Medivir announces that Janssen submitted supplemental New Drug Application to U.S. FDA for OLYSIO® (simeprevir) in combination with sofosbuvir

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces that Janssen Products, LP (Janssen), has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) to update the label for once-daily, all-oral OLYSIO® (simeprevir).

OLYSIO® is a hepatitis C virus NS3/4A protease inhibitor, currently approved in the U.S. for use with sofosbuvir for adults with genotype 1 chronic hepatitis C (CHC) infection as a 12-week treatment for patients without cirrhosis or a 24-week treatment regimen for patients with cirrhosis. Sofosbuvir is a nucleotide analogue NS5B polymerase inhibitor marketed by Gilead Sciences, Inc.

OLYSIO® was approved in November 2014 in combination with sofosbuvir based on the phase II COSMOS clinical trial. This sNDA is based on results from the phase III OPTIMIST-1 and OPTIMIST-2 trials, which evaluated 12 and eight weeks of therapy for genotype 1 CHC adult patients without cirrhosis, and 12 weeks of therapy for genotype 1 CHC adult patients with cirrhosis.

Results from the OPTIMIST trials were presented in April 2015 at The International Liver Congress™ 2015 of the European Association for the Study of the Liver (EASL) in Vienna.

Please visit www.jnj.com/releases for more information.

For further information, please contact:

Ola Burmark, CFO Medivir AB, mobile: +46 (0)725-480 580.

Medivir is required under the Securities Markets Act to make the information in this press release public. The information was submitted for publication at 8.30 CET on 24 July 2015.

About Simeprevir (OLYSIO®)

Simeprevir is an NS3/4A protease inhibitor jointly developed by Janssen Sciences Ireland UC 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. In November 2013, simeprevir was approved by the U.S. Food & Drug Administration and, in May 2014, it was granted marketing authorisation by the European Commission. Subsequent marketing authorisations have followed in several other countries around the world. Indications vary by market.

About Medivir

Medivir is a research based pharmaceutical company with a research focus on infectious diseases and oncology. We have a leading competence within protease inhibitor design and nucleotide/nucleoside science and we are dedicated to develop innovative pharmaceuticals that meet great unmet medical need. Our commercial organization provides a growing portfolio of specialty care pharmaceuticals on the Nordic market. Medivir is listed on the Nasdaq Stockholm Mid Cap List.