



**NEW SUPPORTING CLINICAL DATA
AND FURTHER STUDIES WITH
MIV-818**

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MEDIVIR

Today's presenters



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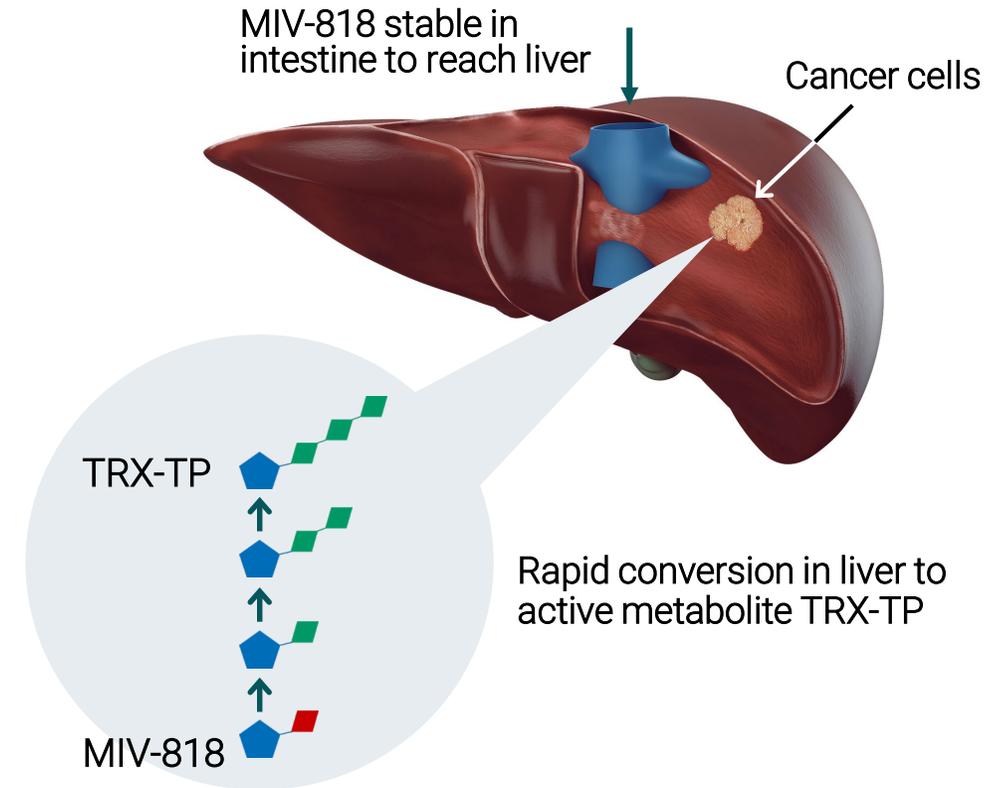
**New and supporting MIV-818
clinical data presented
today at ESMO**

Executive Summary

- Today new clinical data from our phase 1b study with MIV-818 monotherapy was presented as a poster at ESMO, the leading oncology conference in Europe
- The safety, tolerability and signs of efficacy further supports our development of MIV-818 in hepatocellular carcinoma (HCC)
- We look forward to start the recruitment in the planned combination study later this year

MIV-818 – Introduction

- Novel nucleotide prodrug inhibiting DNA-replication of tumor cells, targeting cancer cells in the liver
- Once daily oral dosing
- Orphan Drug Designation has been granted in HCC by the FDA and EMA

