

Medivir reschedules report date to May 5

Stockholm – Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative medical treatments in areas of high unmet medical need, today announces that the company has decided to reschedule the publication of the interim report for the first quarter of the year from April 29 to May 5, as members of the company's management will be in South Korea on April 29 to ensure the best possible conditions for rapid recruitment of patients in the company's FLEX-HCC study.

Medivir's randomized, two-arm Phase 2 study, FLEX-HCC, is now in its final preparatory stage. The study is designed to demonstrate that fostrox in combination with lenvatinib provides superior efficacy compared to lenvatinib monotherapy in second-line treatment of advanced primary liver cancer (HCC). As part of these preparations, members of the company's management team will travel to South Korea next week to visit most of the hospitals that will participate in the study, with the aim of creating the best possible conditions for rapid patient enrollment.

As the trip coincides with the planned publication of the interim report for the first quarter, the company has decided to reschedule the report date to May 5.

The company also announces that the interest from doctors in South Korea in participating in the study has been so significant that the study's Principal Investigator, Dr. Hong-Jae Chon, and the Korean Cancer Study Group have decided to expand the number of participating sites in the study from 8 to 12 hospitals.

Dr. Pia Baumann, Chief Medical Officer of Medivir, comments: "It is very gratifying to see the strong interest in the study and that the Korean Cancer Study Group has chosen to involve additional hospitals. This is a clear indication that the need for effective treatment options in advanced liver cancer is substantial and that the study serves an important scientific purpose. Additional sites provide even better conditions for high quality and rapid patient enrollment. We look forward to our visit to South Korea, as on-site presence at study initiation is critical for engagement and enrollment pace."

For additional information, please contact

Jens Lindberg, CEO
Telefon: 08 5468 3100
E-mail: jens.lindberg@medivir.com

About Medivir

Medivir develops innovative therapies targeting areas of high unmet medical need. Its 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). Both candidates have blockbuster potential, representing significant value creation opportunities for Medivir's shareholders and affected patients. Collaborations and partnerships 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

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 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].