US National Cancer Institute initiates phase I study of treatment of head and neck cancer patients with Medivir's birinapant and radiation therapy

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces that the first patient has been enrolled in a phase I study to investigate the safety and tolerability of a combination treatment of birinapant and radiation therapy in patients with recurrent Head and Neck Squamous Cell Carcinoma (HNSCC). The initiative for the study came from researchers at the US National Cancer Institute (NCI). The study is sponsored and financed as part of NCI's Cancer Therapy Evaluation Program (CTEP). Medivir provides birinapant and will be afforded full access to all reports from the study under its Cooperative Research and Development Agreement with NCI for birinapant. The primary goals of which are to evaluate the safety of the combination treatment and to establish a maximum tolerated dose for further studies. The potential signs of a treatment response in the patients are also investigated. Medivir's decision to support this study was based on preclinical data from NCI showing good effects from birinapant in combination with radiotherapy in models of various types of cancer of the head and neck region[1)]. Further information on the study can be found at clinicaltrials.gov with the reference number NCT03803774.

"We believe that birinapant has the potential to form part of several different combination treatments for various types of cancer," says Uli Hacksell, PhD., CEO of Medivir. "The birinapant-radiation therapy combination treatment yielded impressive results in the preclinical cancer models, and we are eagerly awaiting the results of the phase I study, which will be a good complement to the ongoing phase II combination study of birinapant and Keytruda®."

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About Head and Neck Squamous Cell Carcinoma (HNSCC)
HNSCC is diagnosed in about 550,000 individuals worldwide annually. Of these around 63,000 cases occur in the United States, where around 13,000 patients die from the disease each year. Locoregionally advanced recurrent disease in patients who have had prior chemoradiation therapy has a poor prognosis, with a two year survival rate of less than 50%.

About birinapant
Birinapant is being developed to enhance responses, and extend survival, of patients with solid tumors where existing treatments do not provide sufficient survival benefit, or where patients no longer have treatment options. Based on its unique design and mechanism, birinapant has the potential to enhance patients' responses in combination with other treatments. Medivir's initial focus is on developing birinapant in combination with an immuno-oncology agent.

About Medivir
Medivir develops innovative drugs with a focus on cancer where the unmet medical needs are high. The company is investing in indication areas where available therapies are limited or missing and there are great opportunities to offer significant improvements to patients. Collaborations and partnerships are important parts of Medivir's business model and the drug development as well as the commercialization 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.

DF Eytan et al., SMAC Mimetic Birinapant plus Radiation Eradicates Human Head and Neck Cancers with Genomic Amplifications of Cell Death Genes FADD and BIRC2. Cancer Research (2016) 76, 5442-5454.