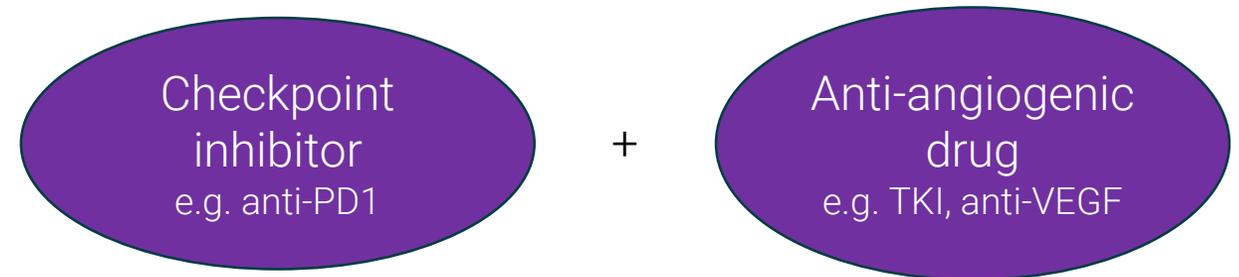


Designed to deliver high levels of active metabolite, troxacitabine-triphosphate (TRX-TP) to the liver while minimizing systemic exposure

MIV-818 – Medivir’s new unique tool for HCC

MIV-818 represents a unique mechanism to treat HCC that selectively targets tumor cells in the liver

- Despite recent advances in treatment of HCC, there is still a large group of patients that do not respond to or are intolerant of current treatments
- A large number of phase 3 studies are currently active in advanced HCC*. However, the vast majority of these studies are investigating a narrow range of Mechanisms of Actions:



*ClinicalTrials.gov 10 Sept 2021

MIV-818 - Phase 1b monotherapy study

Population studied

- advanced inoperable HCC (5), intrahepatic bile duct cancer (iCCA, 2) and liver metastatic disease (LM, 3) from solid tumors in the gastrointestinal tract
- 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

MIV-818 - Safety summary phase 1b monotherapy

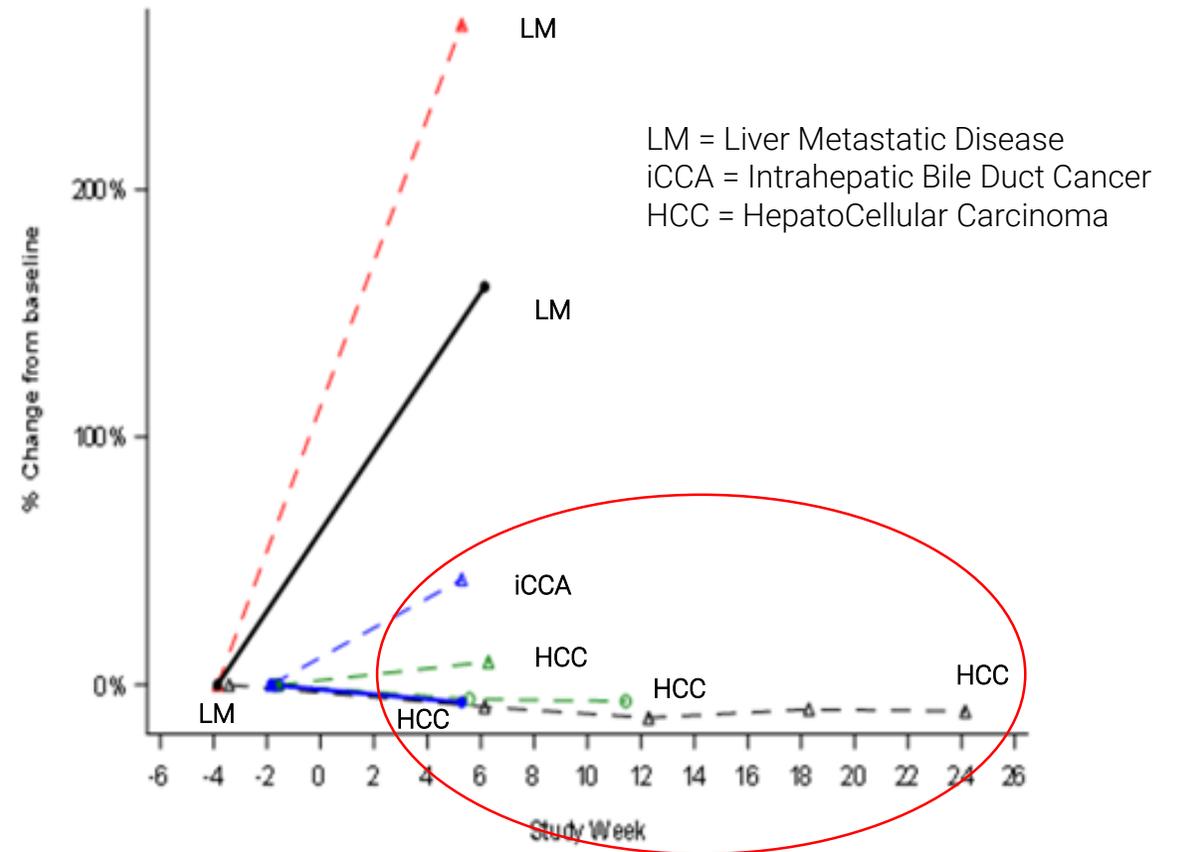
- Overall safety and tolerability profile in line with expectations for this type of advanced cancer patients
 - Decreases in blood counts were seen frequently with MIV-818 but resolved rapidly and are easily monitored
- Supports evaluating MIV-818 in combination with other drugs in next phase of development

