Simeprevir receives positive CHMP opinion for the treatment of adults with chronic hepatitis C in the European Union

- **Positive opinion for the use of simeprevir in combination with other medicinal products for the treatment of chronic hepatitis C (CHC) in adult patients.**

Stockholm, Sweden — Medivir AB (OMX: MVIR) announced today that 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 hepatitis C (CHC) in adult patients.

"The recommendation is one additional step in the global strategy that our partner Janssen has for simeprevir, to offer a new and efficacious treatment option to the many hepatitis C patient groups suffering from this devastating disease" said Maris Hartmanis CEO, Medivir.

Simeprevir is a new generation, NS3/4A protease inhibitor administered as a once daily 150 mg capsule with pegylated interferon (PegIFN) and ribavirin (RBV) offering proven efficacy across a range of different HCV patient types.

The CHMP opinion was based on positive and consistent results from three pivotal phase III studies in patients with GT1 HCV; QUEST-1 and QUEST-2 in treatment-naïve patients and PROMISE in patients (who have relapsed after previous interferon-based therapy). QUEST-1 and QUEST-2 included 785 treatment-naïve patients with chronic HCV GT1 infection. PROMISE included 393 relapsed patients with chronic HCV GT1 infection. All three studies met their primary end points and demonstrated simeprevir in combination with PegIFN/RBV achieves superior cure rates when compared with PegIFN/RBV alone, in treatment naïve and relapsed patients.

Hepatitis C in the European Union
Hepatitis C is a major health problem in the European Union, where nine million people are living with the disease. The current standard of care is not always tolerable due to significant side effects of interferon based therapy and improvements in efficacy for difficult to treat patients, such as prior null responders, represent a high medical need. Treatment of HCV is complex because of the heterogeneous population of patients it affects and that treatment efficacy is highly dependent on the genotype of the virus.

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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 will retain marketing rights for simeprevir in these countries under the marketing authorization held by Janssen-Cilag International NV. Simeprevir was approved for the treatment of genotype 1 hepatitis C in September 2013 in Japan and in November 2013 in Canada and the U.S.

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