New Phase III Data from Once-Daily Simeprevir Presented at the Conference of the Asian Pacific Association for the Study of the Liver (APASL)

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announced that new phase III data for the once-daily protease inhibitor simeprevir have been presented at the Conference of the Asian Pacific Association for the Study of the Liver (APASL) in Brisbane, Australia.

- The phase III ATTAIN study in treatment-experienced adult patients with chronic hepatitis C virus (HCV) and compensated liver disease achieved its primary efficacy endpoint by demonstrating non-inferiority of simeprevir compared to telaprevir when both are given in combination with PegIFN/RBV. Simeprevir demonstrated superior safety profile including fewer adverse events (AEs), fewer serious adverse events (SAEs) and less anemia versus telaprevir.

- Pooled analysis of data from the phase III QUEST-1 and QUEST-2 studies confirmed efficacy in treatment-naïve genotype 1b HCV patients, with 85 percent (ITT analysis) of treatment-naïve patients achieving SVR12 when treated with simeprevir in combination with PegIFN/RBV, compared to 53 percent when treated with placebo in combination with PegIFN/RBV.

- In the PROMISE phase III trial of prior relapse patients, a subgroup analysis of genotype 1b patients demonstrated that 86 percent (ITT analysis) of these patients achieved SVR12 when treated with simeprevir in combination with PegIFN/RBV, compared to 43 percent when treated with placebo in combination with PegIFN/RBV.

“We are very pleased to report on the successfully completed phase III ATTAIN study demonstrating non-inferiority of simeprevir compared with telaprevir, and a superior safety profile in this difficult to treat patient group. Moreover, the further analysis of the genotype 1b HCV patients of the phase III studies QUEST-1, QUEST-2 and PROMISE demonstrated very high SVR12 rates supporting the strength of simeprevir as a treatment option for this large patient population” says Charlotte Edenius, EVP Development, Medivir AB.

ATTAIN

About the ATTAIN study

The multicenter phase III clinical study of treatment-experienced genotype 1 HCV patients partial- and null-responder patients to at least one previous course of PegIFN/RBV therapy called the ATTAIN study is a randomized, double-blind, two-arm study. In the trial, 771 patients were randomized (1:1) to treatment with either 150 mg of simeprevir once daily plus PegIFN/RBV or 750 mg of telaprevir three times per day plus PegIFN/RBV for 12 weeks, followed by 36 weeks of PegIFN/RBV alone.

Results from the ATTAIN study

Results from ATTAIN show that simeprevir achieved its primary endpoint of non-inferiority to telaprevir in treatment-experienced HCV patients and demonstrated a superior safety profile. In the study, 54 percent of chronic HCV genotype 1 prior partial- and null-responder patients treated with simeprevir administered once daily in combination with pegylated interferon and ribavirin achieved the primary endpoint of sustained virologic response 12 weeks after end of treatment (SVR12) compared to 55 percent of patients treated with telaprevir administered three-times daily plus pegylated interferon and ribavirin.

Among prior null-responder patients, 44 percent of patients in the simeprevir arm achieved SVR12 versus 46 percent of patients in the telaprevir arm. Among prior partial-responder patients, 70 percent of patients in the simeprevir arm achieved SVR12 versus 69 percent of patients in the telaprevir arm.

SVR12 rates across patient subgroups were generally similar between the simeprevir and telaprevir arms, including among patients with the HCV genotype 1a Q80K mutation. Twenty-seven percent of patients with the HCV Q80K mutation achieved SVR12 in the simeprevir arm versus 26 percent in the telaprevir arm. The study also found that 60 percent of patients with the IL28B CC genotype, 55 percent of CT patients and 48 percent of TT patients in the simeprevir arm achieved SVR12, versus 67, 57 and 50 percent of patients in the telaprevir arm, respectively.

The most common adverse events during the first 12 weeks of treatment occurred at a consistently lower frequency in the simeprevir treatment arm compared to the telaprevir treatment arm, including pruritus (31 percent versus 43 percent), fatigue (32 percent versus 38 percent), headache (25 percent versus 29 percent), anemia (13 percent versus 37 percent), and nausea (17 percent versus 28 percent). Thirty-four percent and 18 percent of simeprevir-treated patients experienced on-treatment failure and relapse, respectively, compared to 32 percent and 17 percent of telaprevir-treated patients, respectively. Two percent of patients in the simeprevir arm and eight percent of patients in the telaprevir arm discontinued treatment early due to an adverse event. Serious adverse events were reported in two percent of patients in the simeprevir arm and nine percent of patients in the telaprevir arm.

QUEST-1, QUEST-2 and PROMISE

Pooled analyses of the QUEST-1, QUEST-2 and PROMISE studies of simeprevir combination therapy in genotype 1b HCV patients

In a pooled analysis of the QUEST-1 and QUEST-2 studies, 89 percent of treatment-naïve genotype 1b HCV patients treated with simeprevir in combination with pegylated interferon and ribavirin and met the criteria for response guided therapy (94 percent) achieved SVR12 compared to 53 percent of patients treated with placebo in combination with pegylated interferon and ribavirin (ITT-analysis 85 and 53 percent, respectively). In patients typically considered difficult to treat, 71 percent of patients with the IL28B TT genotype and 78 percent with METAVIR F3-F4 scores achieved SVR12 in the simeprevir arm. Two percent of patients in each treatment arm discontinued treatment with simeprevir or placebo early due to an adverse event.

An analysis of the PROMISE study found that 89 percent of prior-relapser genotype 1b HCV patients treated with simeprevir in combination with pegylated interferon and ribavirin and met the criteria for response guided therapy (95 percent) achieved SVR12 compared to 43 percent of patients treated with placebo in combination with pegylated interferon and ribavirin (ITT-analysis 86 and 43 percent, respectively). In patients typically considered difficult to treat, 68 percent of patients with the IL28B TT genotype and 84 percent with METAVIR F3-F4 scores achieved SVR12 in the simeprevir arm. No patients discontinued treatment with either simeprevir or placebo due to adverse events during the entire treatment phase in this analysis of PROMISE.

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Medivir is required under the Securities Markets Act to make the information in this press release public. The information was submitted for publication at 08.30 CET on 17 March 2014.

About Simeprevir

Simeprevir is an NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB and indicated for the treatment chronic hepatitis C infection in combination with pegylated interferon and ribavirin in HCV genotype 1 infected patients with compensated liver disease, including cirrhosis.

Janssen is responsible for the global clinical development of simeprevir and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir AB will retain marketing rights for simeprevir in these countries under the marketing authorization held by Janssen-Cilag International NV. The treatment was approved for the treatment of genotype 1 hepatitis C in September 2013 in Japan and in November 2013 in Canada and USA. A Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) in April 2013 by Janssen-Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C. This application is under review by the EMA.

Simeprevir is also being studied in several interferon-free regimens using selected combinations of direct-acting antiviral agents with different mechanisms of action. To date, more than 3,700 patients have been treated with simeprevir in clinical trials.

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's key pipeline asset is simeprevir, a novel protease inhibitor for the treatment of hepatitis C that is being developed in collaboration with Janssen R&D Ireland. 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