Summary of efficacy

- Four HCC patients showed stable disease in the liver over an extended period of time
- Based on objective response (RECIST v1.1) data, 4/7 primary liver cancers (HCC, iCCA) had stable disease as best overall response
- One HCC patient remained on treatment for 8 months
- Two patients with liver metastatic disease showed a rapid increase in tumor volume

Supports our decision to study HCC in upcoming combination study

Change in liver target lesions*



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

Summary of pharmacokinetics and pharmacodynamics

- Further supports that MIV-818 is absorbed and that the active compound is formed in the liver
- Clear signs observed that MIV-818 induces desired DNA-damage in tumor tissue
 - observed across different types of liver cancer
- No DNA damage observed in normal liver tissue

Conclusions

- Safety profile to date supports moving forward with development. Decreases in blood cell counts were the most common side effects, these resolved quickly
- 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 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 1b, supports continued development of MIV-818

Next step will be to explore MIV-818 in combination with two other mechanism of actions,

- checkpoint inhibition - Keytruda[®]
- anti-angiogenic - Lenvima[®]

Next step in our development of MIV-818

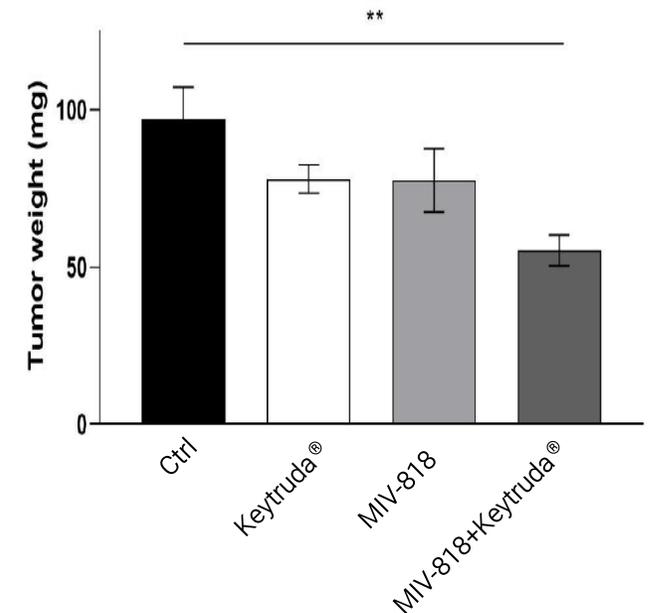
Combination with Keytruda[®] enhances efficacy in tumor models

- Combination of MIV-818 and Keytruda[®] results in stronger inhibition of tumor growth than either drug alone
- Signs of enhanced immune activity in tumors observed

Scientific rationale:

- MIV-818 induces DNA damage and tumor cell death, potentially leading to increased tumor antigen presentation and increased immune response
- Single agent aPD1 therapy have shown limited efficacy in HCC

MIV-818 + Keytruda[®] (tumor model)

