



Press Release 12 December 2013

An all-oral phase IIa study combining Simeprevir, TMC647055 and JNJ56914845 in hepatitis C patients to be initiated

Stockholm, Sweden—Medivir AB (OMX: MVIR), announces the initiation of a phase IIa trial in chronic genotype 1 hepatitis C infected patients to evaluate the efficacy, safety and tolerability of a 12-week combination therapy of simeprevir, TMC647055 and JNJ56914845, a NS5A replication complex inhibitor.

Study design

Approximately 40 patients will be enrolled in this open-label study to assess the efficacy, safety and tolerability of the co-administration of simeprevir, TMC647055 and two different doses of JNJ56914845 without ribavirin. The trial will evaluate genotype 1a and 1b HCV-infected patients who are either treatment-naïve or who have relapsed after prior treatment with interferon and ribavirin. Patients will receive 75 mg of simeprevir, 30 or 60 mg of JNJ56914845 and 450 mg of TMC647055 plus a low dose of ritonavir as a pharmacokinetic enhancer, each once daily for 12 weeks.

For additional information about this study, please visit www.clinicaltrials.gov

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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 08.30 a.m. CET on 12 December 2013.

About Simeprevir

Simeprevir is an NS3/4A protease inhibitor jointly developed by Medivir and Janssen R&D Ireland for the treatment of chronic hepatitis C infection in combination with other antivirals in HCV genotype 1 & 4 infected patients with compensated liver disease, including cirrhosis.

Simeprevir was approved for the treatment of genotype 1 hepatitis C in September 2013 in Japan and in the USA and Canada in November. A Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) in April 2013 by Janssen-Cilag International NV seeking approval of simeprevir for the treatment of genotype 1 or genotype 4 chronic hepatitis C. To date, more than 3,700 patients have been treated with simeprevir in clinical trials.

About TMC647055

TMC647055 is a potent non-nucleoside hepatitis C polymerase inhibitor with broad genotypic coverage. TMC647055 is in phase II clinical development and is developed by Janssen R&D Ireland to treat chronic hepatitis C virus infections. TMC647055 is being investigated in combination with other DAA agents in all oral interferon-free regimens. There have been no treatment-emergent serious adverse events reported in the program.

About JNJ56914845

JNJ56914845, is a potent NS5A replication complex inhibitor. To date phase I and phase II clinical studies conducted demonstrated that JNJ56914845 60 mg once daily is well tolerated and produces rapid, substantial decreases in HCV RNA in treatment-naïve CHC subjects when given alone as a single dose and for 4 weeks in combination with pegIFN and RBV.

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 asset is simeprevir, a novel protease inhibitor for the treatment of hepatitis C that is being developed in collaboration with Janssen R&D Ireland. The company is also working with research and development in other areas, such as bone disorders and neuropathic pain. 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

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