Positive interim data on birinapant in combination with Keytruda®

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announced safety and efficacy data following an interim analysis of phase I data from the ongoing phase I/II study of birinapant in combination with MSD's anti-PD-1 therapy, Keytruda® (pembrolizumab), in patients with advanced solid tumors who have exhausted available treatment options. No dose-limiting toxicity has been observed in the first three groups of patients, and the dose escalation has been continued to the highest planned dose level in the study. One of the 12 patients in this interim analysis has had a confirmed partial response to treatment, which means that the dimensions of their tumor were reduced by 30% or more on two consecutive assessments approximately two months apart when compared to the size of the tumor when treatment started.

In the phase I portion of the trial, three groups of 3-6 patients with advanced solid tumors have been fully recruited so far. Each group has received Keytruda® and one of the following doses of birinapant: 5.6mg/m^2, 11mg/m^2, 17mg/m^2. The interim analysis is based on the safety and response data from the 12 patients in these three groups. The data from the current interim analysis show that the safety profile of birinapant in combination with Keytruda® is consistent with the published clinical safety profiles of Keytruda® and birinapant when used as single agents at equivalent doses. No cases of cranial nerve palsy have been seen in any patient in the study to date.

The patient that responded to treatment with the combination of birinapant and Keytruda® had received four prior anti-cancer drug regimens to treat microsatellite stable (MSS) colorectal cancer, a cancer type in which responses to treatment with Keytruda® alone are very rare. This patient has had a confirmed partial response (by RECIST 1.1) to treatment with birinapant and Keytruda®, maintained this response at the last assessment in this interim analysis, and remains on treatment 45 weeks after starting therapy. Three additional patients in the study, with appendiceal cancer, esophageal cancer and sarcoma respectively, have had periods of stable disease lasting for at least 18 weeks following the start of treatment.

"We are pleased to provide an update on birinapant in combination with Keytruda®", said Christine Lind, Medivir's Chief Executive Officer. "With the clinical safety profile of this combination to date, one encouraging signal of efficacy in a very difficult to treat tumor type, and evidence that several other patients have derived clinical benefit from receiving this combination, we are excited about the potential for this combination therapy for patients and look forward to continuing to advance its development."

The fourth and final group of patients, which will receive birinapant at 22mg/m2 in combination with Keytruda®, is currently ongoing. The recommended phase II dose will be determined once safety data are available for all patients in the four planned dose groups. Further information on the study can be found at www.clinicaltrials.gov with the reference NCT02587962.

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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 7.10 CET on 4 October, 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 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 is to identify the recommended phase II dose of birinapant for use in combination with Keytruda®. This is to be achieved 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.

Once the recommended phase II dose of birinapant has been selected, the second (phase II) part of the study can begin. The primary objective of the phase II part is to evaluate the preliminary efficacy of birinapant in combination with Keytruda® in several different cohorts. Each of the three principal cohorts will be made up of patients with the same treatment-refractory tumor type, including MSS colorectal cancer, ovarian cancer and cervical cancer. An important secondary objective in the phase II part is to further assess safety and tolerability of the combination in each of the cohorts.

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 the Nasdaq Stockholm Mid Cap List (ticker: MVIR). www.medivir.com.