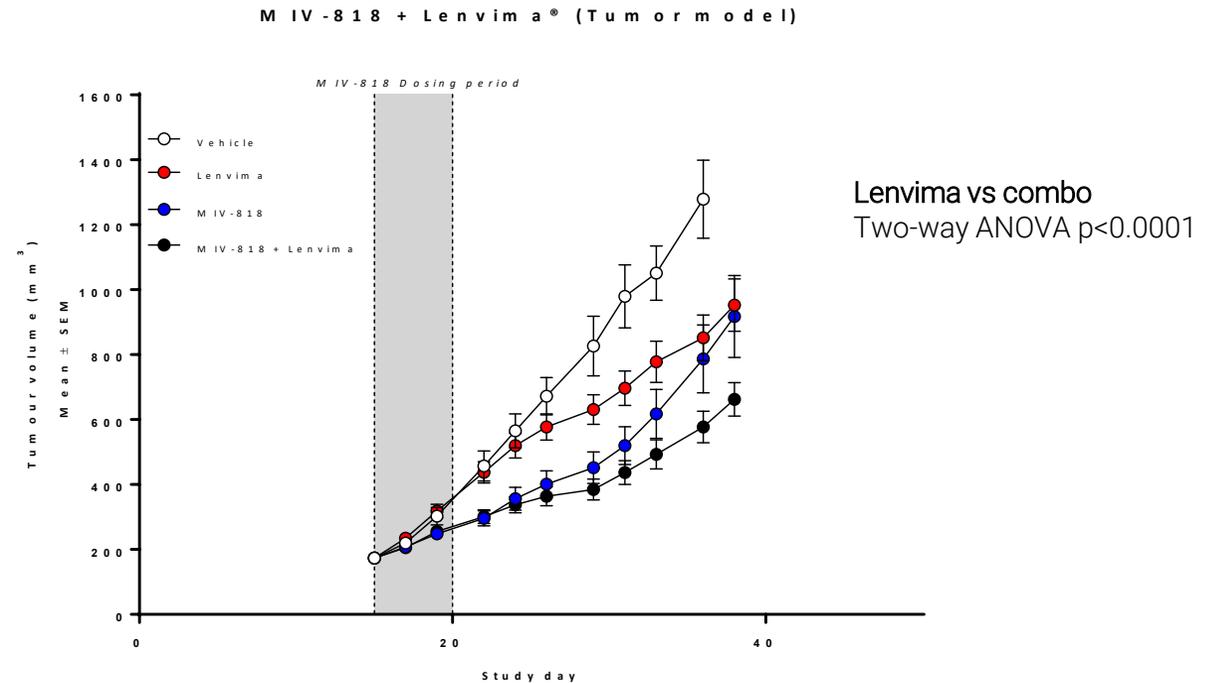


Combination with Lenvima[®] enhances efficacy in tumor models

Addition of MIV-818 to Lenvima[®] in a preclinical model significantly enhances tumor growth inhibition

Scientific rationale:

- The enzyme PKG1 mediates the last step in generating the MIV-818 active metabolite. PKG1 expression is increased by lack of oxygen, leading to higher levels of active metabolite
- Tyrosine kinase inhibitors such as Lenvima[®] induce lack of oxygen in tumors

