Press Release 13 May 2013

U.S. FDA grants priority review to Simeprevir for combination treatment of genotype 1 chronic hepatitis C

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announces that the U.S. Food and Drug Administration (FDA) has granted Priority Review to the New Drug Application (NDA) by Janssen for simeprevir (TMC435), an investigational NS3/4A protease inhibitor administered as a 150 mg capsule once daily with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease.

"This is a very important step bringing simeprevir closer to the market, making this therapy available to hepatitis C patients" comments Charlotte Edenius, EVP Development of Medivir.

The FDA grants priority review to medicines that may offer major advances in care or provide a treatment option where no adequate therapy exists. FDA review will begin approximately 60 days after receipt of the application and will aim to be complete within six months from when the review period begins.

The regulatory submission by Janssen for simeprevir is supported in part by data from three pivotal phase III studies: QUEST-1 and QUEST-2 in treatment-naïve patients and PROMISE in patients who have relapsed after prior interferon-based treatment. Janssen also recently submitted simeprevir for marketing authorization to regulatory authorities in Japan and Europe.

For more information please contact:
Rein Piir, EVP Corporate Affairs & IR
Mobile: +46 708 537 292

About Simeprevir
Simeprevir is a new generation NS3/4A protease inhibitor jointly developed by Medivir and Janssen for the treatment of chronic hepatitis C in adult patients with compensated liver disease.

For additional information about simeprevir clinical trials, please visit www.clinicaltrials.gov.

About Hepatitis C
Hepatitis C, a blood-borne infectious disease of the liver and a leading cause of chronic liver disease and liver transplants, is a rapidly evolving treatment area with a clear need for innovative treatments. Approximately 150 million people are infected with hepatitis C worldwide, and about 350,000 people per year die from the disease.

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 in late phase III clinical development for hepatitis C that is being developed in collaboration with Janssen R&D Ireland. 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 lives.