

MIV-711 phase IIa osteoarthritis study data selected as late breaking abstract 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 have been selected for late-breaking presentation at the 2017 annual meeting of the American College for Rheumatology (ACR), which will take place Nov 3-8 in San Diego, USA. Professor Philip Conaghan, Professor of Musculoskeletal Medicine at the University of Leeds, UK, and lead investigator on the study, will make the presentation.

The abstract summarizing the data that will be presented is now available on the ACR annual meeting website: <http://acrabstracts.org/>. Abstract number 14L, abstract title: Miv-711, a Novel Cathepsin K Inhibitor Demonstrates Evidence of Osteoarthritis Structure Modification: Results from a 6 Month Randomized Double-Blind Placebo-Controlled Phase IIA Trial.

The MIV-711-201 trial enrolled 244 patients with moderate knee osteoarthritis at six sites across Europe. As previously announced, the key objective for the trial, studied as secondary endpoints, were to assess the effect of MIV-711 on joint structure using magnetic resonance imaging. The structural data at week 26 of treatment showed that patients who received 100mg and 200mg doses of MIV-711 had a substantial and statistically significant reduction in medial femur bone area growth when compared with placebo (unadjusted p-values =0.002 and 0.004. Furthermore, treatment with MIV-711 reduced the loss of medial femur cartilage thickness versus placebo (unadjusted p=0.023 for 100mg dose, 0.125 for 200mg dose). The primary endpoint of NRS pain score was not statistically significantly reduced compared to placebo. However, there was a tendency to reduction of pain score for MIV-711 on the NRS and across the majority of patient-reported outcomes (symptom, function and quality of life measures). The study data also indicate that both MIV-711 doses showed acceptable safety and tolerability profiles for this patient population..

"The selection of the abstract setting out the results of the MIV-711-201 study as a late-breaking presentation at the ACR Annual Meeting highlights the level of importance of the clinical findings from this trial" said John Öhd, Chief Medical Officer of Medivir. "The improvements in structural outcomes in patients after just 26 weeks treatment with MIV-711 represent a unique finding and offer the prospect that MIV-711 could be the first oral disease-modifying osteoarthritis drug. Although there was no statistically significant reduction in pain, it should be emphasized that the study duration required to fully realize symptom benefits expected from structure modification is unclear. It is however evident that further evaluation of MIV-711 in longer and larger osteoarthritis disease modification trials are now warranted".

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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 life style 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 IIa studies

MIV-711-201 was a randomized, double-blind, placebo-controlled phase IIa 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.

1. <https://www.cdc.gov/arthritis/basics/osteoarthritis.htm>
2. https://www.oarsi.org/sites/default/files/docs/2016/oarsi_white_paper_oa_serious_disease_121416_1.pdf