Medivir announces positive data from the phase II study of remetinostat in patients with early-stage cutaneous T-cell lymphoma

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces the completion of the phase II clinical study of the topical, skin-directed histone deacetylase (HDAC) inhibitor, remetinostat, in patients with early stage CTCL. The trial included 60 patients with the mycosis fungoides (MF) variant of CTCL, who were randomized to receive either 0.5% remetinostat gel BID, 1% remetinostat gel QD or 1% remetinostat gel BID for between 6 and 12 months. The primary end-point of the study was the proportion of patients with either a complete or partial confirmed response to therapy, assessed using the Composite Assessment of Index Lesion Severity (CAILS). Based on an intent-to-treat analysis, patients in the 1% remetinostat gel BID arm had highest proportion of confirmed responses (8/20, 40%), including 1 complete response. The response rates in the other two arms were 5/20 (25%) and 4/20 (20%) in the 0.5% BID arm and the 1% QD arm respectively, and did not include any complete responses. Across all the dose groups, remetinostat was well-tolerated without signs of systemic adverse effects, including those associated with systemic HDAC inhibitors.

Based on these data, Medivir expects to initiate discussions with regulatory authorities with the aim of initiating a phase III study later this year, and to present full phase II trial data at scientific meetings in the second half of 2017.

CTCL is a chronic, orphan hematologic cancer that presents in the skin. According to the National Cancer Institute, the most common CTCL is the mycosis fungoides (MF) variant of CTCL. MF affects an estimated 15,000 to 20,000 people in the United States, with an estimated 1,500 new cases annually, and around 75% of these have early-stage disease. Patients remain at this stage for extended periods and require long-term topical treatments for their disease, which causes substantial reductions in patients' quality of life. A small proportion of patients go on to develop cutaneous tumors or systemic disease, and these patients then require systemic anti-cancer therapy. Medivir estimates that the addressable market for early-stage CTCL in the US alone is approximately USD 900m annually.

"The results of this study confirm and extend the previously published interim analysis of the phase II study, and show that remetinostat has the potential to be a safe and effective new treatment for patients with early-stage CTCL" said Dr Richard Bethell, Medivir's Chief Scientific Officer. "There are few drugs available for the treatment of the disease, and those currently available have generally poor tolerability. As a result, CTCL patients and their physicians require safe and effective new treatment options. Remetinostat was designed to effectively inhibit HDACs within cutaneous lesions, but to be rapidly broken down in the bloodstream, preventing the side effects associated with systemically administered HDAC inhibitors. Based on the efficacy and safety data from this Phase II study, we believe that remetinostat is capable of meeting a very important unmet need in patients with this chronic and poorly treated orphan disease."

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This information 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 08.30 CET on 7 April 2017.

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 needs. Medivir is listed on the Nasdaq Stockholm Mid Cap List.