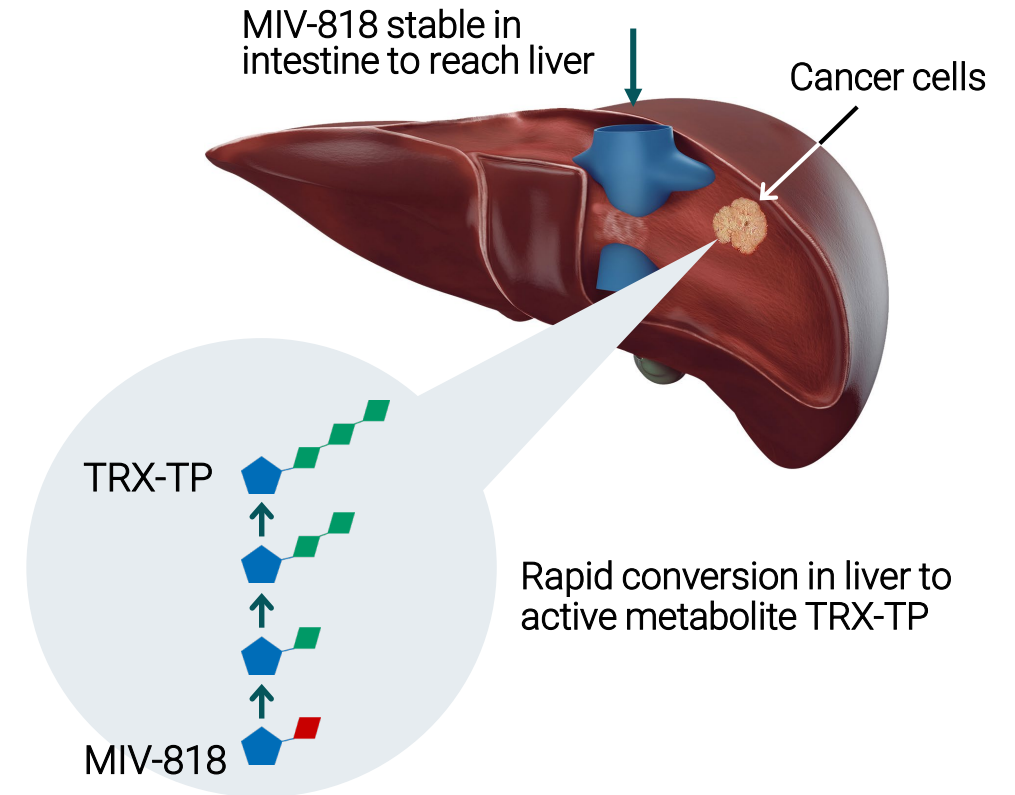


Open-label, Multicenter, Phase I Study with IGM-8444 in combination with Birinapant (IGM-9427) in patients with solid tumors will be in two stages: a dose-escalation stage and an expansion stage (NCT04553692)

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

MIV-818 – Introduction

- Novel nucleotide prodrug inhibiting DNA-replication of tumor cells, targeting cancer cells in the liver
- Designed to deliver high levels of active metabolite to the liver while minimizing systemic exposure



MIV-818 – Study design phase 1 monotherapy

Population studied

- advanced inoperable HCC, intrahepatic bile duct cancer and liver metastatic disease from solid tumors
- 9 patients (phase 1a) doses of 3-70 mg for 3-5 days in 21-day cycles, 10 patients (phase 1b) dose escalation starting at 40 mg for 5 days in 21-day cycles
- adult patients that had exhausted all approved therapies

Primary objective

- to assess safety and tolerability of MIV-818 as monotherapy
- to determine the recommended phase 2 dose for monotherapy

