Olysio® gains additional FDA approval as all-oral treatment in combination with sofosbuvir for treatment of hepatitis C infection

-Expanded indication includes both treatment-naïve and treatment-experienced adult patients with or without cirrhosis-

Stockholm, Sweden – Medivir AB (Nasdaq Stockholm:MVIR) announces that the U.S. Food and Drug Administration (FDA) has approved Olysio® (simeprevir) in combination with sofosbuvir as an all-oral, interferon- and ribavirin-free treatment option for genotype 1 chronic hepatitis C infection in adult patients as part of a combination antiviral treatment regimen. The sNDA was filed in May by Medivir's partner Janssen Research & Development LLC.

Data supporting the Olysio® and sofosbuvir combination regimen are from the COSMOS study, an open-label, randomized phase II clinical trial that investigated the efficacy and safety of 12 or 24 weeks of Olysio® (150 mg once daily) in combination with sofosbuvir (400 mg once daily), with or without ribavirin in HCV genotype 1 chronically infected naïve and treatment-experienced adult patients with compensated liver disease.

The recommended treatment duration of Olysio® with sofosbuvir is 12 weeks for patients without cirrhosis or 24 weeks for patients with cirrhosis.

The COSMOS study

In the COSMOS study 95 percent of patients (20/21) with METAVIR F0-F3 (patients with no liver fibrosis to near cirrhotic liver disease) receiving 12 weeks of Olysio® with sofosbuvir achieved SVR12 (sustained virologic response 12 weeks after the end of treatment).

Regardless of whether patients were treatment-naïve or treatment-experienced 86 percent of patients (6/7) with METAVIR F4 (cirrhosis) receiving 12 weeks of Olysio® in combination with sofosbuvir achieved SVR12, while 100 percent (10/10) of patients with cirrhosis who were treated with the combination for 24 weeks achieved SVR12.

For all patients in the COSMOS trial (treatment-naïve and treatment-experienced, METAVIR F0-F4), 93 percent (26/28) achieved SVR12 after 12 weeks and 97 percent (30/31) achieved SVR12 after 24 weeks of treatment.

In the COSMOS trial, the most common (> 10 percent) adverse reactions reported during 12 weeks of treatment with Olysio® in combination with sofosbuvir without ribavirin were fatigue (25 percent), headache (21 percent), nausea (21 percent), insomnia (14 percent) and pruritus (11 percent). Rash and photosensitivity were reported in 11 percent and 7 percent of patients, respectively. During 24 weeks of treatment, dizziness (16 percent), and diarrhea (16 percent) were also reported.

Janssen has a robust HCV clinical development program, including phase II and III studies combining Olysio® with other direct acting antivirals. For more information please visit www.clinicaltrials.gov.

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Medivir is required under the Securities Markets Act to make the information in this press release public. The information was submitted for publication at 8.30 CET on 6 November 2014.

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 has so far been made available in several EU countries in conjunction with reimbursement. 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 Nordic region with a broad portfolio of prescription pharmaceuticals. Medivir receives royalties from Johnson & Johnson on the global sales of the hepatitis C pharmaceutical, Olysio®. In addition, revenues for sales of Olysio in the Nordic region are generated through the company's own sales and marketing organisation. Medivir's research and development portfolio of pharmaceuticals is based on the company's expertise within protease inhibitor design and nucleoside/nucleotide science. The company's research and development focus is within infectious diseases and oncology and the on-going clinical projects in osteoarthritis and neuropathic pain.
Medivir is listed on the Nasdaq Stockholm Mid Cap List.