Medivir announces that Janssen decided to start a phase IIb study of combinations of Simeprevir, Odalasvir and AL-335 for the treatment of hepatitis C

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces that Janssen Research & Development, LLC., part of the Janssen Pharmaceutical Companies (Janssen), has decided to initiate a phase IIb study to investigate the efficacy, safety and pharmacokinetics of different treatment regimens of AL-335, odalasvir, and simeprevir in treatment-naïve and treatment-experienced patients with chronic Hepatitis C Virus (HCV) genotype 1-6 infection, with and without cirrhosis.

This global phase IIb study is a randomized, open-label, four-arm study of AL-335, a nucleotide-based HCV NS5B polymerase inhibitor, odalasvir, an HCV NS5A inhibitor and simeprevir, an HCV NS3/4A protease inhibitor. Approximately 400 patients will be randomized to one of four treatment arms and receive once daily treatment for a duration of six or eight weeks. Patients in two of the four arms will receive AL-335, odalasvir and simeprevir, a compound jointly developed by Janssen Sciences Ireland UC and Medivir AB, while patients in the other two arms will receive only AL-335 and odalasvir. The primary endpoint of the study is the percentage of chronic HCV-infected subjects who achieve a sustained virologic response 12 weeks after the end of treatment (SVR12). The study is intended to start in June 2016 and the estimated date for completion is July 2017.

Further information about the study can be found at www.clinicaltrials.gov. Study identifier: NCT02765490.

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 9.15 CET on 11 May 2016.

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 oncology and infectious diseases. 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 portfolio of specialty care pharmaceuticals on the Nordic market. Medivir is listed on the Nasdaq Stockholm Mid Cap List.