Phase II IMPACT study initiated to evaluate Simeprevir in combination with Sofosbuvir and Daclatasvir to treat genotype 1 and 4 hepatitis C patients

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announces that its partner Janssen recently initiated patient enrolment in a phase II study called IMPACT. This study evaluates the efficacy, safety and pharmacokinetics of the NS3/4A protease inhibitor simeprevir administered once daily in combination with Gilead's nucleotide inhibitor sofosbuvir and Bristol-Myers Squibb's (BMS) NS5A replication complex inhibitor daclatasvir. The study includes treatment-naïve and treatment-experienced patients with hepatitis C genotype 1 and 4 infection and decompensated liver disease.

In the phase II, open label IMPACT study, patients will receive the once-daily combination of simeprevir 150 mg, sofosbuvir 400 mg and daclatasvir 60 mg, for 12 weeks. The primary efficacy endpoint in the study is the proportion of patients achieving sustained virologic response 12 weeks after the end of treatment (SVR12). The IMPACT study represents the first phase II study of the combination of simeprevir, sofosbuvir and daclatasvir in a regimen without pegylated interferon and ribavirin .

For more information please visit www.clinicaltrials.gov.

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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 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's 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, targeting different disease areas. The company's current research and development focus is within infectious diseases, osteoarthritis, neuropathic pain and oncology. Medivir is listed on the Nasdaq OMX Stockholm Mid Cap List.