Medivir announces that Janssen has started a phase IIa study to evaluate the effect of simeprevir in combination with odalasvir and AL-335

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) today announces that Alios BioPharma Inc., part of the Janssen Pharmaceutical Companies (Janssen), has started a phase IIa clinical trial to evaluate the combination of simeprevir, odalasvir (also known as ACH-3102), and AL-335 in treatment-naïve patients with genotype 1 chronic hepatitis C virus (HCV) infection.

This phase IIa study is a randomized, open-label, three-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. Patients will be randomized to one of three treatment arms and receive once daily treatment for a duration of four, six or eight weeks. The primary objective of the study is to establish the safety of the treatment regimen with secondary endpoints consisting of pharmacokinetics, the proportion of subjects achieving sustained viral response (SVR), and the effect on the viral resistance profile after treatment. The study is expected to enroll approximately 60 patients across the three treatment arms.

Approximately 150 million people are chronically infected with HCV globally*. When left untreated, HCV causes progressive liver disease in many of those who are chronically infected, and this can lead ultimately to cirrhosis, hepatocellular carcinoma and a requirement for liver transplantation. However, combinations of direct acting antiviral agents, including treatment regimens containing a protease inhibitor such as simeprevir, have shown the potential to be curative and convenient regimens for patients infected with HCV.

Further information about the study can be found at www.clinicaltrials.gov. Study identifier: NCT02569710.

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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 12.00 CET on 16 October 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.

*http://www.who.int/mediacentre/factsheets/fs164/en/

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.