Final data from the phase II COSMOS study with Simeprevir in combination with Sofosbuvir presented at EASL

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announces that positive new simeprevir data were presented at The International Liver Congress™ 2014 of the European Association for the Study of the Liver (EASL) in London. The data presented included;

- Final phase II data from the interferon-free COSMOS study
- Phase III efficacy data in patients with genotype 4 hepatitis C
- Subgroup analyses of patients from phase III studies QUEST-1, QUEST-2 and PROMISE

Final phase II data from the interferon-free COSMOS study

Cohort 2

Final results from cohort 2 of the phase II COSMOS study demonstrated that 93 percent of prior null responder and treatment-naïve patients with genotype 1 HCV and advanced liver fibrosis (METAVIR scores F3 and F4) who were treated with simeprevir and sofosbuvir for 12 weeks achieved sustained virologic response 12 weeks after the end of treatment (SVR12). The addition of ribavirin did not improve SVR rates and consistent responses for both treatment arms were seen across HCV genotype subgroups after 12 weeks.

SVR12 Among Patient Subgroups with Genotype 1 HCV and Advanced Liver Fibrosis/Cirrhosis in Cohort 2 of the COSMOS Study*		
12 Weeks of Treatment		
Regimen	Simeprevir/Sofosbuvir (%)	Simeprevir/Sofosbuvir + Ribavirin (%)
Overall	93	93
Genotype 1a HCV without the Q80K polymorphism	88	93
Genotype 1a HCV with the Q80K polymorphism	100	88
Genotype 1b HCV	100	100
METAVIR F4	86	91

*Excluding non-virologic failures.

The most common adverse events reported during the study were fatigue, headache, nausea, anemia, pruritus, dizziness, rash and photosensitivity. One patient discontinued treatment due to adverse events.

Cohort 1

Previously presented data from cohort 1 at AASLD in November 2013, demonstrated that 96 percent and 93 percent of prior null responder patients with METAVIR F0-F2 scores treated with simeprevir and sofosbuvir without or with ribavirin, respectively, for 12 weeks achieved SVR12.

SVR12 Among Patient Subgroups with Genotype 1 HCV and METAVIR Scores of F0-F2 in Cohort 1 of the COSMOS Study*		
12 Weeks of Treatment		
Regimen	Simeprevir/Sofosbuvir (%)	Simeprevir/Sofosbuvir + Ribavirin (%)
Overall	96	93
METAVIR F2	100	94

*Excluding non-virologic failures.

In genotype 1a patients with the Q80K polymorphism at baseline, 83 percent and 89 percent achieved SVR12 after 12 weeks of treatment without and with ribavirin, respectively. The most common adverse events reported during the study were fatigue, headache, nausea and insomnia. Two patients discontinued treatment due to adverse events.

Phase III efficacy data in patients with genotype 4 hepatitis C

Results from the Phase III RESTORE trial of simeprevir in combination with pegylated interferon and ribavirin in HCV genotype 4 treatment-naïve and treatment-experienced patients demonstrated that overall 65 percent of patients achieved SVR12, including 83 percent of treatment-naïve patients, 86 percent of prior relapsers, 60 percent of prior partial responders, and 40 percent of prior null responders. Among patients with more severe liver fibrosis characterized by a METAVIR score of F3 or F4, 67 percent and 47 percent achieved SVR12, respectively. Among patients with genotype 4a and 4d HCV, 69 percent and 52 percent achieved SVR12, respectively. The most frequent adverse events included influenza-like illness, asthenia (weakness) and fatigue.

Genotype 4 HCV is considered particularly difficult to cure and currently only limited treatment options are available.

Subgroup analyses of patients from phase III studies of Simeprevir

Analyses of pooled efficacy data from the QUEST-1 and QUEST-2 studies found 87 percent of European patients treated with simeprevir in combination with pegylated interferon and ribavirin achieved SVR12, compared to 80 in the overall study population. In an analysis from the PROMISE study, 88 percent of European patients treated with simeprevir in combination with pegylated interferon and ribavirin achieved SVR12 compared to 79 percent in the overall study population.

The efficacy of simeprevir in combination with pegylated interferon and ribavirin was also observed among European patients with baseline characteristics typically considered more difficult to cure. In QUEST-1 and QUEST-2, 71 percent of patients with METAVIR F4 scores, 86 percent of patients with the *IL28B* CT genotype, 69 percent of patients with the *IL28B* TT genotype and 64 percent of genotype 1a patients with the Q80K polymorphism at baseline achieved SVR12 in the simeprevir arm, compared to 25 percent, 44 percent, 31 percent and 50 percent of patients in the active placebo arm, respectively. In PROMISE, 85 percent of patients with METAVIR F4 scores, 88 percent of patients with the *IL28B* CT genotype, 77 percent of patients with the *IL28B* TT genotype and 75 percent of genotype 1a patients with the Q80K polymorphism at baseline achieved SVR12 in the simeprevir arm, compared to 30 percent, 41 percent, 18 percent and 57 percent of patients treated in the active placebo arm, respectively.

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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 17.15 CET on 12 April 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 and 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 in September 2013 in Japan, in November 2013 in Canada and the U.S. and in March 2014 in Russia. 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 and the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending Marketing Authorisation in the European Union for the use of simeprevir in combination with other medicinal products for the treatment of chronic HCV. This application is under review by the EMA.

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.