Secondary objective

- to evaluate tumor response rate based on RECIST v1.1

Exploratory objective

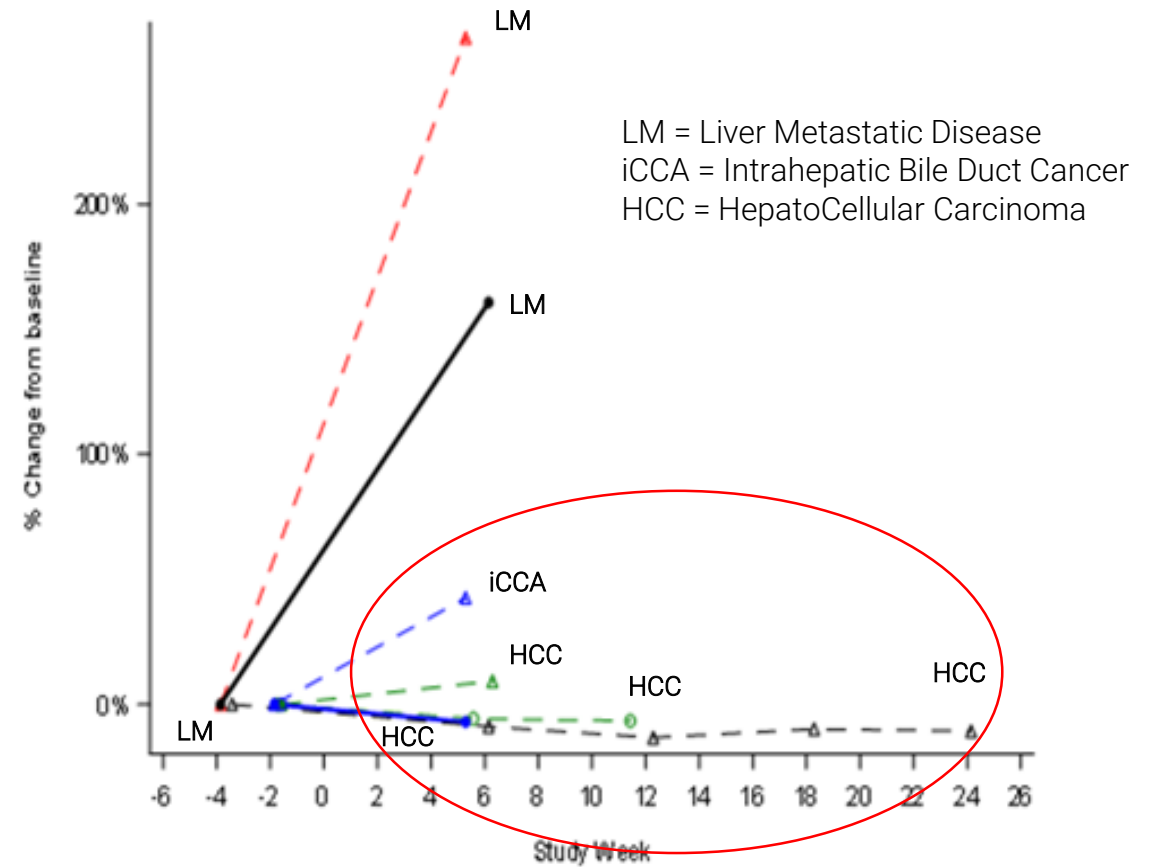
- to assess pharmacokinetics and pharmacodynamic effects of MIV-818

Phase 1b monotherapy results presented at ESMO

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

Phase 1b change in liver target lesions*

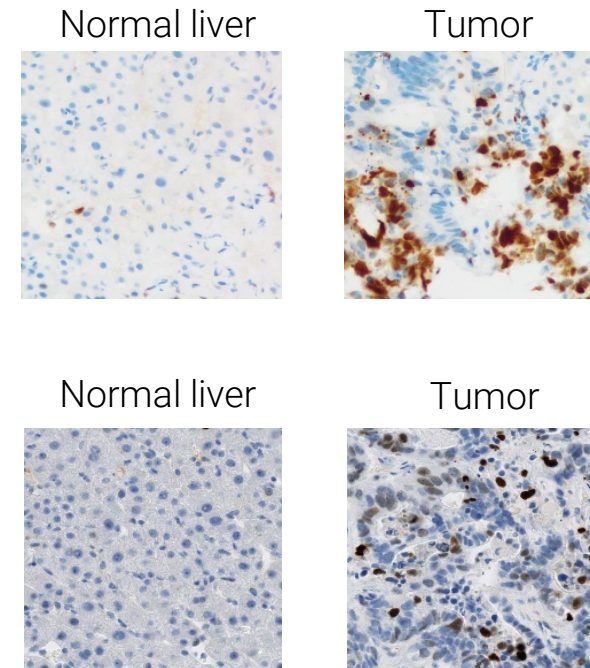


*Out of 10 enrolled patients, one did not complete safety follow up and one lacked independent radiologist assessment

