Futility analysis performed of the phase II combination study with birinapant and Keytruda® in colorectal cancer patients

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) announces today that the independent safety committee (IDMC) for the phase II study of birinapant in combination with pembrolizumab (Keytruda®) in patients with MSS colorectal cancer has performed the planned futility analysis. The primary objective of the phase II study was an improved clinical response to treatment measured as 20% ORR (Overall Response Rate). IDMC’s recommendation is that the study should be terminated as the analysis indicates that it is unlikely that the study’s objectives will be met. Medivir has therefore decided to discontinue the recruitment of patients and to end the study.

“We are disappointed that the combination therapy with birinapant and pembrolizumab did not work better in this difficult-to-treat patient group where monotherapy with pembrolizumab has very limited effect”, said Dr Uli Hacksell, CEO of Medivir. “But we still see a potential for other combination therapies where birinapant could offer patients improved treatment. One example is the ongoing phase I study of a combination of birinapant and radiation therapy in patients with head and neck cancer.”

A total of 15 patients with advanced MSS colorectal cancer were recruited in the phase II study, 14 of which were included in the futility analysis. The combination therapy was considered acceptable from a safety perspective, but none of the patients showed a clear clinical efficacy response. Four patients were judged to have stable disease while 10 were judged to have disease progression.

The phase II study was conducted as a collaboration between Medivir and MSD, who provided pembrolizumab.

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Medivir AB is obliged to make this information public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 16.00 CET on 16 December, 2019.

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.

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 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.