

Medivir announces updated formulation of fostrox, critical to support planned study with accelerated approval intent in second line HCC

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 finalized the development of an updated formulation of fostrox, suitable for commercial manufacture. HCC is a potentially life-threatening form of liver cancer and the third leading cause of cancer-related death worldwide. The need for new treatments is high and the development of an updated commercial formulation is an additional step towards fostrox becoming a treatment option for HCC patients.

The development efforts have been carried out by Quotient Sciences, Medivir's partner for formulation development and manufacture of drug product.

Fostrox is currently being evaluated in an ongoing phase 1b/2a study in combination with Lenvima®, a tyrosine kinase inhibitor. It is an open-label, multicenter study and includes patients with HCC for whom current first- or second-line treatment has proven ineffective or is not tolerable. It has the potential to provide HCC patients, who have progressed on current first line standard of care, with an alternative option where no other treatments are approved.

With the study fully recruited and ~50% of patients still on treatment, interim data indicates clinical benefit without compromising safety, when fostrox is added to Lenvima in second-line HCC. Based on these promising data, 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 formulation suitable for commercial manufacture is a critical component in clinical studies with regulatory intent. With the formulation development program successfully finalized, the next step is to manufacture three different strengths of fostrox together with placebo to ensure momentum in the fostrox development program and enable a timely start of the planned phase 2b study.

- "With the plans to initiate a phase 2b study with registrational intent, it is imperative that we use the formulation intended for commercial launch in the study. We are very pleased with our collaboration with Quotient Sciences on this updated, commercial formulation and having the formulation at this stage enables us to keep maximum momentum in the fostrox development program.", says Jens Lindberg, CEO at Medivir.

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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. Birinapant, a SMAC mimetic, is exclusively

outlicensed to IGM Biosciences (Nasdaq: IGMS) to be developed in combination with IGM-antibodies for the treatment of solid tumors. Medivir's share (ticker: MVIR) is listed on Nasdaq Stockholm's Small Cap list. www.medivir.com.

About Quotient Sciences

Quotient Sciences is a drug development and manufacturing accelerator providing integrated programs and tailored services across the entire development pathway. Cutting through silos across a range of drug development capabilities, we save precious time and money in getting drugs to patients. Everything we do for our customers is driven by an unswerving belief that ideas need to become solutions, and molecules need to become cures, fast. Because humanity needs solutions, fast. For more information, please visit quotientsciences.com.
