

Phase I/II clinical study of MIV-818 started in patients with liver cancer

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces that the first patient has been enrolled and dosed with MIV-818 in a phase I/II study in patients with liver cancer. The purpose of this first-in-human trial is to study the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of MIV-818 in patients with advanced liver cancer. It will enroll patients with hepatocellular carcinoma (HCC), as well as patients with intrahepatic cholangiocarcinoma and patients with liver metastases from solid tumors.

The design of 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 (RP2D), which will be determined by the trial's independent safety review committee. In the third and final part of the study two dose expansion cohorts of patients, one with HCC and the other with intrahepatic cholangiocarcinoma, will receive MIV-818 at the RP2D.

The regulatory application to conduct the study was first reviewed and approved by the United Kingdom Medicinal and Healthcare Products Regulatory Agency (MHRA), and the phase Ia part of the trial will be run at sites in the United Kingdom and Belgium.

"We are very excited to initiate the first clinical study with MIV-818, which is the first oncology drug in development from Medivir's in-house research", said Christine Lind, Medivir's Chief Executive Officer. "Liver cancer is deadly disease with very few available treatment options, making MIV-818 a key part of Medivir's mission to improve life for cancer patients with transformative drugs."

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This is information that Medivir AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 14.00 CET on October 1, 2018.

About liver cancer

Liver cancer is the second highest cause of cancer-related death worldwide¹. 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. Intrahepatic cholangiocarcinoma, a cancer of the bile duct located inside the liver tissue, accounts for about 15 percent of liver cancers. It has a poor prognosis and no treatment that effectively improves survival. Liver metastases from other tumor sites (principally from colorectal cancer, but also from breast, ovarian and pancreatic cancer) are also a major cause of cancer-related death.

About MIV-818

MIV-818, the first oncology drug in development from Medivir's in-house research, has been specifically designed for liver cancers both in its delivery to the liver and in its way of acting, aimed to make it more effective against liver cancer cells specifically. 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 Medivir

Medivir is a research-based pharmaceutical company with a focus on oncology. We have a leading competence within protease inhibitor design and nucleotide/nucleoside science and we are dedicated to develop innovative pharmaceuticals that meet great unmet medical need. Medivir is listed on the Nasdaq Stockholm Mid Cap List (ticker: MVIR). www.medivir.com.

- 1) WHO World Cancer Report (2014), <http://publications.iarc.fr/Non-Series-Publications/World-Cancer-Reports/World-Cancer-Report-2014>