Positive data from the remetinostat phase II study in basal cell carcinoma presented at SID Annual meeting

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces that positive data from the investigator-initiated study evaluating the effects of remetinostat in basal cell carcinoma (BCC) patients has been presented at the 2019 Society for Investigative Dermatology (SID) annual meeting in Chicago, USA. This clinical study is conducted at the Stanford University School of Medicine in California, USA under the leadership of the principal investigator, Dr Kavita Sarin. Initial results suggest that remetinostat gel offers a potentially effective and well-tolerated, non-surgical intervention for treatment of localized BCCs.

Interim results of an open-label clinical trial of the topical HDAC inhibitor, remetinostat, as neoadjuvant treatment for BCC were presented. The patients enrolled had at least one BCC of any subtype between 5 and 25 mm in size. Participants applied remetinostat gel 1% 3 times daily under bandage occlusion to BCC(s) for 6 weeks prior to undergoing surgical excision. The primary outcome was overall response rate (ORR) and secondary objectives include safety and tolerability.
Interim results from the study:

- The ORR, at least a 30% decrease in longest diameter, was 64% (9/14).
- The average decrease in tumor area is 70% (n=14), while the average decrease in longest diameter is 62% (n=14). 43% (6/14) of tumors were fully cleared.
- No systemic toxicities have been observed.
- Grade 2 eczematous local site reactions occurred in 71% (10/14) tumors treated with topical remetinostat under bandage occlusion.
- 2 of 14 subjects had their study drug temporarily discontinued (for 1-3 days) due to adverse events. The reaction improves within 2-4 weeks of discontinuing medication.

“We are pleased about what appears to be a very positive outcome of treating BCC patients with topical remetinostat,” said Dr Uli Hacksell, Medivir’s Chief Executive Officer. “Remetinostat has already demonstrated efficacy in treating MF-CTCL and we are excited about the potential opportunity to develop remetinostat for multiple indications.”

The presentations are available on the Medivir website: www.medivir.com.

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About remetinostat and the investigator sponsored study
Remetinostat is a histone deacetylase (HDAC) inhibitor. 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.

The primary objective of the investigator-initiated study is to assess the effects of topical remetinostat in BCC patients and could establish that remetinostat has the potential for use in other skin-associated cancers in addition to MF-CTCL. Medivir is providing remetinostat drug for this study, and will have full access to, and the rights to use, all clinical data after the study is complete. Further details of the study can be found at www.clinicaltrials.gov with the reference NCT03180528.

About Medivir
Medivir develops innovative drugs with a focus on cancer where the unmet medical needs are high. The company is investing in indication areas where available therapies are limited or missing and there are great opportunities to offer significant improvements to patients. Collaborations and partnerships are important parts of Medivir's business model and the drug development as well as the commercialization is conducted either by Medivir or in partnership. Medivir's share (ticker: MVIR) is listed on Nasdaq Stockholm's Small Cap list. www.medivir.com.