Press release, March 14, 2023

First patient dosed in the phase 2a part of Medivir's study with fostrox in combination with 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, announced today that the first patient with hepatocellular carcinoma (HCC) has started treatment in phase 2a with the candidate drug fostroxacitabine bralpamide (fostrox) in combination with Lenvima®.

In Medivir's ongoing phase 1b/2a study, fostrox is given in combination with two other drugs, either with Lenvima®, a tyrosine kinase inhibitor, or with Keytruda®, an anti-PD-1 checkpoint inhibitor. The study is an open-label, multicenter study and includes patients with HCC for whom current first- or second-line treatment has proven ineffective or is not tolerable. The phase 1b part of the study evaluates which dose of fostrox is most appropriate for the next phase. This dose is then used in the phase 2a part of the study where safety and signals of efficacy are further evaluated.

The preliminary results from the recently completed phase 1b for fostrox in combination with Lenvima® were positive with a good safety and tolerability profile where no dose-limiting toxicity was observed. The recommended dose (RP2D) for fostrox in this combination arm was set at 30 mg.

- "It is really exciting that we have been able to start the important expansion phase of the study so quickly, with the first patient now being treated with fostrox and Lenvima® in phase 2a. The medical need for a new, effective treatment is immense and so is the interest from both investigators and patients, which is why I believe that the recruitment of patients to this part of the study will be completed swiftly," says Pia Baumann, Chief Medical Officer at Medivir AB.

The results from this study will form the basis for the future development plan for fostrox. A total of up to 30 patients with HCC are planned to be recruited in the study that is being conducted at 14 clinics in Great Britain, Spain and South Korea. In the second combination arm where fostrox is administered together with Keytruda®, the phase 1b dose escalation is still ongoing.

For additional information, please contact
Magnus Christensen, CFO, Medivir AB
Telephone: +46 8 5468 3100.
E-mail: magnus.christensen@medivir.com

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.