

## Medivir presents data that strengthens the fostrox/Lenvima combination in primary liver cancer at EASL Liver Cancer Summit

**Stockholm — Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative treatments for cancer in areas of high unmet medical need,** announced today that clinical pharmacokinetic (PK) data on dose linearity and systemic exposure from the first study with fostroxacitabine bralpamide (fostrox) (NCT03781934) will be presented at the European Association for the Study of the Liver (EASL) Liver Cancer Summit on February 23, 2024, in Rotterdam.

The abstract, titled *“Population pharmacokinetic modeling of orally administered fostroxacitabine bralpamide (fostrox, MIV-818) and its metabolite troxacitabine in a phase I/IIa liver cancer study”* will be presented at the conference by Karin Tunblad PhD, Project Director for fostrox at Medivir. The presentation includes pharmacokinetic results from 42 patients in the phase I/IIa clinical study with fostrox monotherapy and the fostrox + Lenvima® combination in advanced liver cancer.

The results show dose linearity and that the systemic exposure, at the recommended phase 2 dose for fostrox, aligns with the encouraging safety and tolerability profile experienced in the ongoing phase 1b/2a study with fostrox in combination with Lenvima in second line treatment of advanced hepatocellular carcinoma (HCC). In addition, the study shows that the exposure of fostrox is not impacted by administration of Lenvima, providing additional support for this combination.

- “Ensuring predictable exposure is crucial when combining two pharmaceutical drugs. The data presented at EASL strengthen the clinical results previously reported where patients treated with fostrox + Lenvima have shown good tolerability and ability to stay on treatment long-term. The data further supports our upcoming regulatory interactions with FDA and continues to build our confidence in the clinical development of fostrox,” says Pia Baumann, Chief Medical Officer at Medivir.

The abstract and the poster will be available on Medivir’s website after the presentation.

### For additional information, please contact;

Magnus Christensen, CFO, Medivir AB

Telephone: +46 8 5468 3100.

E-mail: [magnus.christensen@medivir.com](mailto:magnus.christensen@medivir.com)

### About fostrox

Fostrox is a type of smart chemotherapy 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. The prodrug 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 been completed and a phase 1b/2a combination study in HCC is ongoing.

### About primary liver cancer

Primary liver cancer is the third leading cause of cancer-related deaths worldwide and hepatocellular carcinoma (HCC) is the most common cancer that arises in the liver. Although existing therapies for advanced HCC can extend the lives of patients, treatment benefits are insufficient and death rates remain high. There are approximately 660,000 patients diagnosed with primary liver cancer per year globally and current five-year survival is less than 20 percent<sup>1</sup>. 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 smart, targeted chemotherapy designed to selectively treat liver cancer cells 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](http://www.medivir.com).

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