

New data from the phase I study of birinapant in combination with Keytruda® presented at ASCO

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today informs that new data from the phase I study of birinapant in combination with pembrolizumab (Keytruda®) was presented at an oral session on June 2nd at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago, USA.

The data was presented by Dr. Russel J. Schilder, Thomas Jefferson University, Sidney Kimmel Cancer Center, Philadelphia, USA. The efficacy of the combination treatment is explored in patients with different advanced solid tumors who do not have further available treatment options.

The combination of birinapant and Keytruda® evaluated in 19 patients with advanced solid tumors was well tolerated and the recommended dose for the phase II part of the study is the highest tested dose birinapant 22 mg/m² and 200 mg of pembrolizumab. Two patients achieved a partial response and seven patients achieved stable disease as best response. Two patients are still on treatment, one patient with MSS colorectal cancer has been treated for 80 weeks and has achieved a partial response; and one patient with osteosarcoma is in stable disease has been treated for 24 weeks.

“We are delighted to see these encouraging long-term data from the phase I study of birinapant in combination with Keytruda® in a patient population, who does not have further available treatment options. The long-term data do not indicate any safety concerns related to the combination therapy,” said Uli Hacksell, PhD., CEO of Medivir.

The study is conducted in collaboration with Merck, who provides Keytruda®. Further information on the study can be found at clinicaltrials.gov with the reference number NCT02587962

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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 the birinapant/Keytruda® combination study

The multi-center, single arm, open label study, which is primarily being run in the US, is being conducted in two parts. In the initial dose escalation (phase I) part of the study, the objective was to identify the recommended phase II dose of birinapant for use in combination with Keytruda® by administering increasing doses of birinapant in combination with the approved dose of Keytruda® to groups of up to 6 patients with treatment refractory solid tumors.

The primary objective of the ongoing phase II part is to evaluate the efficacy of birinapant in combination with Keytruda® in colorectal cancer patients. An important secondary objective in the phase II part is to further assess safety and tolerability of the combination.

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.