MIV-711 osteoarthritis program: Enrollment in the phase IIa study is complete and independent safety review committee again recommends Go Ahead

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces that its first phase IIa trial of MIV-711 for the treatment of osteoarthritis has been fully enrolled. In addition, the second planned meeting of the independent Drug Monitoring Committee (DMC) has taken place, and concluded by again recommending that the trial should go ahead.

The phase IIa study, known as MIV-711-201, enrolled 244 patients into 3 arms, each with approximately 80 patients, and is designed to compare MIV-711 dosed at 100mg or 200 mg once daily against placebo. The key objectives are to assess the effect of six months of treatment with MIV-711 on knee joint clinical pain and on knee OA, assessed using magnetic resonance imaging, as well as the safety and tolerability of MIV-711. It is expected that data from the study will available in the third quarter of 2017.

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 100 subjects had completed three months of treatment, the DMC has recommended that the phase IIa trial of osteoarthritis should go ahead.

"The completion of enrollment into MIV-711-201 is an important milestone in the continuing development of MIV-711. Furthermore the timely completion of enrollment into this study demonstrates Medivir's ability to design and run complex clinical development projects", said Dr Richard Bethell, CSO at Medivir. "On behalf of Medivir, I'd like to thank all the patients involved in MIV-711-201 for their participation in this important study."

MIV-711 is being developed as a DMOAD, i.e. a drug to slow or reverse the progression of the 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 life style measures. 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 10.15 CET on 27 October 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.