MIV-711 osteoarthritis phase IIa extension study outcomes show continuing positive effect on joint structure

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces positive top-line joint structure outcomes from the MIV-711 osteoarthritis phase IIa extension study (MIV-711-202). Treatment with MIV-711 over a total 12 months resulted in a continuing treatment effect on joint bone area growth and prevention of cartilage degradation.

The MIV-711 phase IIa extension study included patients with moderate knee osteoarthritis who completed 6 months of treatment in the initial phase IIa clinical trial (MIV-711-201). Patients were eligible to participate in the extension study if the pain associated with their knee osteoarthritis, assessed on the numeric rating scale (NRS), did not worsen after 6 months of treatment with 200mg once daily, or if their NRS pain symptoms worsened after 6 months of treatment with placebo. Of the total 50 patients in the MIV-711-202 study, 46 patients had received MIV-711 in the MIV-711-201 study, and therefore received a total of 12 months treatment with MIV-711, while 4 patients had previously received placebo. Changes in joint structure were determined using the same magnetic resonance imaging methods that were used in MIV-711-201 and were secondary endpoints in the extension study population that had previously received MIV-711.

The top-line joint structure imaging outcomes from the phase IIa extension study are outlined below:

	Outcomes in patients who completed a total 12 months of treatment with 200mg MIV-711 once daily
Mean change in bone area in the central medial femur	1.09% (0.09%/month)
Mean change in cartilage thickness in the central medial femur	33μm increase

These outcomes compare favorably with the outcomes from a historical control group: the patients in the initial phase IIa study treated with placebo for six months. These patients experienced a mean increase of joint bone area in the central medial femur of 0.95%, or a monthly rate of increase in joint bone area of 0.16%/month, and a mean decrease in cartilage thickness in the central medial femur of 66μm. Although there were only four patients in extension study who had previously received placebo in the initial study, the effects of treatment with MIV-711 200mg on both joint structure and clinical symptoms in these patients were consistent with the positive effects that had previously been seen after 6 months of treatment with MIV-711 200mg in the initial study.

As previously announced, the extension study met the primary endpoint, demonstrating that MIV-711 200mg had an acceptable safety and tolerability profile with 6 months of additional treatment with 200 mg MIV-711 following the initial phase IIa study (MIV-711-201) 6-month treatment period (12 months in total).

“The beneficial effects of 12 months of treatment with MIV-711 on joint structure are highly encouraging for its development as a disease-modifying osteoarthritis drug”, said Christine Lind, Medivir’s Chief Executive Officer. “Together with the safety profile of MIV-711 to date, and the consistent positive tendencies we have seen on the clinical symptoms of osteoarthritis throughout the phase II program, these new data provide further strong support for the progression of MIV-711 into later stage development and thus these are important data in our continued discussions with potential partners for MIV-711.”

Medivir plans to submit full data from the MIV-711-202 study for presentation at a future scientific meeting.

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This is information that Medivir AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 07.15 CET on July 27, 2018.

About disease modification in osteoarthritis

Osteoarthritis affects over 30 million adults in the US[1)], 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 osteoarthritis, a prospective Disease Modifying Osteoarthritis Drug (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 osteoarthritis treatments affect only day to day symptoms and have no effect on the degenerative changes in the diseased joint[2)].

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 a potential 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. Work to find a commercial partner for future development is ongoing.

About the MIV-711 phase IIa studies

The initial phase IIa 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 IIa 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 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 need. Medivir is listed on the Nasdaq Stockholm Mid Cap List (ticker: MVIR). www.medivir.com.

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