Press Release
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Positive results for fostrox + lenvatinib published in Clinical Cancer Research

Stockholm — Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative treatments in areas of high unmet medical need, announces that the results from the phase 1b/2a study of fostrox in combination with lenvatinib in patients with advanced liver cancer have been published in Clinical Cancer Research ("CCR"), a peer-reviewed journal of the American Association for Cancer Research dedicated to translational and clinical oncology research and one of the most cited journals in oncology (online first doi: https://aacrjournals.org/clincancerres/article/doi/10.1158/1078-0432.CCR-26-0273). The title of the article is "A phase Ib/2a study of fostrox in combination with lenvatinib as second line therapy in patients with advanced hepatocellular carcinoma", lead authors Chon H J and Heo J et al.

Fostrox was developed as a prodrug using the first-pass metabolism to maximise the exposure of fostrox in the liver tumour while minimising systemic adverse events. The published study evaluated safety and preliminary efficacy of fostrox in combination with lenvatinib as a novel combination treatment for patients with advanced liver cancer. The results showed promising preliminary efficacy and tolerability in the post-immunotherapy setting, supporting further investigation as a second-line option in advanced liver cancer.

- "Advanced primary liver cancer (HCC) has a particularly poor prognosis, and the incidence of HCC is projected to increase dramatically, attributed to lifestyle factors such as obesity and metabolic ("fatty") liver disease. Despite the progress in the development of new first-line treatments with immunotherapy combination regimens, there are still limited options as second-line treatments following immunotherapy. The urgent need for treatment options in second line became even more apparent at the ASCO Congress where IMbrave 251 study did not meet its primary endpoint. Fostrox, with its liver-targeted mechanism has, in this combination study with lenvatinib, shown to be safe and tolerable with preliminary efficacy without negatively impacting liver function, indicating encouraging results compared to previous studies in second-line advanced liver cancer, a patient population lacking a gold standard treatment option", says Professor Jeff Evans, University of Glasgow, one of the investigators in the study and last author of the publication in CCR.

The study results confirmed that fostrox had a liver targeted distribution with tumour selective DNA-damage. The safety profile was consistent with expectations for both agents and most patients (71%) did not require any dose modification to stay on treatment. Fostrox related AEs were mainly transient and fostrox dose reduction and/or discontinuation occurred in only 29% and 5% of patients respectively. The drug combination was associated with tumour control without deterioration of liver function, essential in this population with underlying hepatic co-morbidities. The efficacy outcomes, as measured by ORR (overall response rate), DCR (disease control rate), TTP (time to progression), PFS (progression-free survival) and OS (overall survival), compare favourably with those historically reported for lenvatinib monotherapy or other kinase inhibitors in the post-immunotherapy setting.

- "*In primary liver cancer, it is critical to maximise the anti-tumour effect locally in the liver as the tumour burden and underlying liver disease increase the risk of liver failure. Fostrox has been designed with this challenge in mind, and the study results confirm a liver-directed delivery where fostrox induces DNA damage selectively in tumour cells, to ensure optimal efficacy and safety. This targeted mechanism is unique to fostrox and enables patients to stay on treatment long-term without liver function deterioration or intolerable side effects. The phase 1b/2a study data reinforces our confidence in fostrox as a potential treatment option for patients with advanced liver cancer. An investigator initiated randomised phase 2 study with fostrox plus lenvatinib compared with lenvatinib monotherapy, led by Professor Hong Jae Chon, together with the Korean Cancer Study Group, is currently ongoing in Korea and we are eagerly awaiting the results*", 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].