

Fostrox + Lenvima shows further improved response rates and time to progression in advanced liver cancer (HCC) at ASCO GI Symposium

- Overall Response Rate (ORR) has increased to 25% (local review RECIST 1.1)
- Median time to progression continues to improve as data matures, now 5.1 months¹ with >40% of patients still on treatment
- Continued good safety and tolerability profile. Longest running patient still on treatment after ~17 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 further improved clinical benefit with fostrox + Lenvima® as data from the ongoing phase 1b/2a study in advanced hepatocellular carcinoma (HCC) will be presented at the ASCO (American Society of Clinical Oncology) GI (Gastrointestinal Cancers) Symposium in San Francisco on January 19. The updated data further supports accelerating the fostrox development program to initiate a registrational phase 2b study in second-line HCC in 2024.

- "We are excited by these results in a poor prognosis patient population where low disease control and response rates are usually seen. The updated data presented at ASCO GI has further strengthened our belief in the combination of fostrox + Lenvima as a potential treatment for patients with advanced HCC. In addition to the promising clinical benefit, the combination continues to be tolerable with a good safety profile enabling patients to stay on treatment long-term. It reinforces our confidence in advancing fostrox development and engaging with regulatory authorities to discuss final study design of the planned, registrational phase 2b study with accelerated approval intent," says Dr. Pia Baumann, CMO at Medivir.

The data is from a phase 1b/2a open-label, multi-center, dose-escalation and dose-expansion study evaluating the safety and efficacy with fostrox + Lenvima (fostrox) in combination with Lenvima in patients for whom current first- or second-line treatment has proven ineffective or is not tolerable. The combination remains tolerable with no new, unexpected safety events. Only 5% have discontinued fostrox due to adverse events and lower need for dose reductions than expected. With a high and durable disease control rate of 61% at 18 weeks, the majority of patients in this study have continuous clinical benefit.

- "Hepatocellular cancer is a particularly complex disease," says Dr Maria Reig, Director of the Barcelona Clinic Liver Cancer (BCLC) and the Liver Oncology Unit at the Hospital Clinic of Barcelona in Spain, and investigator in the fostrox + Lenvima study. "A clear unmet need remains for safe and effective combination treatments. These data show that fostrox + Lenvima have encouraging results related to clinical outcome in patients with second-line advanced HCC without jeopardizing safety. I look forward to further explore the efficacy of fostrox added to Lenvima in a randomized, controlled trial."

The results from the phase 1b/2a study will be presented by Dr Maria Reig, poster number 476P, at ASCO GI on Friday January 19. Medivir will host a conference call to provide additional details from the study, comments on the data and the plans moving forward with fostrox, at 14.00 CET on January 23.

Conference call for investors, analysts and the media

Presenters from Medivir: Jens Lindberg, CEO, Pia Baumann, CMO and Fredrik Öberg, CSO.

Time: Tuesday January 23, 2024, at 14.00 CET

To access the webcast and information about the teleconference, please click [HERE](#)!

The webcast will also be streamed via a link on the website: www.medivir.com/investors/calendar

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

The poster will be available on Medivir's website after it has been presented at ASCO GI.

For additional information, please contact;

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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 percent². 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) Data cut-off 2 January, 2024

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