Press Release 20 December 2012

Medivir announces phase III data for Simeprevir demonstrating efficacy and safety in genotype 1 hepatitis C patients

- Simeprevir achieved SVR12 rates (viral cure) of 79% to 81% in the three pivotal phase III trials QUEST-1, QUEST-2 and PROMISE in genotype 1 hepatitis C patients.
- The overall results demonstrate that simeprevir is safe and well tolerated with a safety profile of the simeprevir treatment arms similar to the placebo control.
- A majority of the patients, 85-93%, were able to stop all treatment after 24 weeks.

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announced top-line results from three pivotal phase III trials examining the one pill, once-daily, investigational protease inhibitor, simeprevir (TMC435), administered with pegylated interferon and ribavirin.

Results from the QUEST-1 and QUEST-2 trials found that 80% and 81% of treatment-naive patients with chronic genotype 1 hepatitis C infection who were treated with simeprevir achieved sustained virologic response 12 weeks after the planned end of treatment (SVR12). Results from the PROMISE trial found that 79% of prior relapsed patients treated with simeprevir achieved SVR12. All three studies utilized response-guided treatment (RGT) criteria and 85%, 91% and 93 % of the patients, respectively, were eligible to stop all treatments after 24 weeks.

The overall safety, tolerability and efficacy results from these studies were consistent with those previously obtained in phase II studies.

Final analysis of the phase III trials is ongoing and the full data set from these studies will be submitted for presentation at future scientific conferences.

"We are extremely happy about the data from these phase III studies, which robustly demonstrate high cure rates in both treatment-experienced, so called relapsers, and treatment-naïve patient groups, both including patients with severe liver disease. Together with the very good safety profile and the fact that a large proportion of the patients were eligible to end all treatments in a shorter time frame as compared to current standard of care, should provide new hope for large patient groups with this disease", said Charlotte Edenius, EVP of Research and Development, Medivir AB. "We look forward to seeking regulatory approvals to bring simeprevir forward to help treat people living with chronic hepatitis C."

QUEST-1 (C208), QUEST-2 (C216) and PROMISE (C3007)
In the global QUEST-1 and QUEST-2 trials, 394 and 391 respectively, treatment-naïve patients with genotype 1 hepatitis C were randomized to receive either 150 mg of once-daily simeprevir for 12 weeks plus pegylated interferon and ribavirin for 24 or 48 weeks based upon response guided treatment criteria (simeprevir group) or pegylated interferon and ribavirin alone for 48 weeks (control group).

In the PROMISE study, 393 patients, who had previous relapse after completing HCV treatment with pegylated interferon and ribavirin, were randomized to receive either 150 mg of once-daily simeprevir for 12 weeks plus pegylated interferon and ribavirin for 24 or 48 weeks based on response guided treatment criteria (simeprevir group) or pegylated interferon and ribavirin alone for 48 weeks (control group).

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.

Summary Table

Sustained Virologic Response (SVR12 Rates in Simeprevir (TMC435) Dose Groups (150 mg q.d.) vs PR Placebo Intention-To-Treat (ITT) Population			
	Treatment Naive Patients		Treatment Experienced - Prior Relapser Patients
% (N)	QUEST-1 TMC435 150 mg QD 12wks PR24/48 wks	QUEST-2 TMC435 150 mg QD 12wks PR24/48 wks	PROMISE TMC435 150 mg QD 12wks PR24/48 wks
SVR12	80 (264)	81 (257)	79 (260)
SVR12 Placebo PR48wks	50 (130)	50 (134)	37 (133)
Percentage of Patients in Simeprevir Treatment Arms Meeting RGT Criteria Who Could Stop All Treatment at Week 24			
	QUEST-1	QUEST-2	PROMISE
%	85	91	93
Percentage of Patients Who Displayed Advanced Liver Disease Upon Study Entry			
METAVIR Score F3-F4 (%)	30	22	31

