

Phase II COSMOS study results published in The Lancet on World Hepatitis Day

The phase II COSMOS study evaluated the interferon-free combination of simeprevir and sofosbuvir in treatment-naïve and prior null-responder patients with all stages of liver fibrosis, including cirrhosis.

Stockholm, Sweden — Medivir AB (OMX: MVIR) announces that results from the phase II COSMOS clinical study were published July 28 in The Lancet, demonstrating that 92 percent of genotype 1 chronic hepatitis C virus adult patients treated with simeprevir in combination with sofosbuvir achieved sustained virologic response 12 weeks after the end of treatment (SVR12). The study included patients with compensated cirrhosis and prior null response to treatment with pegylated interferon and ribavirin.

According to results from the study, the all-oral, interferon-free treatment regimen with simeprevir and sofosbuvir resulted in consistent SVR12 rates regardless of degree of fibrosis, and was an effective and well-tolerated therapeutic regimen in both treatment-naïve and prior null-responder patients.

“The Lancet publication of the COSMOS data on World Hepatitis Day gives further recognition to these revolutionizing treatment results. I hope that this will contribute to helping more patients around the world to get cured.” says Henrik Krook, EVP Commercial, Medivir AB.

Based on the findings from the COSMOS study, our partner Janssen in April initiated the phase III studies OPTIMIST-1 and OPTIMIST-2 examining the safety and efficacy of simeprevir and sofosbuvir without interferon or ribavirin for the treatment of chronic genotype 1 hepatitis C infection.

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About Simeprevir (Olysio®)

Simeprevir is an NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB and indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. Simeprevir efficacy has been established in HCV genotype 1 and HCV genotype 4 infected patients with compensated liver disease, including cirrhosis.

Janssen is responsible for the global clinical development of simeprevir and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir AB retains marketing rights for simeprevir in these countries under the marketing authorization held by Janssen-Cilag International NV. Simeprevir was approved for the treatment of chronic hepatitis C infection as part of an antiviral treatment regimen in combination with pegylated interferon and ribavirin in genotype 1 infected adults with compensated liver disease, including cirrhosis. Simeprevir was approved in September 2013 in Japan, in November 2013 in Canada and the U.S., in March 2014 in Russia and in July 2014 in Mexico and Australia.

In May 2014 simeprevir was granted marketing authorization by the European Commission (EC) for the treatment of adult patients with genotype 1 or genotype 4 chronic HCV. Following the EMA approval, it is anticipated that simeprevir will be available across a number of European Union countries in conjunction

with reimbursement, in the second half of 2014. Simeprevir (Olysio) is marketed under the trade name Sovriad® in Japan and Russia, Galexos™ in Canada and Olysio® in the U.S. and European Union.

About Medivir

Medivir is an emerging and profitable research-based pharmaceutical company with an established marketing and sales organisation in the Nordics with a broad portfolio of prescription pharmaceuticals. Medivir receives royalty from Johnson & Johnson global sales of the hepatitis C pharmaceutical Olysio. In addition, revenues for sales of Olysio in the Nordic region is generated through the companies own sales and marketing organisation.

Medivir's research and development portfolio of pharmaceuticals is based on the company's expertise in polymerase and protease drug targets for different disease areas. The company's current research and development is focused on infectious diseases, bone related disorders, neuropathic pain and oncology. Medivir is listed on the Nasdaq OMX Mid-Cap list.