Press Release
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Medivir receives Notice of Allowance for fostrox plus lenvatinib combination patent in the USA

Stockholm — Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative treatments in areas of high unmet medical need, announces today that it has received a Notice of Allowance by the United States Patent and Trademark Office (USPTO) for the company's patent application covering claims for the combination of fostroxacitabine bralpamide (fostrox) with lenvatinib for the treatment of hepatocellular carcinoma (HCC) and cancer metastases to the liver.

This adds to the previous approvals in EU, Japan, Australia and Canada. The Notice of Allowance indicates that the USPTO intends to grant the application once standard procedural steps have been completed. The fostrox plus lenvatinib combination patent provides protection and market exclusivity until at least April 2041.

"This Notice of Allowance for the fostrox plus lenvatinib combination is, together with the fostrox composition of matter patent, part of our strategy to protect clinically relevant combinations with fostrox in liver cancer. The notice provided by USPTO is especially critical considering the commercial importance of the US market and further confirms the innovative features of the fostrox plus lenvatinib combination", 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 therapies targeting diseases with high unmet medical need. The company's 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) and Legg-Calvé-Perthes disease (Perthes disease). Both candidates have blockbuster potential, representing significant value creation opportunities Medivir's shareholders. Collaborations 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