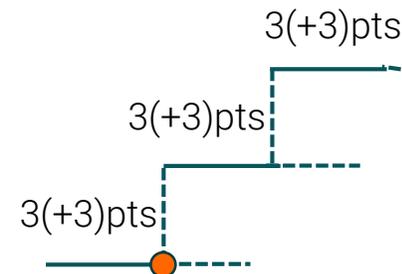
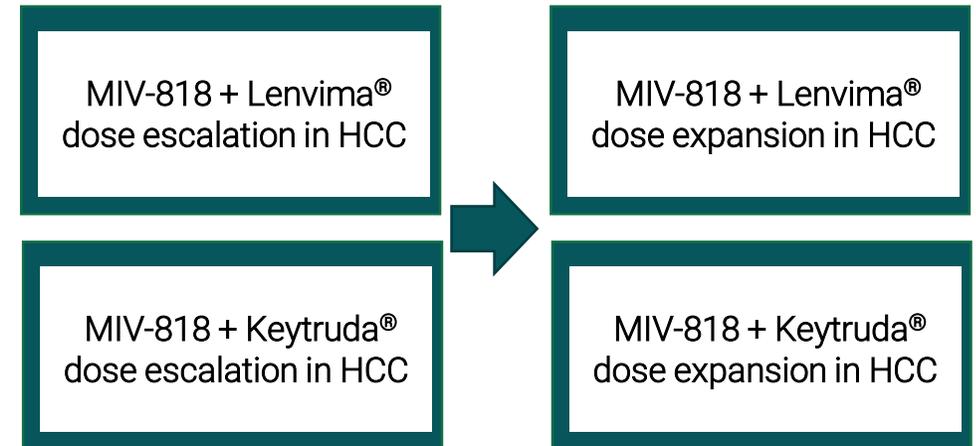


Dosing:

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

The combination study will be conducted in two steps

- First step is a dose-escalating phase to decide which dose of MIV-818 is safe and tolerable in combination with the approved drugs
- The next step is a dose expansion phase, with the objective to explore preliminary clinical efficacy



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[®]

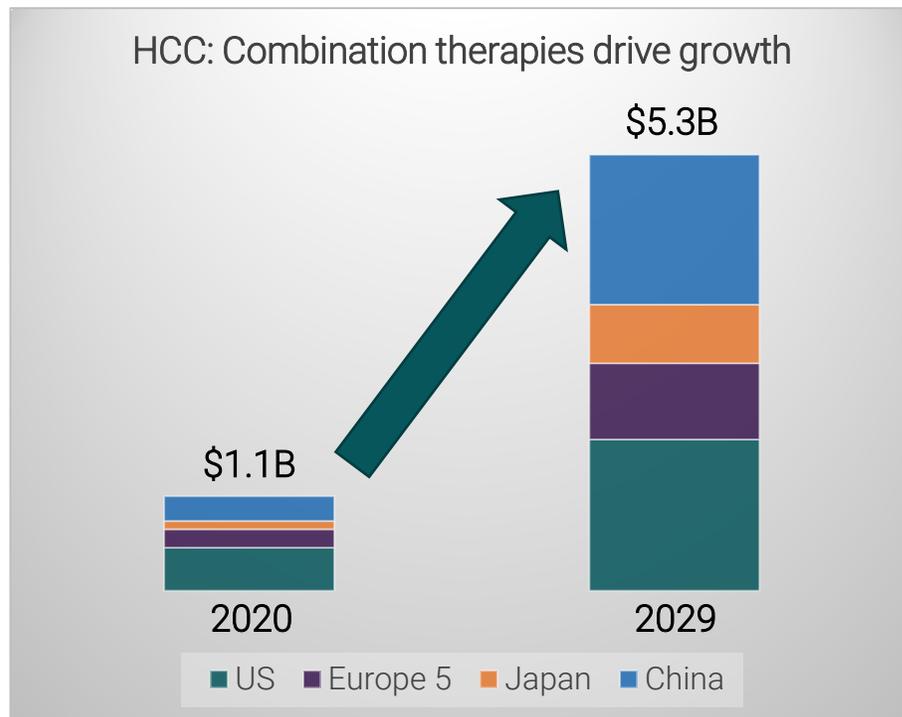
Secondary objective

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

We intend to initiate the study in 2021 as planned

- As previously communicated, the clinical study has been approved in UK, where additional sites will be opened
- We also plan to open sites in Spain and South Korea
- The sites in South Korea will be beneficial from patient recruitment perspective as HCC is much more common in Asia
- Asia is an important future market and exposure in Asian population will aid in finding potential future partners

Hepatocellular carcinoma (HCC) is a growing market



- 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 market growth in HCC
- Increased use of systemic treatments in earlier disease stages

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Q & A