Press Release 9 October 2013

Positive results from a phase I study with MIV-711 for the treatment of osteoarthritis and other bone related disorders

Stockholm, Sweden – Medivir AB (OMX:MVIR) announced further results from the phase I clinical study on the investigational cathepsin K inhibitor MIV-711 for the treatment of osteoarthritis and other bone related disorders. The 7 day data was presented on October 6th at the American Society for Bone and Mineral Research (ASBMR) Annual Meeting in Baltimore, USA.

The key conclusions from the study are:

- Serum levels of the bone resorption marker CTX-I were suppressed in a dose-dependent manner with up to 55% at 24 hours post last dose on Day 7
- Urinary excretion of the cartilage degradation marker CTX-II was reduced in a dose-dependent manner with up to 72% post last dose on Day 7
- Similar effects were seen in post-menopausal women dosed once daily for 28 days at 100 mg
- MIV-711was generally safe and well tolerated at all doses and durations tested

“We are excited by these clinical data with MIV-711, demonstrating it to be safe and tolerable at doses where it potently decreased cartilage degradation and bone resorption as suggested by the biomarker data. Both these phenomena are important characteristics of osteoarthritis and inhibiting bone and cartilage destruction could potentially offer new future treatment options for this large patient group that suffer from pain and progressing disabilities” said Charlotte Edenius, EVP Development, Medivir AB.

MIV-711 is a potent and selective investigational cathepsin K inhibitor for the treatment of skeletal disorders such as osteoarthritis and osteoporosis. Cathepsin K is an enzyme important for bone and cartilage break-down and inhibition of cathepsin K is expected to have a positive effect on these diseases. Preclinical data with MIV-711 have demonstrated significant reductions of biomarkers for bone and cartilage degradation and encouraging protective effects in experimental models of osteoarthritis.

Study Design
A double-blind, placebo-controlled, randomized study was designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple oral doses of 50, 100 and 200 mg of MIV-711 given once daily for 7 days in healthy male and female subjects (n=27). MIV-711 was given as an oral capsule and at each dosing occasion, 7 subjects received MIV-711 and 2 received placebo. In a separate cohort, 100 mg MIV-711 was given once daily for 28 days to postmenopausal women with 8 subjects receiving MIV-711 and 4 placebo.

Medivir is a collaborative and agile pharmaceutical company with an R&D focus on infectious diseases and a leading position in hepatitis C. We are passionate and uncompromising in our mission to develop and commercialize innovative pharmaceuticals that improve people’s lives.

Study Results – efficacy
Seven days of once daily treatment with MIV-711 decreased serum levels of the bone resorption biomarker, CTX-I, in a dose dependent manner. Compared to baseline, 50 mg MIV-711 reduced CTX-I by 40 ± 7%, 100 mg by 54 ± 4%, and 200 mg by 55 ± 8% at 24 h post final dose. MIV-711 also decreased urinary excretion of the cartilage degradation biomarker, CTX-II, in a dose dependent manner. In the last sample collected 12-24 hours after the last dose on Day 7, the rate of CTX-II excretion was reduced by 31 ± 11%, 58 ± 10% and 72 ± 9% in subjects receiving 50 mg, 100 mg and 200 mg MIV-711 respectively as compared to baseline.

In a last cohort of post-menopausal women 28 day once daily treatment with 100 mg MIV-711 decreased serum CTX-I levels on Day 28 by 67 ± 3% compared to baseline at 24 h post final dose. Urinary excretion of the bone resorption biomarkers CTX-I and NTX-I was reduced by 98 ± 1% and 76 ± 1% respectively as compared to baseline. Treatment with 100 mg MIV-711 for 28 days also decreased urinary excretion of the cartilage degradation biomarker, CTX-II, by 55 ± 9% compared to baseline.

Study Results – safety and pharmacokinetics
MIV-711 was generally well tolerated at all doses tested (50, 100 and 200 mg once daily for 7 days and 100 mg for 28 days) with no significant changes in haematology, clinical chemistry, vital signs or ECG parameters. The overall incidence of drug-related adverse events was similar across all dose levels of MIV-711 and was comparable to placebo. MIV-711 was rapidly absorbed after being administered as an oral capsule and mean Cmax values and AUC increased in a slightly more than proportional manner over the 50 to 200 mg OD dose range.

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About Medivir
Medivir is an emerging research-based pharmaceutical company focused on infectious diseases. Medivir has world class expertise in polymerase and protease drug targets and drug development which has resulted in a strong infectious disease R&D portfolio. The company is also working with research and development in other areas, such as bone disorders and neuropathic pain.

Medivir has also a broad product portfolio with prescription pharmaceuticals in the Nordics.

For more information about Medivir AB, please visit the Company's website: www.medivir.com