MIV-818 POC demonstrated by liver biopsies

- Evidence of MIV-818 delivery to the tumor (measured MIV-818 metabolites)
- Clear signs of MIV-818 induced DNA-damage in tumor tissue
- MIV-818 induced effect observed across different types of liver cancer
- No observable effects in normal liver tissue

Biopsies from two MIV-818 treated patients



PD marker γ H2AX (% positive cells/brown stain) shows MIV-818 induced DNA-damage in tumor cells and not normal liver tissue

Conclusions MIV-818 phase 1 monotherapy

- Safety profile to date supports moving forward with development. 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

The clinical data from phase 1a and 1b monotherapy, supports continued development of MIV-818

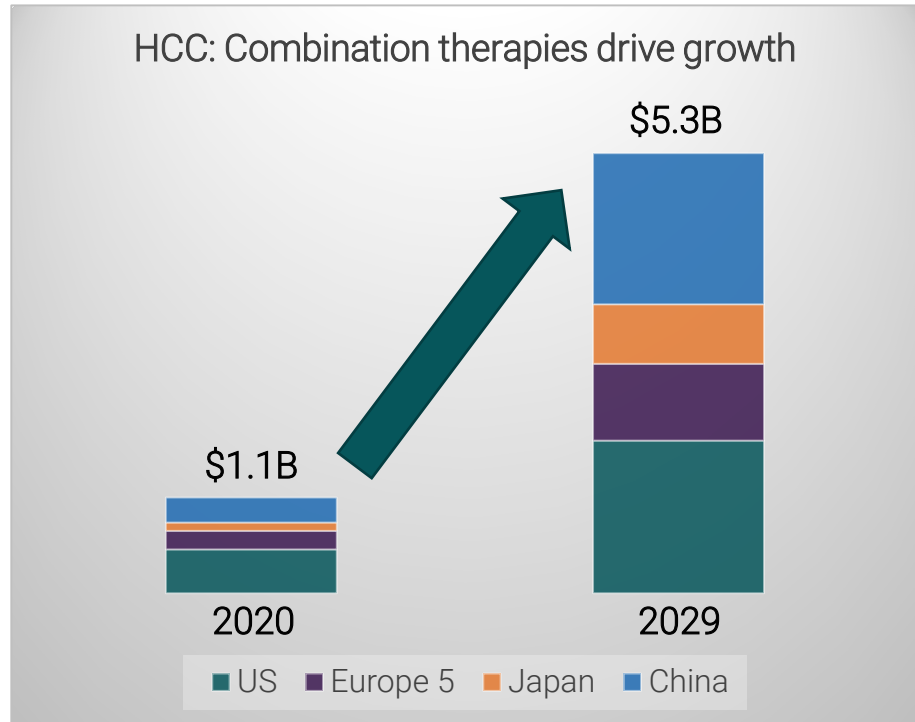
MIV-818 in the treatment landscape of advanced HCC

Focus on hepatocellular carcinoma (HCC)

Based on its liver-targeting design and broad mechanism of action MIV-818 is a potential treatment for several tumors in the liver, and in combination with other therapies

- Clinical development program is initially focused on HCC
- Future opportunities for MIV-818 to be used in other settings and/or other cancer indications in liver (e.g. liver metastases or intrahepatic cholangiocarcinoma)

