

Medivir to present final safety and efficacy data for fostrox + Lenvima in advanced liver cancer at EASL Liver Cancer Summit

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative treatments for cancer in areas of high unmet medical need, today announced that final safety and efficacy data from the phase 1b/2a study of fostrox (fostroxacitabine bralpamide) in combination with Lenvima® (lenvatinib) for the treatment of advanced hepatocellular carcinoma (HCC) has been accepted for presentation at the European Association for the Study of the Liver (EASL) Liver Cancer Summit in Paris, February 20-22, 2025.

The abstract, titled *"Final safety and efficacy results from the phase 1b/2a study of fostrox plus lenvatinib in second/third line patients with advanced hepatocellular carcinoma who progressed on immunotherapy."* will be presented by Dr Jeff Evans, Beatson West of Scotland Cancer Center, Glasgow, UK.

The study was closed on November 26, 2024. The three patients still remaining on treatment after more than 15 months have been transitioned to compassionate use, allowing them continued benefit from the study drug. End of treatment safety and efficacy data will be presented at the conference in Paris.

The poster will be available on Medivir's website after the presentation.

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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 an active chemotherapy (troxacitabine) with a prodrug tail. This design enables fostrox to be administered orally and travel directly to the liver where the active substance is released 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 various types of liver cancer. A phase 1b monotherapy study with fostrox has previously been conducted and a phase 1b/2a combination study in HCC was completed in November 2024, where it has shown encouraging anti-cancer efficacy with a good safety and tolerability profile [1].

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 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 drug candidate designed to selectively treat cancer cells in the liver 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. Medivir's share (ticker: MVIR) is listed on Nasdaq Stockholm's Small Cap list. www.medivir.com.

1) *Chon et al. ESMO 2024, Poster 986*

2) *Bray et al., CA Cancer J Clin. 2024;74:229-263*

3) *Rumgay et al., European Journal of Cancer 2022 vol.161, 108-118.*

4) *Yang, J.D., Hainaut, P., Gores, G.J. et al. A global view of hepatocellular carcinoma: trends, risk, prevention and management. Nat Rev Gastroenterol Hepatol 16, 589–604 (2019).*