Press release, December 13, 2023

# Medivir have agreed with Lonza to manufacture a fostrox GMP campaign, to be tested in 2L HCC with intent to commercialize via accelerated approval

**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 that it has signed an agreement with Lonza for the manufacture of a new GMP campaign of fostrox drug substance for the planned phase 2b to enable study drug availability end of 2024 and ensure maximum momentum in the fostrox development program.**

In addition, Lonza, Medivir's partner for process development and manufacture of drug substance, has developed a process suitable for commercial manufacture of fostrox drug substance with plans underway for the final optimization, qualification and validation activities needed to support an accelerated approval after the planned phase 2b study. Lonza will also provide expert regulatory services to Medivir.

Based on promising clinical data for fostrox + Lenvima in the ongoing phase 1b/2a study in second line HCC, together with the lack of approved medical treatments after tumor progression on first line standard of care, the company has communicated the plan to initiate phase 2b study with accelerated approval intent. A GMP campaign of fostrox, produced with an updated process suitable for commercial manufacture, is critical to enable study start of the planned study.

- "This is another important step in our efforts to ensure speed and momentum in the fostrox development program. It has the potential to become the first, approved treatment option for patients that have progressed on current first line standard of care and it is imperative that we move ahead with as much speed as possible. We are very pleased with our collaboration with Lonza to ensure continued momentum.", says Jens Lindberg, CEO at Medivir.

**For additional information, please contact;**
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**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.