Hepatocellular carcinoma (HCC) is a growing market



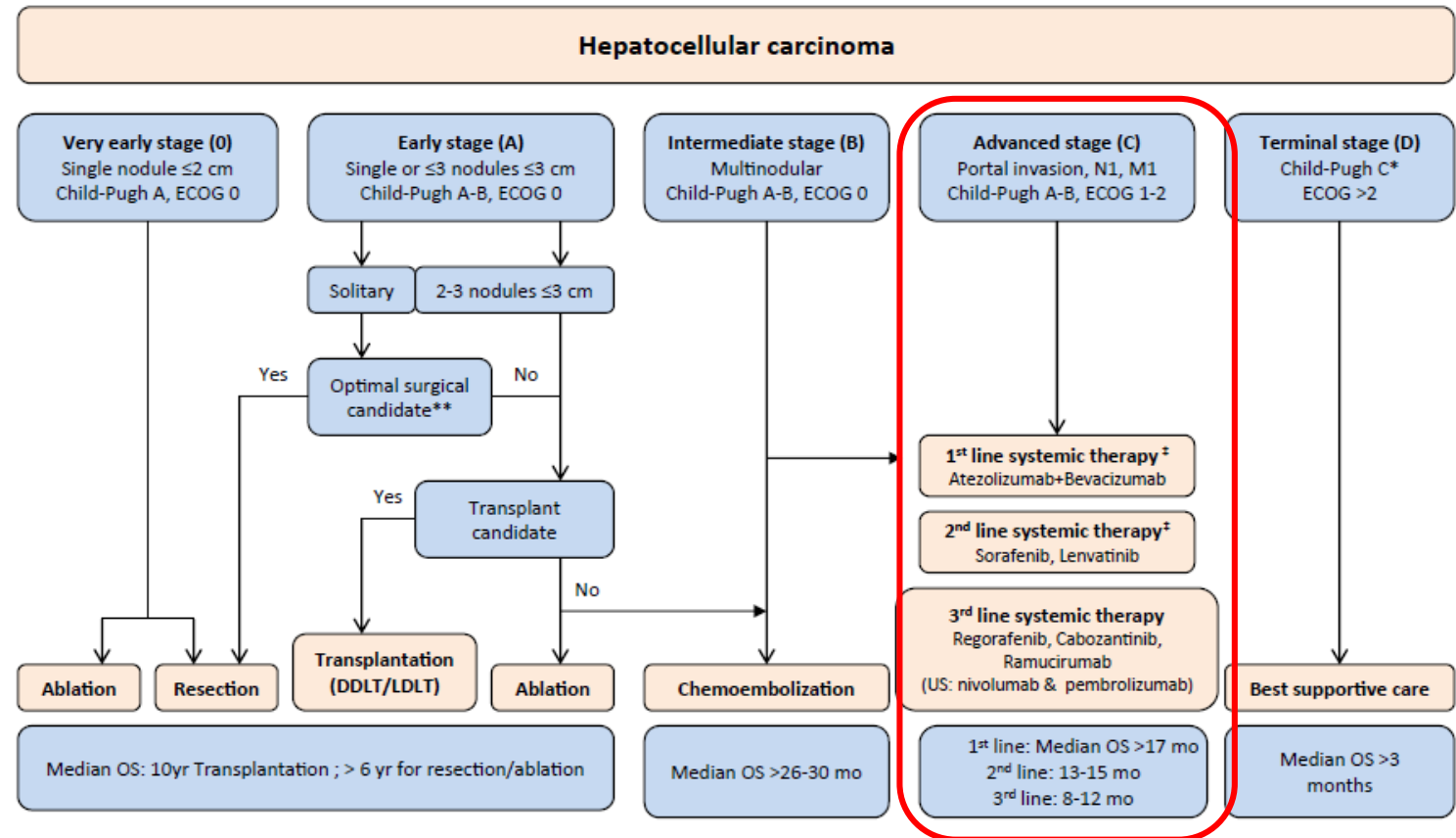
Source: GlobalData 2021

- Continued very high unmet medical need in HCC
 - 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>)

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 worldwide



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 (anti-PD1):

Keytruda®

Opdivo®

Tecentriq®

Blocking blood supply to tumor*

Marketed drugs:

Lenvima® (Tyrosine Kinase)

Nexavar® (Tyrosine Kinase)

Avastin® (anti-Vascular Endothelial Growth Factor)

* Some of these drugs are multifunctional and have additional functions

MIV-818 – to be explored in combinations in HCC

MIV-818 inhibits DNA replication

- represents a unique mechanism to treat HCC selectively targeting tumor cells in the liver
- adds a novel tool that may be combined with or added to any of the two main mechanisms

