

## Medivir announces positive top-line results from the MIV-711 osteoarthritis phase IIa extension study

**Stockholm, Sweden** — Medivir AB (Nasdaq Stockholm: MVIR) today announced positive top-line results from the MIV-711 phase IIa extension study (MIV-711-202). The 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). In addition, the response level of the positive non-significant signals on patient reported pain and other clinical symptoms seen during the initial phase IIa study were maintained with the additional 6 months of treatment in the subgroup continuing in the 202 study. The overall safety and tolerability profile shown in the extension study and the accumulated safety data support the advancement of MIV-711 into further studies as a disease-modifying osteoarthritis drug.

The MIV-701-202 study was conducted in 50 patients with moderate knee osteoarthritis who had previously received 6 months of treatment with either MIV-711 200mg once daily or placebo in the MIV-711-201 study. Patients were eligible to participate in MIV-711-202 based on an assessment of the pain associated with their knee osteoarthritis, assessed on the numeric rating scale (NRS). Patients in MIV-711-201 treated with 200mg once daily were eligible to participate in the extension study if their NRS assessed pain did not worsen after 6 months of treatment. Patients in MIV-711-201 treated with placebo were eligible to participate if their NRS assessed pain worsened after 6 months of treatment. 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.

The outcomes on the secondary endpoint of safety and tolerability after 6 months' treatment in patients with prior placebo treatment were comparable to the profile seen in the MIV-711-201 study.

In addition to the primary and secondary safety endpoints of the MIV-711-202 study, several other secondary and exploratory endpoints were included in the trial design. These included the effects of 200mg MIV-711 on MRI-assessed joint structure as well as patient reported measures of pain and other clinical symptoms of osteoarthritis.

For patients who received 6 additional months of treatment with MIV-711, the positive signals on patient-reported pain and other clinical symptoms observed in the initial study were sustained. The effect of MIV-711 200mg on clinical symptom outcomes in patients who had previously received placebo in the initial study and received six months of treatment with were consistent with what had previously been seen after 6 months' treatment with MIV-711 200mg in the initial study.

"We are pleased to have completed the MIV-711-202 study showing that the safety profile of MIV-711 is acceptable and consistent with the profile seen in the MIV-711-201 study," said John Öhd, Medivir's Chief Medical Officer. He continued, "Although the data on osteoarthritis symptoms are not placebo controlled in the MIV-711-202 study, we are encouraged that the positive signs on pain and function were maintained throughout the six additional months of treatment. We are confident that the overall profile of MIV-711 from the two phase II studies support its progression into longer-term studies."

The analysis of the imaging data by which the structural endpoints are assessed is ongoing and will be published when available.

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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 08.35 CET on June 28, 2018.*

**About disease modification in osteoarthritis**

Osteoarthritis affects over 30 million adults in the US<sup>1</sup>, 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<sup>2</sup>.

**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.

**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](http://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](http://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](http://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](https://www.oarsi.org/sites/default/files/docs/2016/oarsi_white_paper_oa_serious_disease_121416_1.pdf)