**Press Release 28 August 2013**

# Medivir announces interim results from Cohort 2 of the COSMOS study evaluating Simeprevir and Sofosbuvir in HCV patients with METAVIR scores F3-F4

- ***In Hepatitis C patients with advanced liver fibrosis or cirrhosis (METAVIR F3 or F4) 12 weeks all oral treatment with simeprevir and sofosbuvir with or without ribavirin led to SVR4 rates of 96% and 100%, respectively***
- ***Once-daily simeprevir and sofosbuvir with or without ribavirin was generally safe and well tolerated***

**Stockholm, Sweden — Medivir AB (OMX: MVIR)** today announced interim results from the second Cohort in the ongoing COSMOS study evaluating a once daily combination of simeprevir and sofosbuvir in hard to cure hepatitis C (HCV) patients.

SVR4 results from the 12 week arms of Cohort 2, including treatment naïve or previous null responder HCV patients all with METAVIR score F3-F4 were reported. Treatment for 12 weeks with simeprevir and sofosbuvir, with or without ribavirin, led to SVR4 rates of 96% and 100%, respectively.

Interim results from Cohort 1 of the COSMOS study, which include only prior null responder HCV patients (METAVIR F0-F2) have been reported earlier and demonstrated SVR8 rates of 96% and 93% after 12 weeks treatment simeprevir and sofosbuvir with and without ribavirin, respectively.

*"The high SVR rates seen in genotype 1 prior null responders and treatment-naïve patients with advanced liver disease, in the COSMOS study and the safety profile of the combination are highly encouraging. We look forward to the final results of this study in difficult to cure patients." says Charlotte Edenius, EVP Development, Medivir AB.*

**COSMOS - Study Design**
COSMOS is a randomized, open label, phase IIa clinical trial evaluating a once-daily combination of the HCV protease inhibitor simeprevir and the nucleotide sofosbuvir with and without ribavirin (RBV) for 12 and 24 weeks. Cohort 1 (n=80) evaluates prior null responder genotype 1 hepatitis C (HCV) patients with METAVIR scores F0-F2 and Cohort 2 (n=87) evaluates prior null responder and treatment-naïve genotype 1 hepatitis C patients with METAVIR scores 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.

At the time of the interim analysis, SVR4 results were available for all patients (n=41) in the 12 week arms of Cohort 2. In this Cohort, 78.2% of patients had GT1a subtype with 40% of those having a Q80K baseline polymorphism, 79.3% had IL28B CT or TT genotype, 47.1% had Metavir score F4 (cirrhosis) and 54.0% were prior null responders.

In the previously reported Cohort 1, 77.5% of the patients had GT1a subtype with 50% of those having a Q80K baseline polymorphism, 93.7%, had IL28B CT or TT genotype and 58.8% had METAVIR score F2.

**COSMOS - Summary Interim Results: Efficacy**

Efficacy results with 150 mg simeprevir (SMV) and 400 mg sofosbuvir (SOF) once daily for 12 weeks with or without ribavirin (RBV). Intent-to-treat (ITT) population.

| | **Cohort 1*** **Prior null responder HCV patients (METAVIR score F0-F2)** | | **Cohort 2** **Prior null responder and treatment naïve HCV patients (METAVIR scores F3 or F4)** | |
|---|---|---|---|---|
| | SMV / SOF+ RBV (n=27) | SMV / SOF (n=14) | SMV / SOF + RBV (n=27) | SMV / SOF (n=14) |
| **SVR4** | 26/27(96%) | 13/14(93%) | 26/27(96%) | 14/14(100%) |
| **SVR8** | 26/27(96%) | 13/14(93%) | - | - |

***** Data reported at the 20th Conference on Retroviruses and Opportunistic Infections (CROI) in March 2013 in Atlanta, USA. SVR: Sustained Virologic Response 4 or 8 weeks (SVR4 or SVR8) after end of treatment.

There were no viral breakthroughs in either Cohort. At the time of respective cut-off there was 1 relapse in Cohort 2, which was detected 4 weeks after end of treatment. As previously reported there were 2 relapses detected in Cohort 1 both at the 4 week time point after end of treatment.

**COSMOS - Summary Interim Results: Safety**

Once-daily simeprevir and sofosbuvir with or without ribavirin for 12 weeks was generally considered safe and well tolerated. Among events defined in the protocol as being of special interest, increased bilirubin was observed in 9.3% of the patients in the ribavirin containing arms, compared with 0%, for the non-ribavirin containing arms. Anemia was observed in 13.0% of the patients in the ribavirin containing arms, compared with 0% for the non-ribavirin containing arms.

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**About Simeprevir**

Simeprevir is a new generation NS3/4A protease inhibitor jointly developed by Medivir and Janssen R&D Ireland, part of the Janssen Pharmaceutical Companies 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 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, Inc. 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**

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**