Press Release
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Medivir announces first patient enrolled in FLEX-HCC study

Stockholm — Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative treatments in areas of high unmet medical need, announced today that the first patient has been enrolled in the FLEX-HCC study. FLEX-HCC is a randomized, comparative phase 2 study evaluating fostrox in combination with lenvatinib vs lenvatinib monotherapy in second-line advanced liver cancer (HCC).

The study is an investigator-initiated study led by Dr. Hong Jae Chon from CHA Bundang Hospital within the Korean Cancer Study Group. The study will be performed at 12 major hospitals in Korea. The primary objective of the study is to confirm superior efficacy with fostrox + lenvatinib over lenvatinib monotherapy, with objective response rate (ORR) as the primary endpoint and secondary endpoints that includes progression free survival (PFS), time to progression (TTP) and overall survival (OS). Evaluation of response/disease progression will be carried out with MRI and /or CT every 6 weeks.

- “The inclusion of the first patient in the FLEX-HCC study is an important step for the continuous development of fostrox in advanced liver cancer, where there is still a significant unmet medical need for therapies that will provide long-term tumor control while preserving liver function. The early clinical experience of the fostrox + lenvatinib combination showed far more encouraging results compared to traditional second-line lenvatinib monotherapy. In order to objectively validate and confirm these promising data, a randomized comparative study with fostrox + lenvatinib versus lenvatinib monotherapy in a larger patient population is needed. I am pleased that we now have the opportunity to run this important phase 2 study within the Korean Cancer Study Group.” says Dr. Hong Jae Chon, principal investigator of FLEX-HCC, CHA Bundang Hospital in Korea.

- "It is truly gratifying to see the FLEX-HCC study up and running in Korea and we are delighted to collaborate with the passionate and hard-working Dr. Chon, his team at CHA Bundang University Hospital and the Korean Cancer Study Group. We just had the opportunity to experience first-hand the dedication to FLEX-HCC and the high quality of the different teams and hospitals participating in the study, on our recent visits to 8 of the 12 hospitals participating in the study. We look forward with great anticipation to the progress and results of the study, which, if successful, will add an important treatment option for patients suffering from advanced liver cancer." says Dr. Pia Baumann, CMO at Medivir.

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About Medivir
Medivir develops innovative therapies targeting areas of high unmet medical need. Its drug candidates focus on indications where current treatment options are limited or non-existent, offering the potential to deliver meaningful improvements for patients. Medivir's two lead programs are fostrox, a precision chemotherapy designed to selectively target liver cancer cells while minimizing side effects, and MIV-711, aimed at treating Osteogenesis Imperfecta (brittle bone disease). Both candidates have blockbuster potential, representing significant value creation opportunities for Medivir's shareholders and affected patients. Collaborations and partnerships play a key role in Medivir's business model, with drug development conducted either in-house or in partnership. Medivir (Nasdaq Stockholm: MVIR) is listed on the Small Cap segment of Nasdaq Stockholm. More information is available at www.medivir.com

About primary liver cancer
Primary liver cancer is the third leading cause of cancer-related deaths worldwide. Hepatocellular carcinoma (HCC) is the most common cancer that arises in the liver, and it is the fastest growing cancer in the USA. Although existing therapies for advanced HCC can extend the lives of patients, treatment benefits are insufficient, and death rates remain high. There are approximately 860,000 patients diagnosed with primary liver cancer per year globally and current five-year survival is less than 20 percent [2], [3], [4]. 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 fostrox
Fostrox is a liver-targeted inhibitor of DNA replication that delivers the cell-killing compound selectively to the tumor while minimizing the harmful effect on normal cells. This is achieved by coupling a chemotherapy (troxacitabine) with a prodrug tail. This design enables fostrox to be administered orally and travel inactive to the liver where activation and release takes place locally in the liver. With this unique mechanism, fostrox has the potential to become the first liver-targeted, orally administered drug that can help patients with primary liver cancer and liver metastases from other tumor types. A phase 1b monotherapy study with fostrox has previously been conducted that established clinical proof-of-concept. A phase 1b/2a combination study with fostrox in combination with Lenvima in advanced HCC was completed in November 2024, where data showed encouraging anti-cancer efficacy with a good safety and tolerability profile [1].

This information is information that Medivir 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 2026-05-21 09:00 CEST.