



Press Release 21 May 2013

Positive results from a phase Ia study with MIV-711 for the treatment of skeletal disorders

- Single doses of MIV-711 were safe and well tolerated in healthy subjects and displayed linear pharmacokinetics over the investigated dose range (20 – 600 mg)
- Serum levels of the bone resorption biomarker CTX-I were suppressed in a dose dependent manner) with up to 79% reduction at 24 hours after dose

Stockholm, Sweden – Medivir AB (OMX:MVIR) announced that data from a first in man study on the investigational cathepsin K inhibitor MIV-711 for the treatment of osteoarthritis and osteoporosis was presented today at the European Calcified Tissue Society (ECTS) Annual Meeting in Lisbon, Portugal.

“We are excited by these first clinical data with MIV-711, demonstrating it to be safe and tolerable at doses which potently decrease bone resorption biomarkers indicating that MIV-711 exerts the intended pharmacological effect on bone resorption” said Charlotte Edenius, EVP Development, Medivir AB. “MIV-711 is currently being evaluated in a phase Ib multiple ascending dose study for up to 4 weeks, which will provide us with further information on the pharmacological effects on both bone and cartilage turnover. The top line data will be available around mid-year, while further phase I data will be presented at a scientific conference later this year”.

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 an experimental model of osteoarthritis.

Study Design

A double-blind, placebo-controlled, randomized study was designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of single oral doses of 20 to 600 mg of MIV-711 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.

Study Results – effect on bone resorption biomarker

MIV-711 decreased serum levels of the bone resorption biomarker, CTX-I, in a dose dependent manner. Maximal reduction occurred with 600 mg ($79 \pm 4\%$ reduction at 24 h post dose) and at 100 mg of MIV-711 CTX-I levels were reduced by $51 \pm 4\%$ at 24 h post dose compared to baseline levels. Anticipating a target reduction of circulating CTX-I levels of approximately 50%, the results indicate that low doses will be sufficient for the desired pharmacological effects.

Study Results – safety and pharmacokinetics

MIV-711 was well tolerated at all doses tested (20 - 600mg). No serious adverse events occurred and most commonly reported adverse events were skin reactions (predominantly at electrode sites which appeared both after active drug and placebo), GI symptoms, headache and musculoskeletal pain.

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.

No apparent effects were seen on vital signs and no significant changes in hematology or clinical chemistry were observed. MIV-711 was rapidly absorbed after being administered as an oral capsule and mean C_{max} values and AUC increased proportionally with increasing dose. The pharmacokinetic and pharmacodynamic data support once-daily dosing with MIV-711.

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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. But 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