Continued discussions with FDA on proposed remetinostat phase III design results in delay in planned start of study

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announced that the Board of Directors have decided to continue the discussions with the US Food and Drug Administration (FDA) to agree on the design of the planned pivotal phase III clinical study of remetinostat for the treatment of early-stage cutaneous T-cell lymphoma (CTCL).

The aim of the continued dialog with the FDA is to agree upon the design for a phase III study that could, if successfully completed, lead to the approval of the company's most advanced candidate drug within oncology. The start of the study will not be possible earlier than 2019, and thus not in 2018 as previously communicated.

"We firmly believe that remetinostat has an important role in the treatment of various cancers, including early-stage cutaneous T-cell lymphoma, where there is a great unmet medical need", commented Christine Lind, CEO of Medivir.

"Medivir's commitment to develop remetinostat is based on its significant commercial potential, and therefore it is of utmost importance that we design a phase III study that meets the expectations of the regulatory agencies. Further discussions with the FDA are needed to ensure that we can initiate a pivotal study that will allow us to bring this drug through approval and to patients", she continued.

Details of the phase III study design will be published at a future date when finalized.

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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 08.30 CET on June 18, 2018.

About remetinostat

Medivir is developing remetinostat as a topical application for use in early stage CTCL. Remetinostat is a histone deacetylase (HDAC) inhibitor. HDAC inhibitors are approved for treatment of CTCL in late-stage patients but are not recommended for early-stage patients due to their significant side effects. The unique design of remetinostat enables topical application, making it active only in the skin. As soon as it reaches the blood stream, it is degraded, avoiding the side effects associated with other HDAC inhibitors. In the phase II study, remetinostat demonstrated a dose-dependent efficacy on skin lesions (the primary endpoint) and on pruritis (itching), and high tolerability with no systemic adverse events.

About early-stage cutaneous T-cell lymphoma

Cutaneous T-cell lymphoma (CTCL) is a rare form of blood cancer that shows up first in the skin. A key unmet medical need for patients in early-stages of CTCL is efficacy on cancerous skin lesions and the symptom of significant itching. CTCL affects around 20,000 people in each of the US and Europe and approximately 75 percent of patients are in early stages [(1)]. In its early stages, the disease is confined to the skin and is not

immediately life threatening. Patients do however experience a reduction in quality of life due to disfiguring lesions and disease symptoms, mainly significant itching. Patients also suffer an increased risk of infections as the protective skin barrier is no longer intact. Existing treatments do not sufficiently address the patient need. Thus, patients are in need of an efficacious but also highly tolerable treatment, since the early stages of disease may last for many years.

[1)]Leukemia & Lymphoma Society.

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.