Data from OPTIMIST trials show SVR12 rates of 97 percent in HCV patients without cirrhosis and 84 percent in HCV patients with cirrhosis

Stockholm, Sweden — Medivir AB (Nasdaq Stockholm: MVIR) announces that our partner Janssen Sciences Ireland UC, today publish positive results for simeprevir, the NS3/4A protease inhibitor for the treatment of hepatitis C virus (HCV) infection, at The International Liver Congress™ 2015 of the European Association for the Study of the Liver (EASL) in Vienna. Late-breaking results from the phase III OPTIMIST-1 and OPTIMIST-2 trials highlight the clinical outcomes of simeprevir in an all-oral combination regimen in a wide range of patients with hepatitis C virus (HCV) infection.

The results from the OPTIMIST-1 and OPTIMIST-2 trials are the first phase III data to be presented on simeprevir in combination with sofosbuvir (SMV/SOF) in patients with genotype 1 chronic HCV infection, both with and without cirrhosis. Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor developed by Gilead Sciences, Inc.

OPTIMIST-1[i]

- OPTIMIST-1 is a phase III, randomized, open-label trial to investigate the efficacy and safety of the all-oral regimen of SMV/SOF among treatment-naïve and treatment-experienced genotype 1 chronic HCV infected patients without cirrhosis. The primary objective was to show superior sustained virologic response (SVR) at 12 weeks after treatment (SVR12) with twelve and 8 weeks of treatment with SMV/SOF versus a historical control (patients previously treated with approved regimens containing a direct-acting antiviral, pegylated interferon and ribavirin).

- Ninety-seven (97) percent of patients treated with SMV/SOF for 12 weeks (n=150/155) achieved SVR12, which was superior to the SVR12 rate of 87 percent among the historical control.
    - SVR12 rates of 100 percent were seen among patients with *IL28B* CC genotype (n=43/43) and those with baseline NS5A and NS3 Q80K polymorphisms (n=9/9).

- Patients treated with eight weeks of SMV/SOF achieved an SVR12 rate of 83 percent (n=128/155), which was not superior to the SVR12 rate of 83 percent in the historical control.
    - High SVR12 rates were seen among patients with baseline HCV RNA <4 million IU/mL (96 percent; n=46/48), *IL28B* CC genotype (93 percent; n=38/41), patients with genotype 1b HCV infection (92 percent; n=36/39), and patients without baseline NS5A and Q80K polymorphisms (89 percent; n=78/88).

- The most frequently reported adverse events in the 12-week and eight-week treatment arms were headache (14 and 17 percent, respectively), fatigue (12 and 15 percent, respectively) and nausea (15 and 9 percent, respectively).

OPTIMIST-2[ii]

- OPTIMIST-2 is a phase III, open-label, single-arm trial to investigate the efficacy and safety of SMV/SOF in treatment-naïve and treatment-experienced genotype 1 chronic HCV infected patients with cirrhosis. The primary objective was to show superior SVR12 with twelve weeks of treatment with SMV/SOF versus a historical control.

- Twelve (12) weeks of treatment with SMV/SOF resulted in SVR12 rates of 84 percent (n=86/103), which was superior to the SVR12 rate of 70 percent in the historical control.

- Higher SVR12 rates were seen in patients with baseline NS5A polymorphisms with or without NS3 Q80K polymorphisms (100 percent, n=13/13), patients with albumin ≥4 g/dL (94 percent; n=47/50), and treatment-naïve patients (88 percent; n=44/50).

- The most common adverse events were fatigue (20 percent), headache (20 percent) and nausea (11 percent).

For further information, please contact:

Ola Burmark, CFO Medivir AB, mobile: +46 (0)725-480 580.
Charlotte Edenius, EVP Development Medivir AB, mobile +46 (0)73-386 42 46.

Medivir is required under the Securities Markets Act to make the information in this press release public.
The information was submitted for publication at 10.30 CET on 23 April 2015.

About Simeprevir (OLYSIO®)

Simeprevir is an NS3/4A protease inhibitor which has been developed by Janssen Sciences Ireland UC in collaboration with Medivir AB. In November 2013, simeprevir was initially approved by the U.S. Food and 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. 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 authorisation held by Janssen-Cilag International NV.

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.

---

[i] A Phase 3, randomised, open-label study to evaluate the efficacy and safety of 12 and 8 weeks of treatment with simeprevir plus sofosbuvir in treatment-naïve and -experienced patients with chronic HCV genotype 1 infection without cirrhosis: The OPTIMIST-1 study. Abstract presented at The International Liver Congress™ 2015.

[ii] A Phase 3, open-label, single-arm study to evaluate the efficacy and safety of 12 weeks of simeprevir plus sofosbuvir in treatment-naïve or –experienced patients with chronic hepatitis c virus genotype 1 infection and cirrhosis: The OPTIMIST-2 study. Abstract presented at The International Liver Congress™ 2015.