Medivir initiates phase IIa study of MIV-711 in knee osteoarthritis

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces the enrolment of the first patient into a randomized double-blind phase IIa clinical study of the in-house developed cathepsin K inhibitor MIV-711 in patients with moderate knee osteoarthritis (OA).

The phase IIa study will enrol 240 patients into 3 arms, each with approximately 80 patients, and compare MIV-711 dosed at 100mg or 200 mg once daily against placebo. The key objectives are to assess the effect of six months of treatment with MIV-711 on knee joint clinical pain and on knee OA, assessed using magnetic resonance imaging, as well as the safety and tolerability of MIV-711. Timing of data from the study is on plan and expected to be available in the third quarter of 2017. Further information on the trial planning and conduct can be found on www.clinicaltrialsregister.eu.

"Despite very large numbers of patients with osteoarthritis – 250m with knee osteoarthritis alone - there are currently no disease-modifying osteoarthritis drugs (DMOADs) available for use. Patients with this disease are therefore in urgent need of improved therapies to manage this debilitating condition." says Dr Richard Bethell, EVP R&D at Medivir. "Data from preclinical models have shown that MIV-711 holds potential as a DMOAD and this has been further supported by the effects of MIV-711 on biomarkers of bone resorption and cartilage degradation that were seen in the phase I studies. The initiation of this large, well-designed phase IIa study offers patients with OA the prospect of improved treatment, and demonstrates Medivir´s capabilities to advance innovative new therapies through the clinical phases of development".

Approximately SEK 140 m of Medivir´s cash is allocated for this phase IIa program through 2017, of which approximately SEK 25 m was spent during 2015. DMOADs for osteoarthritis represent a very large and attractive market opportunity. We estimate 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 just to patient populations with moderate osteoarthritis in weight-bearing joints.

For further information, please contact:

Ola Burmark, CFO Medivir AB, mobile: +46 (0) 725 480 580
Richard Bethell, EVP Research & Development Medivir AB, mobile: +46 (0) 727 043 211

Medivir is required under the Securities Markets Act to make the information in this press release public. The information was submitted for publication at 10.30 CET on 28 January 2016.

About Medivir

Medivir is a research based pharmaceutical company with a research focus on infectious diseases and 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. Our commercial organization provides a growing portfolio of specialty care pharmaceuticals on the Nordic market. Medivir is listed on the Nasdaq Stockholm Mid Cap List.