Our upcoming trial will study MIV-818 with each of these mechanisms:

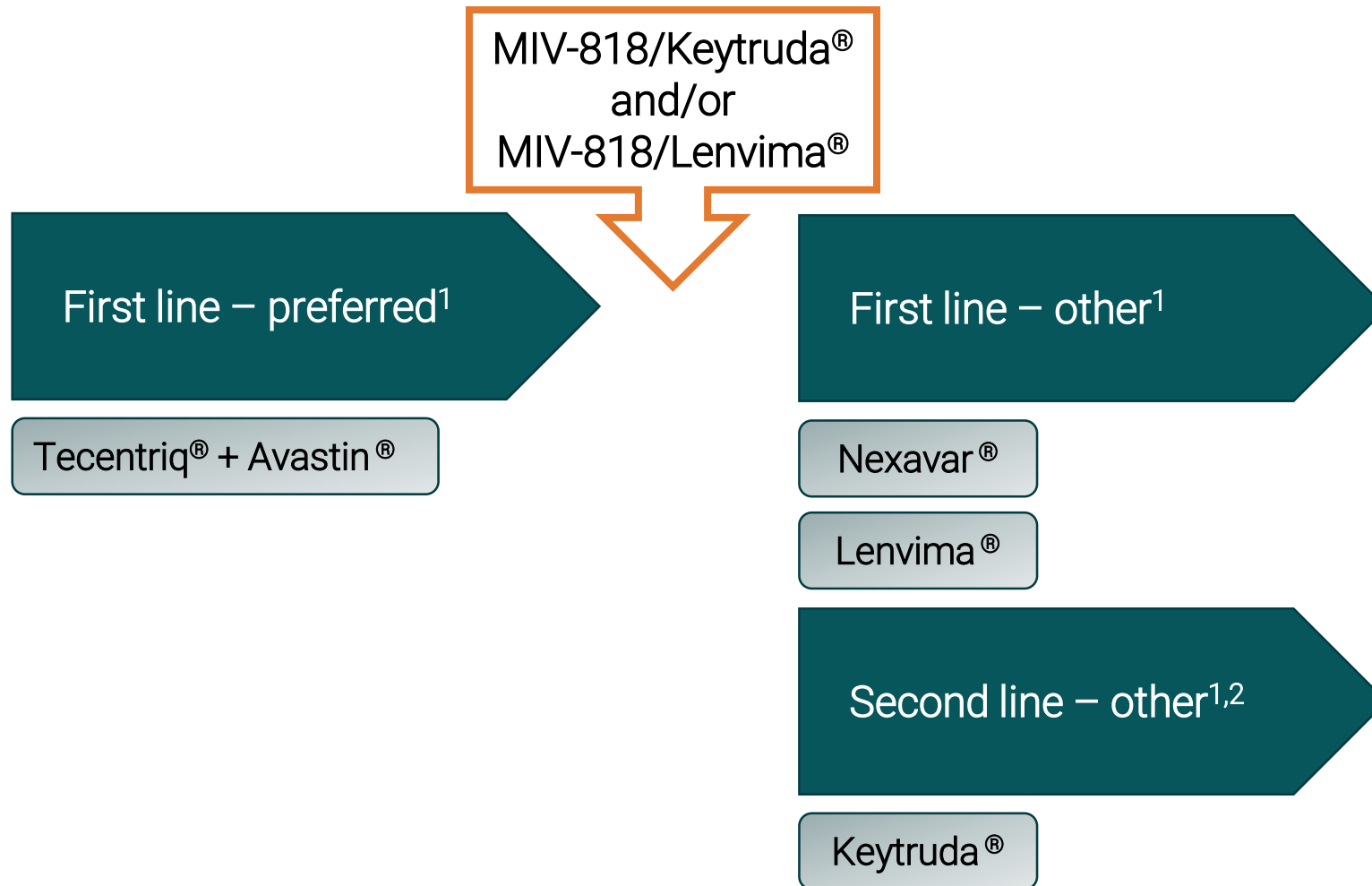
Stimulation of immune system

MIV-818 + Keytruda®

Blocking blood supply to tumor

MIV-818 + Lenvima®

MIV-818 positioning in second line advanced HCC



¹ NCCN Guidelines 5.2021 (in US)

