Safety and efficacy data from the MIV-711 phase II open label extension study presented at the OARSI world congress

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today informs that new data from the phase II program of MIV-711, has been presented as a poster during the Osteoarthritis Research Society International (OARSI) world congress. The poster title was Safety and Efficacy of Six Months’ Open Label Extension Post-RCT Using the Novel Cathepsin K Inhibitor MIV-711 in Patients with Osteoarthritis.

Data from the six months’ open label extension study of MIV-711 in patients with osteoarthritis were presented. This study demonstrated that MIV-711 has acceptable safety and tolerability in knee osteoarthritis patients, with the overall safety profile in patients completing 12 months’ of treatment similar to that seen in the placebo-controlled study. The beneficial effects on both bone and cartilage measures as well as symptom measures that were seen in the placebo-controlled study were maintained during the second 6-month treatment period.

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

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About MIV-711
Osteoarthritis affects over 30 million adults in the US\(^1\), and as many as 240 million people worldwide. 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 a potential 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. Work to find a commercial partner for further development is ongoing.

About the MIV-711 phase II studies
The initial phase II study, MIV-711-201, was a randomized, double-blind, placebo-controlled 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. Further information about MIV-711-201 can be found at www.clinicaltrials.gov with the identifier NCT02705625.

The open-label phase II extension study, MIV-711-202, assessed 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.
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.

1) https://www.cdc.gov/arthritis/basics/osteoarthritis.html