

## OLYSIO™ available soon in all Nordic countries for the treatment of adults with hepatitis C genotype 1 and 4 infection

Treatment of hepatitis C patients with Olysio (simeprevir) has begun in Sweden, Finland and Denmark

**Stockholm, Sweden** — **Medivir AB (OMX: MVIR)** today announces that Olysio will be available in all of the Nordic countries within the next few weeks. Treatment with Olysio began in Sweden in late May, followed by Finland and Denmark, where the first patients recently began their treatment.

"It is immensely gratifying to now be able to offer a new and much sought-after treatment option for hepatitis C patients in the Nordic region. The growing awareness of Olysio and other new antivirals has been welcomed by doctors, who now have access to safer, more effective treatment options. Our Nordic commercial organisation has been carefully built up and is staffed by people with a track record of successful specialist care launches. Our aim is to continue adding new and innovative specialist care pharmaceuticals to our product portfolio. In the spring of this year, we launched not only Olysio, but also Adasuve (a psychiatric pharmaceutical for the treatment of agitation). It is a fantastic feeling to work with such a competent launch team and receive regular positive feedback from the health care sector on the ways in which these new treatment options offer great value for the patients," says Henrik Krook, EVP Commercial, Medivir.

The marketing authorisation granted by the European Commission in mid-May represents a significant milestone in the development of new triple therapy hepatitis C treatment options for genotype 1 and 4 patients. It also includes Olysio as part of an all oral 12-week interferon-free direct-acting antiviral (DAA) regimen with or without ribavirin (RBV), in genotype 1 or 4 patients, who are intolerant to or ineligible for IFN treatment.

The European Commission approval for Olysio with PegIFN + RBV is based on a clinical trial programme involving three pivotal phase III studies, QUEST-1, QUEST-2 and PROMISE. The use of Olysio in combination with sofosbuvir was also approved on the basis of, amongst others, the COSMOS clinical phase II study. This study enrolled treatment-naïve patients who were prior null responders. Patients with fibrosis or cirrhosis of the liver were evaluated in all of these studies with very good efficacy and safety data.

## For more information please contact:

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## **About Olysio**

Olysio is an NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB and indicated for the treatment chronic hepatitis C infection in combination with pegylated interferon and ribavirin in HCV genotype 1 and 4 infected patients with compensated liver disease, including cirrhosis.

Janssen is responsible for the global clinical development of Olysio and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir AB retains marketing rights for Olysio in these countries under the marketing authorization held by Janssen-Cilag International NV. Olysio 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 in September 2013 in Japan, in November 2013 in Canada and the U.S. and in March 2014 in

Russia. Following the EMA approval, it is anticipated that Olysio will be available across a number of European Union countries in conjunction with reimbursement, in the second half of 2014.

## **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 Olysio, a novel protease inhibitor for the treatment of hepatitis C that is being developed in collaboration with Janssen R&D Ireland. The company is also working with research and development in other areas, such as bone disorders and neuropathic pain. Medivir has also a broad product portfolio with prescription pharmaceuticals in the Nordics.