MIV-711 phase IIa osteoarthritis study data presented as a late breaking poster at the Annual Meeting of the American College for Rheumatology

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) announces that data from the initial phase IIa study of MIV-711 in patients with moderate knee osteoarthritis were presented as a late-breaking poster at the 2017 annual meeting of the American College for Rheumatology (ACR), which took place from November 3-8 in San Diego, USA. The presentation, entitled “MIV-711, a Novel Cathepsin K Inhibitor Demonstrates Evidence of Osteoarthritis Structure Modification: Results from a 6 Month Randomised Double-Blind Placebo-Controlled Phase IIa Trial”, was made by Professor Philip Conaghan, Professor of Musculoskeletal Medicine at the University of Leeds in the UK and lead investigator on the study.

The principal conclusions of the study were as follows:

- Treatment with MIV-711 did not result in a statistically significant reduction in knee pain relative to placebo-treated patients, but there was consistent tendency favoring patients treated with MIV-711 in all symptom measures. In addition, analgesic use showed a tendency to be lower in both of the MIV-711 treated arms.

- Treatment with MIV-711 resulted in substantial joint protective effects after 6 months of treatment, reducing both joint bone area growth and cartilage loss compared to placebo.

- Administration of MIV-711 resulted in substantial and sustained reductions in biomarkers related to bone and cartilage degeneration, serum CTX-I and urine CTX-II respectively. The effects of MIV-711 on these biomarkers indicate robust engagement of MIV-711 with its biological target, cathepsin K, throughout the duration of treatment.

- MIV-711 had an acceptable safety and tolerability profile at both doses.

- Taken together, the data from the MIV-711-201 study are consistent with joint structure disease modification already after 6 months’ treatment. Further evaluation of MIV-711 in longer and larger DMOAD trials is therefore warranted.

The poster is available on the Medivir website: www.medivir.com

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About disease modification in osteoarthritis (OA)
OA affects over 30 million adults in the US¹, and as many as 240 million people worldwide. There are currently no disease-modifying therapies approved for the treatment of the disease. In order to exert a disease modifying effect on OA a prospective DMOAD needs to show efficacy on the degenerative changes seen in the joint in terms of bone and cartilage, as well as on clinical benefit. To date, all approved OA treatments affect only day to day symptoms and have no effect on the degenerative changes in the diseased joint².
**About MIV-711**

MIV-711 is a potent and selective inhibitor of cathepsin K, the principal protease involved in breaking down collagen in bone and cartilage. It is being developed to slow or reverse the progressive degeneration of joints affected by osteoarthritis, and is therefore referred to as a Disease Modifying Osteoarthritis Drug (DMOAD). Since there are no DMOADs approved for use currently, the standard of care for osteoarthritis patients is based on changes in lifestyle and the use of analgesics. The long-term use of analgesics by osteoarthritis patients is associated with an increased risk of side effects such as gastrointestinal bleeding and opioid dependency. DMOADs 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 to patient populations with moderate osteoarthritis in weight-bearing joints.

**About the MIV-711 phase Ila studies**

MIV-711-201 was a randomized, double-blind, placebo-controlled phase Ila clinical trial evaluating the safety and efficacy of 6 months of treatment with MIV-711 compared to placebo for the treatment of patients with moderate knee osteoarthritis. MIV-711-201 enrolled 244 patients. The primary endpoint was the change in patient-reported average knee pain. The change in joint bone area, assessed using magnetic resonance imaging (MRI), was a key secondary endpoint as it has been shown to be a sensitive and precise measure of the long-term degenerative changes that take place in the structure of joints affected by osteoarthritis. Further information about MIV-711-201 can be found at www.clinicaltrials.gov with the identifier NCT02705625.

An open-label extension study, MIV-711-202, is assessing the safety, tolerability and efficacy of six additional months of treatment with MIV-711 in patients treated in the initial study for six months who showed evidence of response, and the safety, tolerability and efficacy of six months of treatment with MIV-711 in patients who received placebo in the initial study and whose osteoarthritis worsened. Further information about MIV-711-202 can be found at www.clinicaltrials.gov with the identifier NCT03037489.

The initial study and the extension study together provide an opportunity to assess the effect of 12 months of treatment on the structure of the diseased knee, and to assess the effect of 6 months of treatment on the structure of the diseased knee in a patient population whose symptoms may be progressing rapidly, and who may therefore derive greater benefit from treatment with a potential DMOAD.

**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 needs. Medivir is listed on the Nasdaq Stockholm Mid Cap List.


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