q.d.: once daily; PR: pegIFNalpha and ribavirin;
SVR12: patients with undetectable HCV RNA (<25 IU/mL Undetectable) 12 weeks after planned EoT.
All simeprevir (TMC435) groups: p<0.001 vs placebo.
Prior Relapser: undetectable HCV RNA at EoT and detectable within 12/24 weeks of follow-up
RGT: Response Guided Treatment: HCV RNA < 25 IU/mL (detectable or undetectable) at Week 4 and undetectable HCV RNA (< 25 IU/mL undetectable) at Week 12 (all other patients continued Peg-IFN/RBV up to W48)

Summary – Safety and Tolerability

Simeprevir was generally safe and well tolerated and overall incidence of adverse events (AEs), including rash and anemia was similar to the placebo control and consistent with prior simeprevir phase II studies. In all three phase III studies, AEs leading to permanent discontinuation were lower in the simeprevir treated subjects compared to the placebo control (pegylated interferon and ribavirin).

Mild and reversible increases in bilirubin (total, direct and indirect) were observed in simeprevir dose groups. There were no meaningful differences between treatment groups for any of the other laboratory parameters. There were no clinically significant findings on vital signs. Mean alanine aminotransferase (ALT) levels decreased in all simeprevir treatment groups.

For more information please contact:

Medivir
Rein Piir, EVP Corporate Affairs & IR Direct: +46 8 440 6550 or: Mobile: +46 708 537 292.

Conference call Today, 20 December, at 14.00 (CET)

Phone numbers for participants from:

Sweden	0200 89 63 77
Europe	+44 (0)20 3003 2666
USA	+1 866 966 5335

The conference call will also be streamed live via a link on the website: www.medivir.com

About Simeprevir (TMC435)
Simeprevir, a potent investigational NS3/4A protease inhibitor jointly developed by Janssen and Medivir, is currently in phase III studies as a one pill once-daily treatment taken in combination with pegylated interferon and ribavirin for the treatment of genotypes 1 and 4 chronic hepatitis C infection.

Global phase III studies of simeprevir include QUEST-1 and QUEST-2 in treatment-naïve patients, PROMISE in patients who have relapsed after prior interferon-based treatment, ATTAIN in prior null-responder patients and studies in Japanese HCV genotype 1 patients. In parallel to these trials, phase III studies for simeprevir are ongoing in treatment-naïve and treatment-experienced HIV-HCV co-infected patients and in HCV genotype 4 patients.

Simeprevir is also being studied in phase II interferon-free trials both with and without ribavirin:

- Simeprevir in combination with Gilead Sciences' sofosbuvir (GS7977) in hepatitis C genotype 1 treatment-naïve or prior null responder patients.
- Simeprevir in combination with BMS's, daclatasvir in hepatitis C genotype 1 treatment-naïve or prior null responder patients
- Simeprevir in combination with Janssen's TMC647055 and low dose ritonavir in hepatitis C genotype 1 treatment-naïve, prior relapser or null responder patients
- Simeprevir in combination with Vertex's VX-135 in hepatitis C genotype 1 treatment-naïve patients to commence in 2013

For additional information about simeprevir, please visit www. clinicaltrials.gov

About Hepatitis C
Hepatitis C is a blood-borne infectious disease of the liver and is a leading cause of chronic liver disease and liver transplants. The World Health Organization estimates that nearly 170 million people worldwide, approximately 3% of the world's population, are infected with hepatitis C virus (HCV). The CDC (Centers for Disease Control and Prevention) has reported that more than three million people in the United States are chronically infected with HCV.

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 (TMC435), a novel protease inhibitor in phase III clinical development for hepatitis C that is being developed in collaboration with Janssen R&D Ireland.

In June 2011, Medivir acquired the specialty pharmaceutical company BioPhausia and today Medivir has a broad product portfolio with prescription pharmaceuticals in the Nordics.

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