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Results from a phase IIa study evaluating Simeprevir and Sofosbuvir in prior null responder Hepatitis C patients have been presented at CROI

- In an all-oral regimen of simeprevir and sofosbuvir 96.3 percent (26/27) and 92.9 percent (13/14) of patients in the 12-week arm with ribavirin and without ribavirin achieved sustained virologic response 8 weeks after the end of treatment (SVR8).
- Once-daily all-oral simeprevir and sofosbuvir with or without ribavirin was generally well tolerated.

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announced that interim results from the COSMOS study (**C**ombination **O**f **SiM**eprevir and s**O**fosbuvir in HCV genotype 1 infected patient**S**) have been presented at the 20th Conference on Retroviruses and Opportunistic Infections (CROI) on March 6 in Atlanta, Georgia, USA.

These COSMOS interim results are from the first cohort of a phase IIa study of the investigational protease inhibitor simeprevir (TMC435) administered once daily with Gilead's investigational nucleotide inhibitor sofosbuvir (GS-7977) with and without ribavirin (RBV) for 12 and 24 weeks in genotype 1 prior null-responder hepatitis C patients with mild to moderate fibrosis (METAVIR F0-2). Simeprevir is jointly developed by Medivir AB and Janssen R&D Ireland, an affiliate of the Janssen Pharmaceutical Companies.

At the time of the interim analysis, 26 out of 27 patients (96.3%) in the 12-week arm with RBV achieved SVR4 and 13 out of 14 patients (92.9%) in the 12-week arm without RBV achieved SVR4. A subsequent analysis confirmed that all patients with SVR4 have also achieved SVR8. In the 24-week arms, SVR4 rates with RBV were 66.7% (one patient discontinued due to an AE and one withdrew consent in this arm) and without RBV 100 percent. The number of patients reaching this time point was limited, however.

The COSMOS regimen of once-daily simeprevir and sofosbuvir with or without ribavirin was generally well tolerated and no serious adverse events occurred during the treatment period.

"The COSMOS study specifically include hard-to-treat HCV patients, why the high response rates seen so far in the study with simeprevir as part of an interferon-free or interferon/ribavirin free combination regimen are very encouraging," says Charlotte Edenius, EVP of Research and Development, Medivir AB

COSMOS study Design
Cohort 1 of the randomized, open-label study investigates the efficacy and safety of 12 or 24 weeks of simeprevir and sofosbuvir with or without ribavirin (RBV) in HCV genotype 1 null responders to prior pegylated interferon (IFN) and RBV therapy with METAVIR scores F0-F2.

Cohort 2, which has been fully enrolled to date, will investigate similar regimens and durations in HCV genotype 1 prior null-responder and treatment-naïve patients with METAVIR scores F3-F4.The study is being conducted in the United States.

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.

In total, 80 patients were randomized in Cohort 1. Sixty-one percent of patients were male, 29 percent were African American, 25 percent were Hispanic, 100 percent were prior null responders to pegylated interferon and ribavirin, 75 percent had genotype 1a, and 94 percent were IL28B CT or TT status. These characteristics represent a difficult-to-cure population.

COSMOS summary - efficacy:
In patients infected with HCV genotype 1 (including 1a) with a prior null response to PegIFN/RBV, once daily SMV + SOF +/- RBV for 12 or 24 weeks resulted in high SVR rates in this interim analysis as summarized.

