Medivir receives regulatory approval from MHRA for phase 1/2a combination study with MIV-818

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announced that the company has received regulatory approval from the British Medicines & Healthcare products Regulatory Agency (MHRA) for its upcoming phase 1/2a combination study with the company's leading candidate drug MIV-818 against liver cancer. In the study, MIV-818 will be administered in two combinations, either with lenvatinib, a tyrosine kinase inhibitor or pembrolizumab, an anti-PD-1 check-point inhibitor.

The planned trial will be an open-label, multi-center phase 1/2a study starting with a dose escalation part to establish the recommended phase 2 dose (RP2D). This is followed by the expansion study (phase 2a) with an initial evaluation of the safety and efficacy of the combination of MIV-818 with lenvatinib or pembrolizumab. The study will include patients with hepatocellular carcinoma (HCC) who have progressed on, or are intolerant of, first line standard therapy.

The study is planned to have two parallel dose-escalation streams. Once the RP2D has been established for the combinations, further cohorts of up to 30 patients with HCC will be enrolled in the phase 2a part of the study. The study will start in the UK and is planned later to include centers in Spain and South Korea. The first patient is expected to be enrolled in the second half of 2021.

- ”It is satisfactory that the preparations for the study are progressing according to plan. The MHRA approval is also an important seal of quality in the planning and design of the study,” said Magnus Christensen, Interim CEO of Medivir.

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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 and orally administered drug for patients with HCC and other forms of liver cancer. MIV-818 has completed a phase 1b monotherapy study, and a combination study in HCC is now planned to be initiated during the second half of 2021.

About primary liver cancer

Primary 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 can extend the lives of patients, treatment benefits are insufficient and death rates remain high. There are 42,000 patients diagnosed with primary liver cancer per year in the US and current five-year survival is 11 percent. HCC is a heterogeneous disease with diverse etiologies, and lacks defining mutations observed in many other cancers. 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 drug candidates are directed toward indication areas where available therapies are limited or missing and there are great opportunities to offer significant improvements to patients. Medivir is focusing on the development of MIV-818, a pro-drug designed to selectively treat liver cancer cells and to minimize side effects. Collaborations and partnerships are important parts of Medivir's business model, and the drug development is conducted either by Medivir or in partnership. Birinapant, a SMAC mimetic, is exclusively outlicensed to IGM Biosciences (Nasdaq: IGMS) to be developed in combination with IGM-antibodies for the treatment of solid tumors. Medivir's share (ticker: MVIR) is listed on Nasdaq Stockholm's Small Cap list. www.medivir.com.