Selective effect signal on liver cancer tissue in phase Ia study with MIV-818

Stockholm, Sweden – Medivir AB (Nasdaq, Stockholm: MVIR) today announces the results of an analysis of data from the first six patients with advanced cancer in the liver treated with increasing MIV-818 doses. The primary objective of the study is to evaluate the tolerability, safety and pharmacokinetics of MIV-818. Evaluated doses have been shown to be well-tolerated by patients. An effect signal, measured as DNA damage, has been observed in liver biopsies from tumor tissue in MIV-818 treated patients. In contrast to the tumor, normal liver tissue does not appear to have been affected by the treatment. This tumor selective effect was observed at low measured levels of MIV-818 in plasma and is an early indication that MIV-818 works as expected, i.e. the substance has the intended liver-directed effect. Based on the positive results from the first six patients, Medivir has decided to initiate the phase Ib part of the MIV-818 study.

- ”It is very promising to already at this early stage of clinical development see clear indications that MIV-818 has a liver-directed effect. It is therefore with great expectations that we will proceed with the clinical program for MIV-818,”says Medivir's CEO, Dr. Uli Hacksell." The development of MIV-818 is a central part of our vision – creating shareholder value and improving the lives of cancer patients through transformative drugs.”

Today, Thursday June 13 at 10.00 CET, Medivir will host a telephone conference for investors, analysts and the media where the study results and the next step will be presented.

Phone numbers for participants from:
Sweden + 46 8 566 426 93
Europe + 44 33 3300 9270
US + 1 833 526 8398

The conference call will also be streamed via a link on the website: www.medivir.com
The presentation will be available on Medivir’s website after completion of the conference.

For further information, please contact:
Uli Hacksell, CEO, Medivir AB, phone: +46 (0)73 125 0615.

Medivir AB is obliged to make this information public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08.00 CET on 13 June, 2019.

About MIV-818

MIV-818 is a pro-drug designed to selectively treat liver cancers and to minimize side effects. It has the potential to become the first liver-targeted, orally administered drug to benefit patients with HCC and other forms of liver cancer.

About the study

The phase I/II study of MIV-818 consists of three parts: a phase Ia study in which individual patients receive escalating doses of MIV-818. This will be followed by a phase Ib study in which the dose is escalated in cohorts of three patients in a 3+3 design in order to identify the recommended phase II dose, which will be determined by the trial’s independent safety review committee. In the phase II part of the study two cohorts

of patients with liver cancer, will receive the recommended dose of MIV-818. More information about the study is available at www.clinicaltrials.gov, reference number NCT03781934.

About liver cancer

Liver cancer is the third leading cause of cancer-related deaths worldwide and hepatocellular carcinoma (HCC) is the most common cancer that arises in the liver. Although existing therapies for advanced HCC are capable of extending the lives of patients, treatment benefits are low while death rates remain high. HCC is a very diverse disease with multiple cancer cell types and without specific mutations seen in other tumor types. This has contributed to the lack of success of molecularly targeted agents in HCC. The limited overall benefit, taken together with the poor overall prognosis for patients with intermediate and advanced HCC, results in a large unmet medical need.

About Medivir

Medivir develops innovative drugs with a focus on cancer where the unmet medical needs are high. The company is investing in indication areas where available therapies are limited or missing and there are great opportunities to offer significant improvements to patients. Collaborations and partnerships are important parts of Medivir's business model and the drug development as well as the commercialization is conducted either by Medivir or in partnership. Medivir's share (ticker: MVIR) is listed on Nasdaq Stockholm's Small Cap list. www.medivir.com.