² Only approved in the US

**Next step:
Phase 1b/2a MIV-818 combination**

Phase 1b and phase 2a combination study

Patient population to be studied

- advanced inoperable HCC
- must have progressed on or are intolerant of first line standard therapy for HCC and are candidates for Keytruda[®] or Lenvima[®] treatment

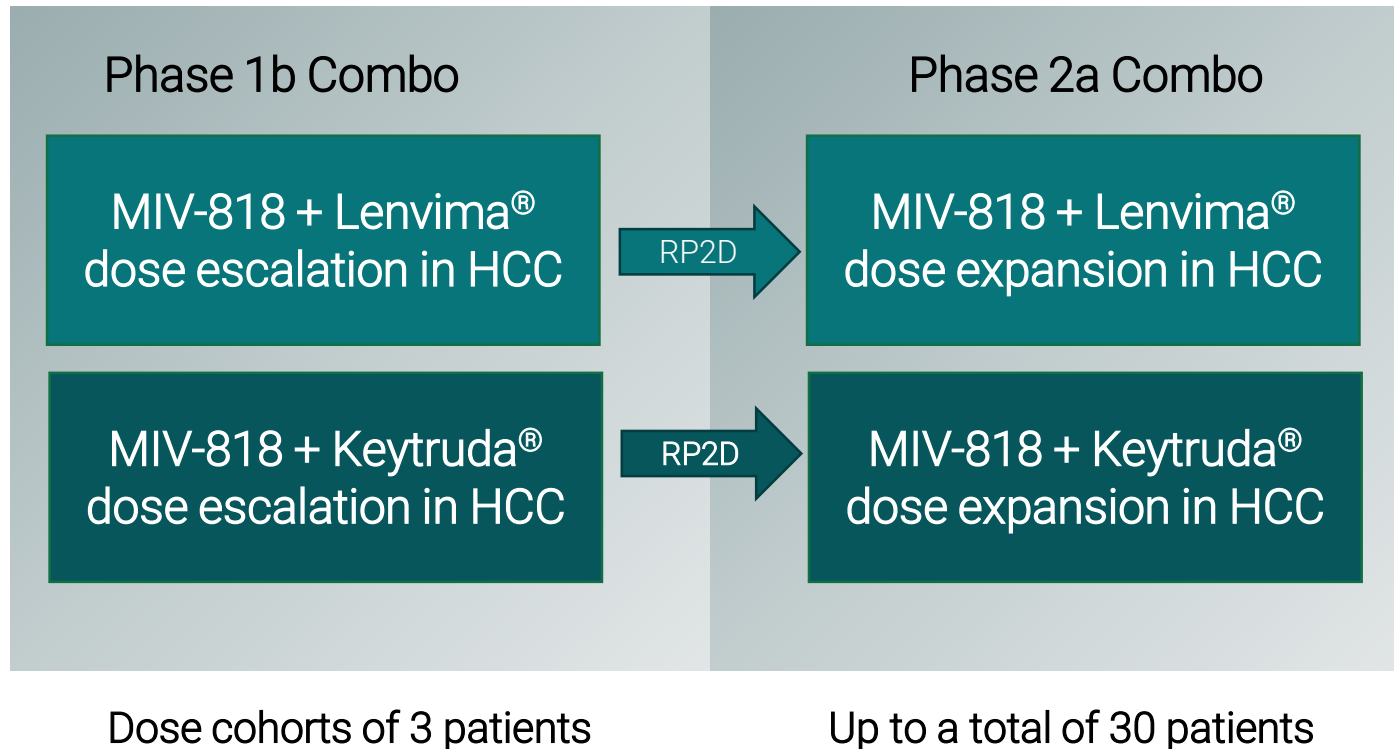
Primary objective

- to assess safety and tolerability of MIV-818 in combination with Keytruda[®] or Lenvima[®]
- to determine recommended phase 2 dose for MIV-818 in combination with Keytruda[®] or Lenvima[®]

