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Medivir announces a phase II all-oral study of Simeprevir (TMC435) and VX-135 for the treatment of Hepatitis C to be conducted by Janssen and Vertex

- *Companies to evaluate a two-drug combination of Medivir/Janssen's investigational protease inhibitor simeprevir (TMC435) and Vertex's investigational nucleotide analogue VX-135*
- *Phase II proof-of-concept study to begin in early 2013 to evaluate safety, tolerability and viral cure rates of 12-week treatment regimen*

Stockholm, Sweden—Medivir AB (OMX: MVIR), announced today plans for a phase II proof-of-concept study of an all-oral regimen for the treatment of hepatitis C containing of Medivir/Janssen's protease inhibitor simeprevir and Vertex's nucleotide analogue hepatitis C virus (HCV) polymerase inhibitor VX-135. Janssen will conduct a drug-drug interaction study with simeprevir and VX-135 to support the planned initiation of a phase II proof-of-concept study in early 2013, pending discussions with regulatory authorities.

The phase II study is expected to evaluate safety, tolerability and viral cure rates using a 12-week combination of simeprevir and VX-135, with and without ribavirin. Janssen and Vertex will jointly fund development costs associated with the collaboration. There are no up-front or milestone payments associated with the agreement.

Simeprevir is a potent, once-daily investigational hepatitis C protease inhibitor, currently in phase III trials, being jointly developed by Medivir AB and Janssen R&D Ireland.VX-135 is an investigational uridine nucleotide analogue pro-drug designed to inhibit the replication of the hepatitis C virus by acting on the NS5B polymerase.

"This study will broaden our understanding of simeprevir, which we believe has the necessary characteristics to become a key component of future hepatitis C treatment regimens, including combination with interferon and ribavirin as well as interferon-free therapies and is in line with Medivir's and Janssen's strategy to evaluate different interferon-free HCV treatment possibilities" comments Charlotte Edenius, EVP of Research and Development, Medivir AB.

Clinical development plans
Vertex and Janssen expect to initiate a phase II proof-of-concept study of VX-135 and simeprevir in early 2013, following the completion of a drug-drug interaction (DDI) study. Costs associated with the studies will be shared equally between the two companies. The goals of the study will be to evaluate safety, tolerability and viral cure rates of multiple 12-week combination regimens (SVR12*) of VX-135 and simeprevir, with and without ribavirin. The study will include patients who have chronic non-cirrhotic genotype 1 hepatitis C and have not previously been treated (treatment-naïve). Additional information on the phase II study will be provided upon initiation of the study.

** SVR12 = undetectable hepatitis C virus 12 weeks after the end of treatment.*

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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 lives.

About Simeprevir(TMC435)
Simeprevir is a once-daily potent investigational hepatitis C protease inhibitor in late phase III clinical development being jointly developed by Medivir AB and Janssen R&D Ireland to treat chronic hepatitis C virus infections. Simeprevir is being investigated in combination with PegIFN/RBV in phase III trials and is also being evaluated with Direct-acting Antiviral (DAA) agents in three other phase II interferon-free combinations both with and without ribavirin (RBV).

Global phase III studies of simeprevir include QUEST-1 and QUEST-2 in treatment naïve patients, PROMISE in patients who have relapsed after prior IFN-based treatment and ATTAIN in treatment experienced patients. In parallel to these trials, phase III studies for simeprevir are ongoing in both treatment naïve and treatment experienced HIV-HCV co-infected patients, HCV genotype 4 infected patients and in Japanese HCV genotype 1 patients.

The phase II interferon-free combinations both with and without ribavirin with simeprevir are:

- Simeprevir is evaluated in combination with Gilead Science, sofosbuvir (GS7977) in null responder hepatitis C genotype1 infected patients.
- Simeprevir is evaluated in combination with BMS, daclatasvir in treatment-naïve or previous null responder hepatitis C genotype1 infected patients.
- Simeprevir is evaluated in combination with TMC647055 (Janssen R&D) and ritonavir in low doses in treatment-naïve, relapser or null responderhepatitis C genotype1 infected patients.

For additional information about simeprevir please see www.clinicaltrials.gov

About VX-135
VX-135 (ALS-2200) is a uridine nucleotide analogue pro-drug that appears to have a high barrier to drug resistance based on *in vitro* studies. It is designed to inhibit the replication of the hepatitis C virus by acting on the NS5B polymerase. *In vitro* studies of the compound showed antiviral activity across all genotypes, or forms, of the hepatitis C virus, including genotypes more prevalent outside of the United States.

Earlier this year, Vertex announced the first 7-day viral kinetic data for VX-135. Based on these data, the company plans to initiate multiple all-oral, phase II proof-of-concept studies, including a study of VX-135 and ribavirin and a study of VX-135 and telaprevir, the company's approved protease inhibitor marketed as INCIVEK for people with chronic genotype 1 hepatitis C. Vertex is on track to initiate the study of VX-135 in combination with ribavirin by the end of 2012, followed by the study with telaprevir in early 2013. The studies will evaluate safety, tolerability and viral cure rates of 12-week combination regimens in people with chronic non-cirrhotic genotype 1 hepatitis C who have not previously been treated (treatment-naïve).

About Hepatitis C
Hepatitis C is a blood-borne infectious disease of the liver and is a leading cause of chronic liver disease and liver transplants. The World Health Organization estimates that nearly 170 million people worldwide, approximately 3% of the world's population, are infected with hepatitis C virus (HCV). The CDC (Centers for Disease Control and Prevention) has reported that more than three million people in the United States are chronically infected with HCV.

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 (TMC435), a novel protease inhibitor in phase III clinical development for hepatitis C that is being developed in collaboration with Janssen R&D Ireland.

In June 2011, Medivir acquired the specialty pharmaceutical company BioPhausia and today Medivir has a broad product portfolio with prescription pharmaceuticals in the Nordics.

Medivir’s first product, the unique cold sore product Xerese®/Xerclear®, is launched in collaboration with GlaxoSmithKline to be sold OTC under the brand name ZoviDuo in Europe, Japan and Russia.

For more information about Medivir, please visit the Company’s website: www.medivir.com