

## **U.S. FDA has granted Priority Review for OLYSIO® in combination with sofosbuvir supplementary New Drug Application**

**Stockholm, Sweden — Medivir AB (OMX: MVIR)** announces that the Food and Drug Administration (FDA) has assigned a Priority Review designation to the supplemental New Drug Application (sNDA) for the use of once-daily Olysio (simeprevir) in combination with sofosbuvir for 12 weeks treatment of adult patients with genotype 1 chronic hepatitis C. The sNDA was filed in May by Medivir's strategic partner Janssen Research & Development LLC.

The regulatory submission for Olysio and sofosbuvir is supported by data from the phase II COSMOS study which included treatment-naïve patients with advanced fibrosis (METAVIR F3 to F4 scores) and prior null-responder patients with all stages of liver fibrosis (METAVIR F0 to F4 scores).

"The Priority Review designation by the FDA shows the high priority and great importance of making interferon-free treatment regimens available to the many difficult to cure hepatitis C patients groups", says Charlotte Edenius, EVP Development, Medivir.

### **For more information please contact:**

Rein Piir, EVP Corporate Affairs & IR, mobile: +46 708 537 292

### **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.