Fostrox + Lenvima demonstrates further improvement in durable clinical benefit in HCC, supporting the accelerated development plan

- **Sustained disease control at 12 weeks has improved to 80%**
- **Consistent anti-tumor activity, >75% of patients experiencing tumor shrinkage in target lesions**
- **Continued good safety and tolerability profile. Longest running patient still on treatment after 16 months with sustained partial response**

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative treatments for cancer in areas of high unmet medical need, announced today improved durable clinical benefit in maturing data from the ongoing phase 1b/2a study in advanced hepatocellular carcinoma (HCC), measured by local review. These data, where all patients have had minimum 12 weeks follow-up, further supports accelerating the fostrox development program to initiate a registrational phase 2b study in second-line HCC in 2024.

The data is from a phase 1b/2a open-label, multi-center, dose-escalation and dose-expansion study evaluating the safety and efficacy with fostroxacitabine bralpamide (fostrox) in combination with Lenvima® in patients for whom current first- or second-line treatment has proven ineffective or is not tolerable. The study is ongoing with ~50% of patients still on treatment and all patients have had minimum 12 weeks follow-up. The combination remains tolerable with no unexpected new safety events and lower need for dose reductions than expected.

- ”Patients with advanced HCC, who have progressed on at least one prior line of treatment, is a difficult-to-treat population. Achieving durable clinical benefit for the majority of the patients with a good safety and tolerability profile, enables patients to benefit from the combination treatment longer. It provides us with added confidence in accelerating the fostrox development program and we look forward to engaging further with FDA to discuss final study design of the planned, registrational phase 2b study with accelerated approval intent,” says Dr. Pia Baumann, CMO at Medivir.

Additional data from the ongoing phase 1b/2a study will be presented at the ASCO Gastrointestinal Cancers Symposium, January 18-20, 2024 in San Francisco, USA. The abstract, titled “First safety and efficacy data from phase Ib/IIa study of fostroxacitabine bralpamide (fostrox, MIV-818) in combination with lenvatinib in patients with hepatocellular carcinoma (HCC)” will be presented by Dr. Maria Reig, Director of the Barcelona Clinic Liver Cancer (BCLC) and the Liver Oncology Unit at the Hospital Clinic of Barcelona in Spain on January 19th.

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About fostrox

Fostrox is an oral pro-drug, designed to selectively treat liver cancers and to minimize side effects. It has the potential to become the first liver-targeted and orally administered drug for patients with HCC. Fostrox has completed a phase 1b monotherapy study, and a combination study in HCC currently 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[1)]. 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 pro-drug designed to selectively treat liver cancer 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) Rumgay et al.,European Journal of Cancer 2022 vol.161, 108-118.