MIV-711 Osteoarthritis Trial: Recommendation to Go Ahead based on independent review of safety data, and first patient enrolled in extension study

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces new information about its phase IIa program for the treatment of osteoarthritis:

- The independent Data Monitoring Committee (DMC) has recommended continuation of the ongoing randomized, double-blind phase IIa study (MIV-711-201) based on a review of unblinded safety data.
- The first patient has been enrolled into an open label phase IIa extension study, MIV-711-202.

The objective of MIV-711-201 is to evaluate the safety, tolerability and efficacy of six months of treatment with MIV-711 in patients with moderate knee osteoarthritis. As part of the study, an independent DMC is periodically scheduled to review the unblinded safety data from the trial. The DMC's voting members are two expert physicians and one biostatistician. The possible recommendations from such a review, based on the analysis of the accumulated safety data, could be 1) Go ahead, 2) Go ahead but with modification, 3) Suspend enrollment or 4) Stop enrollment. Based on the review of the accumulated safety data after the first 50 subjects had completed three months of treatment, the DMC has recommended that the phase IIa trial of osteoarthritis should go ahead.

In addition, the first patient has been enrolled in an open label extension study that will enroll approximately 50 patients from MIV-711-201. All patients in the study will receive 200mg MIV-711 once daily. Patients will be eligible to roll over into the extension if they have a favorable response to MIV-711 treatment, or if their disease has worsened following placebo treatment. The first objective of the study is to assess the safety and tolerability of six additional months of treatment with MIV-711, as well as its effect on knee joint structure assessed using magnetic resonance imaging (MRI), in patients who have shown evidence of a response to MIV-711 treatment. The other objective of the study is to explore the safety, tolerability and efficacy of six months of treatment with MIV-711 in patients previously on placebo whose osteoarthritis has worsened over the preceding six month period.

It is expected that data from MIV-711-201 will be available in the second half of 2017 and that data from the extension study will be available in the first half of 2018.

> "The DMC's recommendation to continue MIV-711-201 as planned based on the unblinded assessment of the available safety data is an encouraging milestone for MIV-711 and has enabled us to start the MIV-711-202 extension study", says Dr Richard Bethell, CSO at Medivir. "The DMC ruling confirms and extends the phase I data, which indicated that MIV-711 has a favorable safety profile. Long term safety will be of particular importance for disease modifying OA drugs (DMOADs) such as MIV-711, since OA patients require long term treatment and are frequently burdened by co-morbidities. We will continue to closely monitor the safety profile throughout the course of these studies. We are also excited by the opportunity to obtain longer-term safety, tolerability and efficacy data on MIV-711 in patients who have shown evidence of a response to treatment, while at the same time studying the drug in patients from the placebo arm of MIV-711-201 whose disease worsened over a six-month period as these patients may be in particular need of a disease-modifying treatment".

MIV-711 is being developed as a DMOAD, i.e. a drug to slow or reverse the progressive degeneration of joints affected by OA. There are no DMOADs approved for use currently, and the standard of care for OA patients is

based on analgesics , with the potential for associated side effect risks such as GI-bleeding and opioid dependency, and changes in life style. DMOADs for osteoarthritis therefore represent a very large and attractive market opportunity. Medivir estimates that the US market alone is greater than USD 6 billion annually for a drug that impacts disease progression, even if its use was restricted just to patient populations with moderate osteoarthritis in weight-bearing joints.

Further information on the trial planning and conduct can be found on www.clinicaltrials.gov with identifier NCT02705625.

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Medivir is required under the Securities Markets Act to make the information in this press release public. The information was submitted for publication at 8.30 CET on 23 September 2016.

About Medivir

Medivir is a research based pharmaceutical company with a research focus on oncology and infectious diseases. 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. Our commercial organization provides a portfolio of specialty care pharmaceuticals on the Nordic market. Medivir is listed on the Nasdaq Stockholm Mid Cap List.