New data on Simeprevir presented at the Conference of the Asian Pacific Association for the Study of the Liver

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announced that new clinical data for the once-daily HCV protease inhibitor simeprevir have been presented at the 24th Conference of the Asian Pacific Association for the Study of the Liver (APASL) in Istanbul, Turkey. Six oral and poster presentations on three clinical studies spanning over several development programs including simeprevir in different treatment combinations, durations and populations were held.

"We have a long and fruitful relationship with our global partner Janssen on simeprevir. These data show the commitment Janssen has for the HCV area, with studies of simeprevir in a wide range of patient populations and treatment regimens", says Niklas Prager CEO of Medivir

Major findings in the studies presented:

Interferon free combinations

- In a phase II study up to 95% cure rates were achieved in HCV genotype (GT)1 infected patients treated with a 3-DAA combination of simeprevir, TMC647055/ritonavir and JNJ-56914845.

Interferon based triple combinations

- In the phase III TIGER study in treatment-naive patients with chronic HCV GT1 infection conducted in China and Korea 89-91% were cured with simeprevir in combination with pegylated interferon (P) and ribavirin (R) for 12 weeks followed by PR for a further 12 or 36 weeks.

- The potential to shorten the total simeprevir plus PR treatment to 12 weeks in treatment-naïve hepatitis C patients is being investigated in an on-going phase III study. In the GT1 study arm 76% of the patients were eligible to shorten treatment and of those 66% achieved SVR12 (were cured). In the GT4 study arm 48% of the patients were eligible for shortened treatment and of those with evaluable outcome at the time of analysis 94% had achieved SVR4.

About the studies

HPC2001 – an interferon free study with 2 or 3 Direct Acting Antivirals (DAA) including simeprevir
This is an open phase IIa efficacy, safety and pharmacokinetic study of 12 weeks of simeprevir (SMV) in various interferon free combinations in HCV GT1 infected treatment naïve and prior relapser patients without cirrhosis. TMC647055 is a potent non-nucleoside polymerase inhibitor and JNJ-56914845 is a potent NS5A replication complex inhibitor.

Panel 1-3 included a 2-DAA combination (SMV + TMC647055/ritonavir) at different doses +/- ribavirin (n=7-12 per arm). Up to 86% of the patients achieved SVR12 (were cured) with ribavirin while up to 50% of the patients without addition of ribavirin achieved SVR12.

Panel 4 included a 3-DAA combination of SMV + TMC647055/ritonavir and 30 or 60 mg of JNJ-56914845 (n=22 per arm). This combination treatment resulted in overall SVR12 rates of 82% and 95% in the low and high dose groups of JNJ-56914845, respectively. All GT1b patients (100%) were cured regardless of JNJ-56914845 dose, while 71% and 93% of GT1a patients achieved SVR12 with the low and high dose of JNJ-56914845, respectively.

The combination treatments in all panels were generally well tolerated.

HPC3005 - the TIGER study in China and Korea
This is a phase III, randomised three-armed study evaluating simeprevir 150 mg (n=152) or 100 mg (n=153) or placebo (n= 152) plus PR for 12 weeks in treatment-naïve genotype 1 HCV patients in China and Korea. Patients in the simeprevir arms received PR alone for a further 12 or 36 weeks based on response-guided criteria (RGT). All patients in the placebo arm received a further 36 weeks of PR alone. Primary efficacy endpoint was sustained virologic response 12 weeks after planned end of treatment (SVR12).

The treatment was generally well tolerated and highly effective, with 89 % and 91 % SVR12 achieved in the 100 mg and 150 mg dose groups respectively, compared to 76% in the placebo arm; each simeprevir arm demonstrating superiority. 94% of the simeprevir-treated patients were eligible for the shorter 12 weeks follow-up treatment with PR and of those 94% achieved SVR12.

HPC3014 – shortening overall treatment to 12 weeks of simeprevir plus PR in HCV GT1 and GT4 patients
This is an on-going phase III, open-label study of efficacy and safety of 12 weeks treatment with SMV + PR in treatment-naıve GT1 and GT4 HCV infected patients with mild-to-moderate fibrosis (METAVIR F0-F2). The aim of the study is to assess whether overall treatment duration with simeprevir + PR can be shortened to 12 weeks, based on early viral kinetics including a Week 2 assessment. Patients not meeting predefined response criteria continued with additional 12 weeks of PR treatment.

Of the GT1 patients 76% (123 out of 163) were eligible for 12 weeks total treatment duration and of those 66% achieved SVR12. Higher SVR12 rates were seen in: IL28B CC genotype patients, patients with low baseline viral load, or those with mild fibrosis.

Of the GT4 patients 48% (24 out of 50) were eligible for 12 weeks total treatment and of those with evaluable outcome at time of analyses 94% (16 out of 17) had achieved SVR4.

Treatment with simeprevir and PR was generally well tolerated.

The following abstracts were presented:

"Efficacy safety and pharmacokinetics of 12 weeks of simeprevir in combination with TMC647055 ritonavir and JNJ-56914845 in genotype 1 hepatitis C virus infected patients" (presented by S Bourgeois).

"Efficacy safety and pharmacokinetics of 12 weeks of simeprevir in combination with TMC647055 and ritonavir with or without ribavirin in genotype 1 hepatitis C virus infected patients" (presented by S Bourgeois).

"Simeprevir plus peginterferon ribavirin in treatment naïve patients with chronic hepatitis C virus genotype 1 infection results from the phase III tiger study conducted in east asian patients living in China and Korea" (presented by L Wei).

"Simeprevir exposure in Asian treatment naive patients with chronic hepatitis C virus genotype 1 infection results from a population pharmacokinetic model in the phase III tiger study" (presented by E. Hoeben).

"Shortening overall treatment to 12 weeks of simeprevir plus pegylated interferon and ribavirin according to early virologic response in treatment naïve patients with chronic HCV genotype 4 infection and mild to moderate fibrosis" (presented by T Asselah).

"Shortening overall treatment to 12 weeks of simeprevir (smv) plus Peg-IFN and RBV in treatment naïve chronic hepatitis C (CHC) genotype 1 patients assessment of baseline and early (week 2) on treatment predictors of high SVR" (presented by T Asselah).

Further details can be found at www.apasl2015.org, at www.clinicaltrials.gov, and in Hepatol Int (2015) 9 (Suppl 1):S1–S391.

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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 8.30 CET on 16 March 2015.

About Simeprevir (OLYSIO®)

Simeprevir is an NS3/4A protease inhibitor jointly developed by Janssen Sciences Ireland UC and Medivir AB and indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. Simeprevir efficacy has been established in HCV genotype 1 and HCV genotype 4 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 retains marketing rights for simeprevir in these countries under the marketing authorization held by Janssen-Cilag International NV. Simeprevir was approved for the treatment of chronic hepatitis C infection as part of an antiviral treatment regimen in combination with pegylated interferon and ribavirin in genotype 1 infected adults with compensated liver disease, including cirrhosis. Simeprevir was approved in September 2013 in Japan, in November 2013 in Canada and the U.S., in March 2014 in Russia and in July 2014 in Mexico and Australia.

In May 2014 simeprevir was granted marketing authorization by the European Commission (EC) for the treatment of adult patients with genotype 1 or genotype 4 chronic HCV. Following the EMA approval, it has so far been made available in several EU countries in conjunction with reimbursement. Simeprevir (OLYSIO) is marketed under the trade name Sovriad® in Japan and Russia, Galexos™ in Canada and Olysio® in the U.S. and European Union.

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.