First patient with colorectal cancer dosed in the Phase ll study of birinapant in combination with Keytruda®

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announced that the first patient in the phase ll part of the BPT-201 study of birinapant in combination with Keytruda® (pembrolizumab) has been dosed.

The BPT-201 study is a multi-center study that is conducted in two parts. In the recently completed phase I dose-escalation part patients with advanced solid tumours who have exhausted available treatment options were recruited. As has been announced previously, the combination of birinapant and Keytruda® has shown a positive safety profile. The phase II part will initially recruit patients with advanced microsatellite-stable colorectal cancer without any other available therapeutic options. The primary endpoint is overall response rate (ORR). The patients will be treated with Keytruda and birinapant at the dose of 22 mg/m^2 until progression or unacceptable toxicity. In the colorectal cohort, up to 28 patients are planned to be recruited with a futility analysis planned after no more than 14 patients.

“Colorectal cancer is an indication with a large unmet medical need”, said Dr Uli Hacksell, Chief Executive Officer of Medivir. “With the positive safety profile and the clinical signal of efficacy that was observed in the phase l study of birinapant in combination with Keytruda, we are excited about the potential for this combination therapy in patients with colorectal cancer and look forward to completing the phase II part of BPT-201.

For further information, please contact:
Uli Hacksell, CEO, Medivir AB, mobile: +46 (0)73 124 0615
Erik Björk, CFO, Medivir AB, mobile: +46 (0)72 228 2831

This is information that Medivir AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 08:15 CET on December 21, 2018.

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 being run in the US, is 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. This was achieved by administering increasing doses of birinapant in combination with the approved dose of Keytruda to groups of patients with treatment refractory solid tumors.

Now when the recommended phase II dose of birinapant has been selected, 22 mg/m^2, the second (phase II) part of the study is initiated. The primary objective of the phase II part is the preliminary evaluation of the

efficacy of the combination treatment in patients with the same treatment-refractory tumor type, including MSS colorectal cancer. An important secondary objective is to evaluate the safety and tolerability of birinapant in combination with Keytruda.

Under the terms of the agreement between Medivir and MSD (through a subsidiary), MSD provides Keytruda for this study at no cost to Medivir. Keytruda is marketed by MSD (known as Merck & Co., Inc, Kenilworth, NJ, USA in the US and Canada). Keytruda is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. Medivir retains full rights to birinapant. Additional details of the agreement were not disclosed.

About Medivir

Medivir is a research-based pharmaceutical company with a focus on oncology. We have a leading competence within protease inhibitor design and nucleotide/nucleoside science and we are dedicated to develop innovative pharmaceuticals that meet great unmet medical need. Medivir is listed on Nasdaq Stockholm (ticker: MVIR). www.medivir.com.