



Press Release 8 October 2013

## **Janssen has acquired an NS5a replication complex inhibitor that will be evaluated with Simeprevir in future clinical development**

**Stockholm, Sweden — Medivir AB (OMX: MVIR)** announced that Janssen Pharmaceuticals, Inc. (Janssen) has acquired the investigational compound GSK2336805 (GSK805), an NS5a replication complex inhibitor in phase II development for the treatment of chronic hepatitis C. Janssen has acquired all rights to develop and commercialize GSK2336805 including in combination with other drugs. Janssen acquired the compound from an affiliate of GlaxoSmithKline plc, financial details of the agreement have not been disclosed.

Janssen plans to initiate phase II studies to evaluate the use of GSK805 in interferon-free combinations with simeprevir (TMC435) and TMC647055, Janssen's non-nucleoside polymerase inhibitor, for the treatment of chronic hepatitis C in adult patients with compensated liver disease.

"The acquisition shows our partner Janssen's commitment in the area and their long term effort to evaluate different treatment possibilities for hepatitis C. This together with other ongoing interferon free trials will guide how simeprevir may be used in the best way in different patient groups and markets" says Maris Hartmanis, CEO of Medivir AB.

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### **About Simeprevir**

Simeprevir is an investigational NS3/4A protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB, for the treatment of genotype 1 and genotype 4 chronic hepatitis C in adult patients with compensated liver disease, including all stages of liver fibrosis. Simeprevir works by blocking the protease enzyme that enables the hepatitis C virus to replicate in host cells.

Janssen is responsible for the global clinical development of simeprevir and has acquired exclusive, worldwide marketing rights, except for in the Nordic countries. Medivir will retain marketing rights for simeprevir in these countries.

Simeprevir was approved in Japan in September 2013 for the treatment of genotype 1 hepatitis C. In the U.S., the New Drug Application (NDA) filed by Janssen for simeprevir administered once daily in combination with pegylated interferon and ribavirin for the treatment of genotype 1 chronic hepatitis C in adult patients was granted Priority Review designation by the Food and Drug Administration (FDA) in May. A Marketing Authorisation Application was submitted to the European Medicines Agency (EMA) in April 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. Simeprevir is also being studied in several interferon-free regimens using selected combinations of direct-acting antiviral agents with different mechanisms of action.

For additional information about simeprevir clinical trials, please visit [www.clinicaltrials.gov](http://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](http://www.medivir.com)