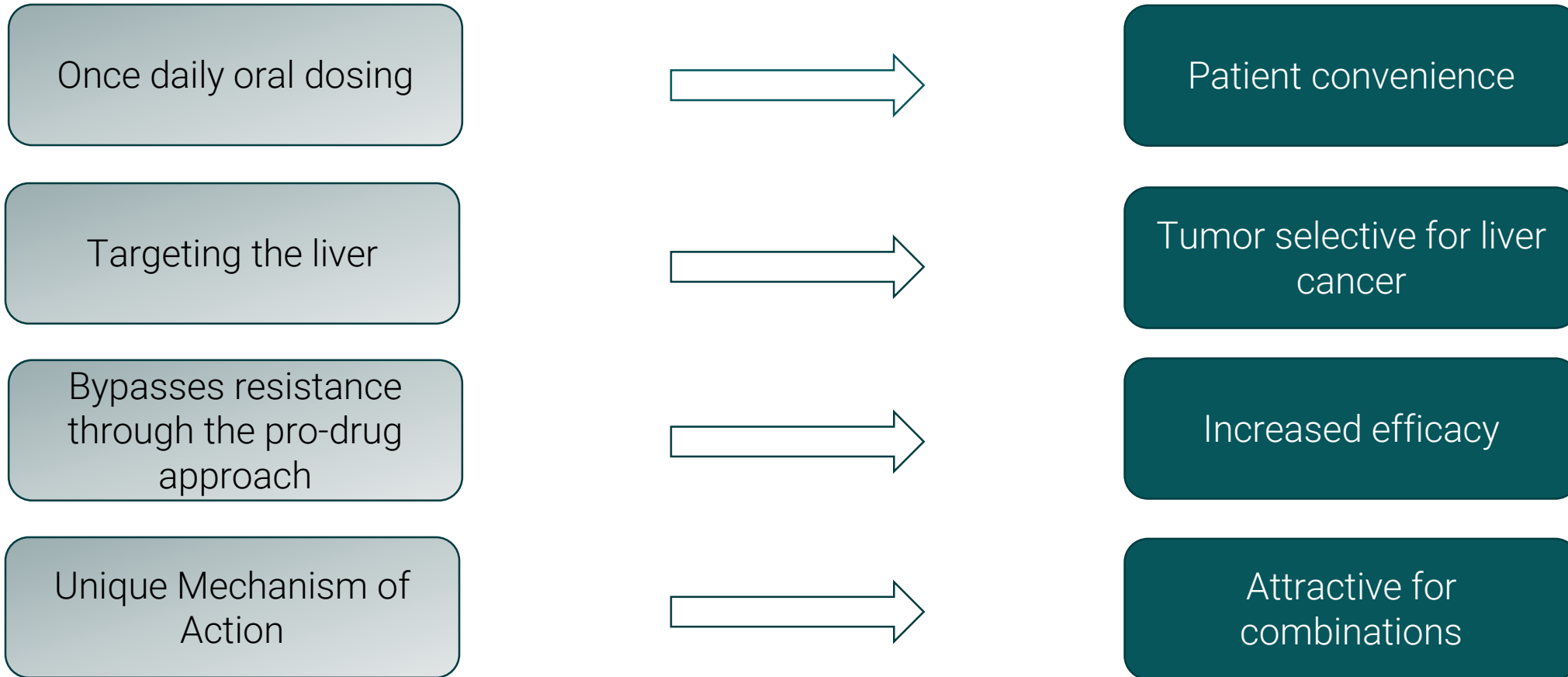
Secondary objective

- to evaluate tumor response rate based on RECIST v1.1

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



MIV-818 – Key advantages



Progressing clinical development of MIV-818 for HCC

- Orphan drug designation by EMA and FDA for the treatment of hepatocellular carcinoma (HCC)
- Positive data from phase 1b monotherapy, demonstrating Proof-Of-Concept, presented at ESMO in September
- Regulatory approval for the phase 1b/2a study of MIV-818 in combination with Keytruda[®] or Lenvima[®] have been received in UK and South Korea
- Clinical trial centers open in UK and additional sites planned to open in Spain and South Korea
- On track to initiate the phase 1b/2a combination study in 2021 as planned

Q&A