Press Release
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Medivir receives European patent for fostrox plus lenvatinib in treatment of hepatocellular carcinoma (HCC) and cancer metastases in the liver

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 the European patent authority has granted the company's patent application covering claims for the combination of fostroxacitabine bralpamide (fostrox) with lenvatinib (Lenvima) for the treatment of hepatocellular carcinoma and cancer metastases to the liver. The patent provides protection and market exclusivity until April 2041.

- “This patent approval is, together with the fostrox composition of matter patent, part of our strategy to protect clinically relevant combinations with fostrox in liver cancer. In light of our positive, final data from the phase 1b/2a study presented at the EASL Liver Cancer Summit last month, and the ongoing activities to initiate a phase 2b study in 2nd line HCC, it is key to protect the unique fostrox plus lenvatinib combination in HCC”, says Jens Lindberg, CEO, Medivir.

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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 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].

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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) Evans et al., EASL Liver Cancer Summit 2025, Poster P02-13
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).*