Positive results from investigator-initiated phase II clinical study of remetinostat in patients with squamous cell carcinoma published

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces that results from the investigator-initiated phase II clinical study in patients with squamous cell carcinoma (SCC) have been published on ClinicalTrials.gov. The primary objective of the study was to assess the effects of topical remetinostat on biopsy-proven SCC and SCC in situ tumors. This clinical study was conducted at the Stanford University School of Medicine in California, USA under the leadership of the principal investigator, Dr Kavita Sarin. Medivir is providing remetinostat drug supply for this study, and has full access to, and the rights to use, all clinical data after the study is complete.

Four patients with five cutaneous SCCs were included in this case series and treated with remetinostat gel 1%. All five tumours, including a range of histological subtypes, demonstrated complete clinical and pathological resolution after up to 8 weeks of treatment. All patients experienced a localized cutaneous reaction in response to the treatment, which required one patient to discontinue therapy. No systemic adverse events were reported. Further details of the study can be found at www.clinicaltrials.gov, reference number NCT03875859.

- "These very encouraging results further supports the potential of remetinostat to be used in multiple skin-associated cancers beyond cutaneous T-cell lymphoma (CTCL)", said Magnus Christensen, interim CEO of Medivir.

For more information please contact:
Magnus Christensen, interim CEO, Medivir AB, phone: +46 (0)8 5468 3100.
magnus.christensen@medivir.com

About squamous cell carcinoma

Squamous cell carcinoma (SCC) is the second most common form of cancer in humans occurring in the skin. Surgical excision is standard of care and there are currently no marketed products approved for the treatment of SCC. Other therapies for SCC exist, such as imiquimod, 5-fluorouracil and photodynamic therapy, however their use is limited to SCC in situ (SCCIS). There is a clear need for efficacious and safe treatments when surgery is impractical, e.g. multiple lesions and/or difficult treatment sites.

About remetinostat

Remetinostat is a topical histone deacetylase (HDAC) inhibitor. A clinical phase II study in mycosis fungoides-cutaneous T-cell-lymphoma (MF-CTCL) has been completed demonstrating that remetinostat reduced severity of CTCL skin lesions with an objective response rate (ORR) of 40%. The study also showed a clinically significant reduction in the severity of pruritus (itching) in 80% of the patients. In addition, two investigator-initiated phase II studies have been conducted at Stanford University in the USA, demonstrating efficacy in both cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC). In BCC, 25 patients who were treated with remetinostat showed an ORR of 69.7%.

About Medivir

Medivir develops innovative drugs with a focus on cancer where the unmet medical needs are high. The drug candidates are directed toward indication areas where available therapies are limited or missing and there are great opportunities to offer significant improvements to patients. Medivir is focusing on the development of MIV-818, a pro-drug designed to selectively treat liver cancer cells and to minimize side effects. Collaborations and partnerships are important parts of Medivir's business model, and the drug development is conducted either by Medivir or in partnership. Birinapant, a SMAC mimetic, is exclusively outlicensed to IGM Biosciences

(Nasdaq: IGMS) to be developed in combination with IGM-antibodies for the treatment of solid tumors. Medivir's share (ticker: MVIR) is listed on Nasdaq Stockholm's Small Cap list. www.medivir.com