Press Release 6 June 2013

Primary efficacy and safety data from four phase III Japanese studies of Simeprevir presented at The Japan Society of Hepatology

Stockholm, Sweden — Medivir AB (OMX: MVIR) reports that its partner Janssen Pharmaceutical R&D Ireland (Janssen) today announced primary efficacy and safety results from four Japanese phase III clinical studies demonstrating that the use of the investigational NS3/4A protease inhibitor simeprevir (TMC435) led to sustained virologic response 12 weeks after the end of treatment (SVR12) in patients with genotype 1 hepatitis C, when administered once daily with pegylated interferon and ribavirin. The four studies examined the use of simeprevir in genotype 1 chronic hepatitis C patients who were treatment naïve, as well as patients who were non-responders to prior therapy or relapsed following treatment with pegylated interferon with or without ribavirin.

The data were presented today at The Japan Society of Hepatology's 49th Annual Meeting in Tokyo. The CONCERTO studies supported the new drug application for simeprevir, which was submitted to Japanese regulatory authorities in February 2013.

Janssen's phase III clinical program for simeprevir in Japan consists of four studies in patients with genotype 1 HCV: CONCERTO-1 in treatment-naïve patients, CONCERTO-2 and -3 in prior non-responders or patients who relapsed after prior interferon-based treatment, and CONCERTO-4 using different pegylated interferon treatments (pegylated interferon alfa-2b) in a broad patient population.

More information about the study design could be found at www.clinicaltrials.gov.

SVR12 in the CONCERTO Trials			
Trial	Patient Type	Treatment + pegylated interferon and ribavirin	Proportion of Patients Achieving SVR12 (%)
CONCERTO-1	*Treatment-naïve*	Simeprevir (12 weeks)	89
		Placebo (12 weeks)	62
CONCERTO-2	*Prior Non-responder*	Simeprevir (12 weeks)	53
		Simeprevir (24 weeks)	36
CONCERTO-3	*Prior Relapser*	Simeprevir (12 weeks)	96
CONCERTO-4	*Treatment-naïve*	Simeprevir (12 weeks)	92
	Prior Relapser	Simeprevir (12 weeks)	100
	Prior Non-responder	Simeprevir (12 weeks)	39

The most common adverse events seen in patients receiving simeprevir plus pegylated interferon and ribavirin in CONCERTO-1 were similar to those observed with pegylated interferon and ribavirin alone and were also similar in the other studies (decreased white blood cell count, fever, anemia, decreased neutrophil count, malaise, headache and rash). Treatment discontinuation rates due to an adverse event in CONCERTO-1 were five percent in the simeprevir arm and 8 percent in the placebo arm, four percent in CONCERTO-2, four percent in CONCERTO-3 and one percent in CONCERTO-4.

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About Simeprevir
Simeprevir is a new generation NS3/4A protease inhibitor jointly developed by Medivir and Janssen for the treatment of chronic hepatitis C in adult patients with compensated liver disease.

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

About Hepatitis C
Hepatitis C, a blood-borne infectious disease of the liver and a leading cause of chronic liver disease and liver transplants, is a rapidly evolving treatment area with a clear need for innovative treatments. Approximately 150 million people are infected with hepatitis C worldwide, and about 350,000 people per year die from the disease.

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 in late phase III clinical development for hepatitis C that is being developed in collaboration with Janssen R&D Ireland. 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