Press release, June 2, 2023

Medivir has completed the dose escalation part (phase 1b) of the 1b/2a study in HCC and focuses on the combination of fostrox and Lenvima

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative treatments for cancer in areas of high unmet medical need, announces today that a safe dose has been established for treatment with the drug candidate fostroxacitabine bralpamide (fostrox) in combination with Keytruda® in the initial dose escalation part (phase 1b) of the company's 1b/2a study in hepatocellular carcinoma (HCC). In the ongoing expansion part of the study (phase 2a) Medivir is focusing on the fostrox and Lenvima combination and intends to explore the possibility of fostrox in a triple combination together with immunotherapy in earlier lines.

The absolute majority of first-line HCC patients are currently treated with Tecentriq® (anti-PD-L1) plus Avastin®. Lenvima® is a targeted therapy and there is a clear rationale for using a different mechanism of action in second line- than in first line treatment, to overcome the development of resistance. This makes fostrox + Lenvima® the most relevant combination to explore further in the second line setting.

With immunotherapy as the standard treatment in first line, the chance, at progression, of responding to further immunotherapy in the following lines is limited, which is why fostrox plus Keytruda® will not be studied further as a second-line therapy at the moment. With a safe dose established for the fostrox + Keytruda® arm, the intention is instead to explore the possibility of fostrox as a triple combination partner in earlier lines of immunotherapy combinations.

- ”It is very gratifying that we have now completed the dose escalation part for both dose arms and established a safe dose,” says Medivir’s CMO Pia Baumann. ”We see a continued large engagement in the inclusion of patients in the dose expansion part for the combination fostrox + Lenvima®, as an attractive treatment option in second-line treatment. At the same time, there is a clear interest from clinical expertise in fostrox's potential, thanks to the unique and liver-directed mechanism of action, as a combination partner with immunotherapy in earlier treatment lines, which we look forward to exploring further.”

In the two dose arms of the study, fostrox has been combined with Keytruda®, an anti-PD-1 checkpoint inhibitor, or Lenvima®, a tyrosine kinase inhibitor, in patients with HCC for whom first-line treatment has been ineffective or not tolerated. The aim of the study is to evaluate safety, tolerability and also to get an indication of the effect of fostrox in combination with two already existing drugs. Medivir announced in February that the dose arm with fostrox + Lenvima® showed a safe dose and proceeded to the expansion phase (phase 2a), where the first 11 patients have been dosed in a short time. The study is being conducted at 15 clinics in the UK, Spain and South Korea.

For additional information, please contact

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About fostrox

Fostrox 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. Fostrox has completed a phase 1b monotherapy study, and a combination study in HCC currently ongoing.

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 fostroxacitabine bralpamide (fostrox), 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.