A supplemental New Drug Application has been submitted to the U.S. FDA for Simeprevir in combination with Sofosbuvir

- **The Supplemental New Drug Application for OLYSIO™ (simeprevir) for once-daily use in combination with sofosbuvir is for 12 Weeks treatment of adult patients with genotype 1 chronic hepatitis C.**
- **The filing includes data from treatment naïve patients with advanced liver fibrosis and prior null responders with all stages of liver fibrosis.**

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announces that Janssen has submitted a supplemental New Drug Application (sNDA) to the Food and Drug Association (FDA) for simeprevir, an NS3/4A protease inhibitor marketed as OLYSIO™ in the United States, in combination with the nucleotide analogue NS5B polymerase inhibitor sofosbuvir developed by Gilead Sciences, Inc.

"It is of great importance to continue to improve the treatments for hepatitis C. The supplemental filing of the data available on the combination of simeprevir and sofosbuvir is an important step towards making an efficacious once daily all-oral treatment available for these patients", says Charlotte Edenius, EVP Development, Medivir.

OLYSIO™ is currently approved in the U.S. for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. OLYSIO™ efficacy has been established in combination with peginterferon alfa and ribavirin in HCV genotype 1-infected patients with compensated liver disease, including cirrhosis.

This regulatory submission is for the treatment of genotype 1 chronic hepatitis C (HCV) in adult treatment-naïve patients with advanced fibrosis and null responders with all stages of liver fibrosis.

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).

Our partner, Janssen R&D Ireland Ltd initiated in April 2014 the phase III OPTIMIST (**Op**timal **T**reatment w**i**th a si**m**eprev**i**r and **s**ofosbuvir **T**herapy) trials examining the safety and efficacy of simeprevir and sofosbuvir without interferon or ribavirin for the treatment of chronic genotype 1 HCV infection. In the first trial, known as OPTIMIST-1, the combination will be administered once daily for 8 or 12 weeks in chronic HCV genotype 1 infected patients without cirrhosis who are HCV treatment naive or treatment experienced. In the second trial, known as OPTIMIST-2, the combination will be administered once daily for 12 weeks in HCV genotype 1 infected patients with cirrhosis who are HCV treatment naive or treatment experienced.

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 13.50 CET on 7 May 2014.

About Simeprevir

Simeprevir 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 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 in September 2013 in Japan, in November 2013 in Canada and the U.S. and in March 2014 in Russia. A Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) in April 2013 by Janssen-Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C and the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending Marketing Authorisation in the European Union for the use of simeprevir in combination with other medicinal products for the treatment of chronic HCV. This application is under review by the EMA.

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 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.