Press release, November 9, 2022

Medivir presents new data on additive efficacy of fostrox in combination with anti-PD1 in nonclinical tumor models at the SITC Immunotherapy Conference

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR), a pharmaceutical company focused on developing innovative treatments for cancer in areas of high unmet medical need, today announces that the poster, titled "Fostrox (MIV-818) in combination with anti-PD-1 shows increased efficacy in nonclinical tumour models in vivo" will be presented at the SITC 2022 conference, on November 10 by Fredrik Öberg, CSO at Medivir.

Fostroxacitabine bralpamide (fostrox) is an orally administered liver-targeted troxacitabine-based nucleotide prodrug currently undergoing phase 1/2a clinical trial in advanced hepatocellular carcinoma (HCC), in combination with pembrolizumab or lenvatinib (NCT03781934). Liver-selective fostrox-induced DNA-damage and tumor cell killing has the potential to enhance the efficacy of checkpoint blockade by increasing tumor antigen presentation and changing the tumor microenvironment.

The poster supports this potential as it shows that combination therapy with fostrox and anti-PD1 significantly improved anti-tumor efficacy in a pre-clinical mouse model for HCC, compared with either treatment alone. Analysis of immune-related gene expression indicated increased tumor infiltrating lymphocytes (TILs), and included upregulation of genes involved in cancer antigen presentation in the tumors. In addition, the combination of fostrox with pembrolizumab treatment, in a chorioallantoic membrane lung carcinoma model, showed enhancement of efficacy and increased tumor infiltration of CD8+ T-cells.

In conclusion the combination of fostrox with anti-PD1 showed enhanced efficacy in nonclinical tumor models, and changes in the tumor microenvironment consistent with increased immune-mediated anti-tumor activity. The results indicate a potential for combining anti-PD1 with fostrox in the treatment of HCC. The abstract and the poster will be available on Medivir's website after the presentation.

For additional information, please contact
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About fostrox

Fostrox is a 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 and other forms of liver cancer. 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 42,000 patients diagnosed with primary liver cancer per year in the US and current five-year survival is 11 percent. 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 cells 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.