



Press Release November 23, 2013

Simeprevir has been approved in the USA as a new treatment for hepatitis C

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announced that U.S. Food and Drug Administration (FDA) has approved simeprevir for the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin in adults with compensated liver disease, including cirrhosis, who are treatment-naïve or who have failed previous interferon therapy (pegylated or non-pegylated) with ribavirin.

“The USA approval is a large and important milestone in the global strategy that our partner Janssen has for simeprevir, to offer a new treatment option to many different hepatitis C patient groups” said Maris Hartmanis CEO, Medivir.

The approval of simeprevir in the USA is based on several studies of patients with CHC genotype 1 infection. These studies include treatment-naïve patients (QUEST-1 and QUEST-2), and patients who have failed prior treatment with pegylated interferon and ribavirin; in PROMISE (prior relapsers) and ASPIRE (prior non-responders).

The USA approval triggers a milestone payment of €10m to Medivir.

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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 11.30 a.m. CET on 23 November 2013.

About Simeprevir

Simeprevir is an investigational NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and its affiliated companies and Medivir AB for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including all stages of liver fibrosis. Janssen is responsible for the global clinical development of simeprevir and has acquired exclusive, worldwide marketing rights, except for the Nordic countries. Medivir AB will retain marketing rights for simeprevir in these Nordic countries under the marketing authorization held by Janssen-Cilag International NV.

Simeprevir is approved in Japan, Canada and in the USA for the treatment of genotype 1 chronic hepatitis C. A Marketing Authorisation Application was submitted in April to the European Medicines Agency (EMA) by Janssen-Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C.

Simeprevir is also being studied in several interferon-free regimens using selected combinations of direct acting antiviral agents with different mechanisms of action. To date, more than 3,700 patients have been treated with simeprevir in clinical trials.

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.

For more information about Medivir AB, please visit the Company's website: www.medivir.com

Medivir is a collaborative and agile pharmaceutical company with an R&D focus on infectious diseases and a leading position in hepatitis C. We are passionate and uncompromising in our mission to develop and commercialize innovative pharmaceuticals that improve people's health and quality of life.