Press Release 2 November 2013

Medivir announces that new Simeprevir data will be presented at the AASLD meeting

Stockholm, Sweden — Medivir AB (OMX: MVIR) announces that new data will be presented on the investigational protease inhibitor simeprevir (TMC435) in treatment-naïve genotype 1 chronic hepatitis C patients and in treatment-experienced patients with compensated liver disease. These data will be presented at the ongoing Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) taking place during November 1 to 5 in Washington, D.C.

In the analyses of the QUEST-1 and QUEST-2 phase III studies in treatment-naïve patients and the phase III PROMISE study in prior relapse patients, efficacy of simeprevir was demonstrated in hepatitis C patients, including patients with the *IL28B* TT genotype and METAVIR scores of F4 (cirrhosis).

On October 24, the U.S. Antiviral Drugs Advisory Committee of the FDA voted unanimously (19-0) to recommend approval of the new drug application filed by Janssen Research & Development, LLC for simeprevir administered once daily with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C virus (HCV) in adult patients with compensated liver disease.

The data to be presented at the 2013 AASLD Annual Meeting include:

Poster Presentations: HCV Therapeutics: New Agents, Poster Hall, November 3, 8:00 a.m. - 5:30 p.m. (EST):

Simeprevir (TMC435) with peg-interferon α-2a/ribavirin for treatment of chronic HCV genotype 1 infection in patients who relapsed after previous interferon-based therapy: Efficacy and safety in patient sub-populations in the PROMISE Phase III trial
- Lead Author: Xavier Forns, Hospital Clinic, Barcelona, Spain

Adding simeprevir to peginterferon/ribavirin for HCV shortens time with patient-reported symptoms and impairment in quality of life: Results from the simeprevir Phase III QUEST 1, QUEST 2, and PROMISE studies
- Lead Author: Jane A. Scott, Janssen

Simeprevir (TMC435) with peginterferon/ribavirin for treatment of chronic HCV genotype 1 infection in treatment-naïve patients: Efficacy in difficult-to-treat patient sub-populations in the QUEST-1 and 2 Phase III trials
- Lead Author: Ira M. Jacobson, Weill Cornell Medical College, New York, USA

Resistance analyses of HCV isolates from patients treated with simeprevir in Phase 2b/3 studies
- Lead Author: Oliver Lenz, Janssen

The relative efficacy and safety of simeprevir-based triple therapy compared to boceprevir and telaprevir in treatment naïve patients chronically infected with genotype-1 hepatitis C virus: Bayesian network meta-analyses
- Lead Author: George Wan, Janssen

More information about these presentations can be accessed in a press release issued by Janssen, http://www.janssenrnd.com

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 health and quality of life.

The Phase 2a COSMOS data will be presented during the late-breaking oral session on Monday, November 4, 2:45-4:30 p.m. (EST) in Hall E:
SVR results of a once-daily regimen of simeprevir (TMC435) plus sofosbuvir (GS-7977) with or without ribavirin in cirrhotic and non-cirrhotic HCV genotype 1 treatment-naïve and prior null responder patients: The COSMOS study.

- Lead Author: Ira M. Jacobson, Weill Cornell Medical College, New York, USA

Full session details and data presentation listings for the 2013 AASLD Annual Meeting can be found at: http://www.aasld.org/livermeeting.

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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 Simeprevir
Simeprevir (TMC435) is an investigational NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and its affiliated companies and Medivir AB for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including all stages of liver fibrosis. Simeprevir works by blocking the viral protease enzyme that enables the hepatitis C virus to replicate in host cells.

Janssen is responsible for the global clinical development of simeprevir and has acquired exclusive, worldwide marketing rights, except for the Nordic countries. Medivir AB will retain marketing rights for simeprevir in these Nordic countries under the marketing authorization held by Janssen-Cilag International NV.

Simeprevir was approved on September 27, 2013 in Japan for the treatment of genotype 1 hepatitis C and a Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) by Janssen-Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C. Simeprevir is also being studied in several interferon-free regimens using selected combinations of direct-acting antiviral agents with different mechanisms of action. To date, more than 3,700 patients have been treated with simeprevir in clinical trials.

In October, Janssen Pharmaceuticals, Inc. acquired the investigational compound GSK2336805, an NS5a replication complex inhibitor in phase II development for the treatment of chronic HCV, from an affiliate of GlaxoSmithKline plc. Since being acquired, the compound has been renamed JNJ-56914845. Janssen Pharmaceuticals plans to initiate phase II studies to evaluate the use of JNJ-56914845 in interferon-free combinations with simeprevir and TMC647055, Janssen's non-nucleoside polymerase inhibitor, for the treatment of chronic HCV in adult patients with compensated liver 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 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