Press Release 27 September 2013

Simeprevir has been approved in Japan for the treatment of genotype 1 chronic hepatitis C infection

Stockholm, Sweden — Medivir AB (OMX: MVIR) today reports that Janssen Pharmaceutical R&D Ireland (Janssen) has been informed by the Japanese Ministry of Health, Labour and Welfare (MHLW) that simeprevir has been approved for the treatment of genotype 1 chronic hepatitis C virus (HCV) infection.

"The approval in Japan is a very important step in providing patients with new treatment options. It is the first approval based on the series of global filings that our partner initiated during 2013. Japan is commercially a very exciting market with a huge unmet medical need among hepatitis C patients", says Maris Hartmanis, CEO of Medivir.

The approval in Japan triggers a milestone payment of €5m to Medivir.

Simeprevir, a new direct-acting antiviral agent (DAA), is a protease inhibitor for the treatment of genotype 1 chronic HCV infection. Simeprevir is administered once-daily for 12 weeks as part of a “triple combination” with pegylated interferon and ribavirin followed by an additional 12 or 36 weeks of pegylated interferon and ribavirin alone.

In the CONCERTO clinical trials, simeprevir, as part of a regimen with pegylated interferon and ribavirin, demonstrated strong efficacy, with 89 percent of patients with previously untreated genotype 1 HCV infection achieving a sustained virological response (SVR). The primary endpoint in all clinical studies for simeprevir was a SVR 12 weeks after the last dose of treatment. In studies that included patients who had relapsed after stopping previous HCV treatment, results showed an SVR rate of 96 percent. These results were presented in June at The Japan Society of Hepatology.

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About hepatitis C in Japan
In Japan, the number of patients with chronic HCV infection is estimated at approximately 1.5 to 2 million. Approximately 70 percent of Japanese patients who have HCV are infected by genotype 1 HCV. After infection with HCV occurs, the infection may persist in about 70 percent of cases, leading to the development of chronic hepatitis. Continued inflammation causes liver fibrosis to develop and progress, potentially developing into liver cirrhosis and liver cancer.[1] Currently, in Japan about 35,000 people are dying from liver cancer every year, and hepatitis C is said to be the cause of liver cancer in about 80 percent of cases.[2]

About simeprevir
Simeprevir is a new DAA (direct-acting antiviral agent), is a protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB for the treatment of genotype 1 chronic hepatitis C infection. Simeprevir works by blocking the protease enzyme that enables the hepatitis C virus to replicate in host cells.

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

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 health and quality of life.

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. 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

References
1. Treatment Guidelines of Hepatitis C in 2012. The Committee for Hepatitis Clinical Guidelines, Japan Society of Hepatology.
2. Latest Statistics on Cancer (2010 Updated Version)" The Center for Cancer Control and Information Services, National Cancer Center.