Efficacy results with 150 mg simeprevir (SMV) and 400 mg sofosbuvir (SOF) q.d. +/- ribavirin (RBV);

Patients n/N (%)	SMV + SOF +RBV 24 weeks (n=24)	SMV + SOF 24 weeks (n=15)	SMV + SOF +RBV 12 weeks (n=27)	SMV + SOF 12 weeks (n=14)
RVR (week 4)	18/22 (81.8)	10/15 (66.7)	23/27 (85.2)	8/14 (57.1)
EoT*	10/12 (83.3)	8/9 (88.9)	27/27 (100)	14/14 (100)
Relapse, n	0	0	1	1
SVR4	4/6 (66.7)	5/5 (100)	26/27 (96.3)	13/14 (92.9)
SVR8	4/6 (66.7)	5/5 (100)	26/27 (96.3)	13/14 (92.9)

q.d.: once daily; RVR: Rapid Viral Response; EoT: End of Treatment; SVR4 and SVR8: patients with undetectable HCV RNA (<25 IU/mL, undetectable) 4 and 8 weeks after EoT
* = Undetectable at EoT

COSMOS - Summary - Safety and Tolerability
The regimen of once-daily simeprevir and sofosbuvir with or without ribavirin was generally well tolerated and no serious adverse events occurred during the treatment period for the patients involved in the study. There were two discontinuations due to an AE; 1 at least possibly related to study drug. Most common Adverse Events were fatigue, headache, insomnia and nausea in >10%. Anemia occurred only in subjects who received ribavirin. Grade 3/4 bilirubin increases were infrequent, were not associated with increases in other liver tests (AST, ALT, ALP, GGT), were only seen in patients who received ribavirin and resolved when treatment was discontinued. Isolated Grade 3/4 amylase/lipase increases were observed but not associated with other laboratory/clinical findings and were not confirmed on re-testing.

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About the COSMOS Trial
COSMOS is a randomized, open-label study investigating the efficacy and safety of 12 or 24 weeks of simeprevir and sofosbuvir with or without ribavirin in HCV genotype 1 patients who are treatment naïve or have prior null response to pegylated interferon and ribavirin therapy.

Cohort 1 of the COSMOS study enrolled 80 genotype 1 prior null-responder HCV patients with METAVIR scores of F0-F2. Randomization was stratified by IL28B status and genotype 1 subtype, into one of four arms including once-daily simeprevir (150 mg) plus sofosbuvir (400 mg) for 24 weeks with or without ribavirin, or once-daily simeprevir (150 mg) plus sofosbuvir (400 mg) for 12 weeks with or without ribavirin.

Cohort 2 of the study will investigate the same treatment regimens and durations in genotype 1 prior null-responder and treatment-naïve patients with METAVIR scores of F3-F4. The METAVIR score is used to quantify the degree of inflammation and fibrosis of the liver. Liver fibrosis is scored on a four-point scale.

About Simeprevir
Simeprevir, an investigational NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB, is currently in late phase III studies as a once-daily capsule (150 mg) taken in combination with pegylated interferon and ribavirin for the treatment of genotypes 1 and 4 HCV.

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 and ATTAIN in null-responder patients. In parallel to these trials, phase III studies for simeprevir are ongoing in treatment-naïve and treatment-experienced HIV-HCV co-infected patients, HCV genotype 4 patients and Japanese HCV genotype 1 patients. Janssen Pharmaceutical K.K. recently announced the submission of a new drug application for simeprevir in Japan for the treatment of genotype 1 hepatitis C.

Simeprevir is 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 (BMS-790052) in treatment-naive and previous null-responder genotype 1 HCV patients.

In addition, Janssen Pharmaceutical Inc. recently announced that it 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 Pharmaceutical Inc. will conduct a drug-drug interaction (DDI) study with simeprevir and VX-135. Janssen Pharmaceutical Inc. also recently announced plans to initiate a phase IIa trial of an investigational interferon-free regimen with simeprevir, TMC647055 and Idenix's IDX719, a once-daily NS5A inhibitor, with and without ribavirin.

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

About Sofosbuvir
Sofosbuvir (formerly referred to as GS-7977) is a once-daily nucleotide analog polymerase inhibitor for the treatment of HCV infection being developed by Gilead Sciences. Sofosbuvir is being evaluated as part of multiple therapeutic regimens, including programs with RBV alone and in combination with peg-IFN and RBV.

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 350,000 people per year die from the disease.

About Medivir AB
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