Press Release 18 October 2013

Medivir announces data from two phase III studies with Simeprevir in hepatitis C subpopulations – HCV/HIV co-infected and genotype 4 infected patients

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announced preliminary data from two phase III studies conducted by Janssen R&D Ireland evaluating simeprevir in genotype 4 chronic hepatitis C in adult patients with compensated liver disease, and in genotype 1 hepatitis C and HIV-1 co-infected adult patients. The data were presented today at the ongoing European AIDS Conference (EACS), October 16-19 in Brussels.

"Based on these encouraging data with the high cure rates seen in patients co-infected with HCV genotype 1 and HIV-1 we believe that simeprevir could provide a new treatment option in this specific patient group" says Charlotte Edenius, EVP Development, Medivir AB. *"We are also delighted to see the positive interim results from patients infected with HCV genotype 4, a strain of virus which currently have limited treatment options."*

HCV/HIV co-infected patients - Study Design
This phase III, open-label trial evaluated the safety and efficacy of simeprevir (150 mg QD) with peginterferon and ribavirin (PR) for 12 weeks in patients co-infected with HCV genotype-1 and HIV-1 (N=106). Treatment-naïve patients (N=53) and prior relapsers (N=15) (without cirrhosis) received response-guided therapy (RGT) with PR up to 24 or 48 weeks. All other patients (prior null responders [N=28], partial responders [N=10] and all patients with cirrhosis) received PR up to 48 weeks. The primary endpoint was sustained virologic response (SVR) rate 12 weeks after end of treatment. In the study 93 patients were receiving antiretroviral therapy (ART), 12% of patients had cirrhosis, 82% had genotype 1a subtype and 73% had an IL28B CT or TT genotype.

HCV/HIV co-infected patients - Summary Primary Results
High SVR12 rates were observed regardless of prior HCV treatment response with 79% in HCV treatment-naive patients, 87% in prior relapsers, 70% in partial responders and 57% in null responders. Most patients eligible for shorter duration of treatment met the RGT criteria (89%; 54/61), of whom 87% (47/54) achieved SVR12.

The SVR12 rate in genotype 1b was 89% (16/18) and in genotype 1a 70% (62/88) where genotype 1a patients with Q80K polymorphism at baseline achieved SVR12 rates of 67% (20/30). SVR12 rates were high irrespective of baseline METAVIR fibrosis score (80% and 64% for patients with of F0–F2 and F3–F4 respectively).

Simeprevir once daily with PR was well tolerated with a safety profile similar to that observed in studies of mono-infected patients.

Primary efficacy endpoint with 150 mg simeprevir for 12 weeks with peginterferon and ribavirin (PR) for up to 24 or 48 weeks). Intent-to-treat (ITT) population.

Patients co-infected with HCV genotype-1 and HIV-1:					
% (n/N)	Overall (N=106)	Treatment naive (N=53)	Prior relapsers (N=15)	Prior partial responders (N=10)	Prior null responders (N=28)
SVR12	74 (78/106)	79* (42/53)	87 (13/15)	70 (7/10)	57* (16/28)

* p<0.001 vs historical PR-only controls: SVR12 for PR controls was assumed to be 29% in treatment naive (from PEGASYS® USPI, co-infected patients) and 5% in prior null responders (from INCIVEK™ USPI, mono-infected patients).

HCV Genotype 4 Patients - Interim Results

In this phase III study, 107 patients with chronic HCV genotype 4 received simeprevir once daily with peginterferon and ribavirin (PR) for 12 weeks. Treatment-naïve patients and prior relapsers received response-guided therapy (RGT) with PR up to 24 or 48 weeks. Prior partial responders and prior null responders received PR up to 48 weeks.

At the time for this interim analysis only data from patients eligible to shorten therapy and who had reached study visit W28 (SVR4) and W36 (SVR12) were included. In these patients SVR4 rates of 89-91% (N=20) and SVR12 of 67-100% (N=9) were achieved. Overall simeprevir was well tolerated and most AEs were grade 1 or 2.

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About Simeprevir

Simeprevir is an investigational NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB, for the treatment of genotype 1 and genotype 4 chronic hepatitis C in adult patients with compensated liver disease, including all stages of liver fibrosis. Simeprevir works by blocking the protease enzyme that enables the hepatitis C virus to replicate in host cells.

Janssen R&D Ireland, and its affiliated companies, are responsible for the global clinical development of simeprevir and have acquired exclusive, worldwide marketing rights, except for the Nordic countries where Medivir AB have retained the marketing rights under the marketing authorization held by Janssen-Cilag International NV.

Simeprevir was approved in Japan in September 2013 for the treatment of genotype 1 hepatitis C. In the U.S., the New Drug Application (NDA) filed by Janssen Research & Development, LLC (Janssen) for simeprevir administered once daily in combination with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C in adult patients was granted Priority Review designation by the Food and Drug Administration (FDA) in May. A Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) in April by Janssen- Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C.

To date, more than 3,700 patients have been treated with simeprevir in clinical trials

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, is the focus of a rapidly evolving treatment landscape. Approximately 150 million people are infected with hepatitis C worldwide – including approximately 3.2 million people in the United States – and 350,000 people per year die from the disease globally. When left untreated, hepatitis C can cause significant damage to the liver including cirrhosis. Additionally, hepatitis C may increase the risk of developing complications from cirrhosis, which may include liver failure.

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