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Primary efficacy and safety findings from phase III study of Simeprevir in treatment-experienced patients demonstrate sustained virologic response

Stockholm, Sweden — Medivir AB (OMX: MVIR) reports that its partner Janssen R&D Ireland (Janssen) today announced primary efficacy and safety results from the global phase III PROMISE study. Results demonstrated that use of the investigational protease inhibitor simeprevir (TMC435) led to sustained virologic response 12 weeks after the end of treatment (SVR12) in 79 percent of treatment-experienced genotype 1 chronic hepatitis C adult patients with compensated liver disease, including all stages of liver fibrosis. Simeprevir was administered once daily with pegylated interferon and ribavirin.

In the study, 37 percent of patients receiving pegylated interferon and ribavirin (placebo) alone achieved SVR12. In the simeprevir arm, on-treatment failure rates were 3 percent and relapse rates were 19 percent, compared to 27 percent and 48 percent in the placebo arm. All patients had previously relapsed following pegylated interferon-based therapy.

The data were presented today as a late breaker oral presentation at Digestive Disease Week 2013 in Orlando, Florida based on abstract number 869b, “Simeprevir (TMC435) With Peginterferon/Ribavirin for Treatment of Chronic HCV Genotype 1 Infection in Patients Who Relapsed After Previous Interferon-Based Therapy: Results From PROMISE, a Phase III Trial.”

“We are very pleased with these data from this phase III study in relapsers. The data demonstrate high cure rates in these treatment-experienced patients. 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 Research and Development, Medivir AB.

Study design
In PROMISE, patients were randomized to receive simeprevir or placebo for 12 weeks plus pegylated interferon and ribavirin for 24 or 48 weeks. In findings related to a secondary endpoint, 93 percent of patients receiving simeprevir were able to shorten therapy with pegylated interferon and ribavirin to 24 weeks as a result of meeting response-guided therapy (RGT) criteria. 83 percent of those patients meeting response-guided therapy criteria to stop treatment at 24 weeks achieved SVR12.

Patients enrolled in PROMISE were stratified by hepatitis C virus (HCV) genotype 1 subtype and *IL28B* genotype. SVR12 rates among patients treated with simeprevir according to *IL28B* genotype were 89 percent for the CC allele, 78 percent for the CT allele, and 65 percent for the TT allele, compared to 53 percent for the CC allele, 34 percent for the CT allele and 19 percent for the TT allele in the placebo arm.

Efficacy
Among patients with METAVIR scores F0 to F2, 82 percent of patients treated with simeprevir and 41 percent with placebo achieved SVR12. Among patients with METAVIR scores F3 and F4, 73 percent and 74 percent of patients treated with simeprevir and 20 percent and 26 percent treated with placebo achieved SVR12, respectively. The METAVIR score is used to quantify the degree of inflammation and fibrosis of the liver and patients are scored on a five-point scale.

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.

Safety
The most common adverse events seen in patients receiving simeprevir in PROMISE were fatigue (32 percent versus 42 percent for placebo), headache (32 percent versus 36 percent for placebo) and influenza-like illness (30 percent versus 20 percent for placebo). In the simeprevir arm, rash (19 percent versus 14 percent for placebo), itching (24 percent versus 17 percent for placebo), neutropenia (15 percent versus 17 percent for placebo), anemia (11 percent versus 6 percent for placebo), increased bilirubin (6 percent versus 2 percent for placebo), and photosensitivity conditions (4 percent versus none for placebo) were also observed. One patient in the simeprevir arm and no patients in the placebo arm discontinued treatment due to an adverse event.

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About PROMISE
PROMISE is a global, phase III, randomized, double-blind, placebo-controlled clinical trial assessing the efficacy, safety and tolerability of simeprevir plus pegylated interferon and ribavirin versus pegylated interferon and ribavirin alone in adult patients with genotype 1 chronic hepatitis C with compensated liver disease, including all stages of liver fibrosis, who relapsed after previous interferon-based therapy.

In the PROMISE trial, 393 patients were randomized to receive one 150 mg capsule of simeprevir or placebo once daily plus pegylated interferon and ribavirin for 12 weeks, followed by pegylated interferon and ribavirin alone for either 12 or 36 weeks based on response-guided therapy criteria. Patients in the simeprevir arm were considered to have met response-guided therapy criteria if their HCV RNA levels were <25 IU/mL (detectable or undetectable) at week 4 and <25 IU/mL undetectable at week 12. In patients meeting response-guided therapy criteria, HCV therapy was stopped at week 24. All other patients continued treatment until week 48.

About Simeprevir
Simeprevir is an investigational NS3/4A protease inhibitor jointly developed by Medivir AB and Janssen R&D Ireland 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 protease enzyme that enables the hepatitis C virus to replicate in host cells. New drug applications were recently submitted for simeprevir in Japan and the United States for the treatment of genotype 1 hepatitis C, and a Marketing Authorisation Application was submitted to the European Medicines Agency seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C. The U.S. FDA has granted Priority Review to the New Drug Application. Janssen Pharmaceutical K.K. also recently announced the submission of a new drug application for simeprevir in Japan for the treatment of genotype 1 hepatitis C.

Global phase III studies of simeprevir include PROMISE in adult patients who have relapsed after prior interferon-based treatment, QUEST-1 and QUEST-2 in treatment-naïve adult patients, and ATTAIN in prior null-responder adult 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 HCV genotype 4 patients.

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

- Janssen’s non-nucleoside inhibitor TMC647055 and ritonavir in treatment-naïve genotype 1a and 1b HCV patients;
- Gilead Sciences, Inc.’s nucleotide inhibitor sofosbuvir (GS-7977) in treatment-naïve and previous null-responder genotype 1 HCV patients; and
- Bristol-Myers Squibb's NS5A replication complex inhibitor daclatasvir in treatment-naive and previous null-responder genotype 1 HCV patients.

In addition, Janssen Pharmaceuticals, Inc. has entered into a non-exclusive collaboration with Vertex Pharmaceuticals to evaluate in a phase II study the safety and efficacy of an all-oral regimen of

simeprevir and Vertex's investigational nucleotide analogue polymerase inhibitor VX-135 for the treatment of HCV. As a first step, Janssen Pharmaceuticals, Inc. is conducting a drug-drug interaction (DDI) study with simeprevir and VX-135.

Janssen Pharmaceuticals, Inc. also has plans to initiate a phase II trial of an investigational interferon-free regimen with simeprevir, TMC647055 and Idenix's IDX719, a once-daily, pan-genotypic NS5A inhibitor, with and without ribavirin.

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. 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 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