



Press Release 28 January 2013

Phase II all-oral combination studies of Simeprevir, TMC647055 and IDX719 for the treatment of Hepatitis C to be initiated shortly

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announced a non-exclusive collaboration between Janssen Pharmaceuticals Inc. (Janssen) and Idenix Pharmaceuticals for the clinical development of an all-oral (interferon-free) direct-acting antiviral (DAA) hepatitis C (HCV) combination therapy. The collaboration will evaluate combinations including simeprevir (TMC435), a once-daily protease inhibitor jointly developed by Janssen R&D Ireland and Medivir, TMC647055, a potent once-daily NNI (non-nucleoside inhibitor) of the HCV polymerase, boosted with low dose ritonavir, being developed by Janssen and IDX719, Idenix's once-daily pan-genotypic NS5A inhibitor.

Clinical development plans include an initial drug-drug interaction study to begin in the first quarter of 2013, followed by phase II studies as agreed between the companies, and pending approval from regulatory authorities. The phase II program is expected to first evaluate the two-DAA combination of IDX719 and simeprevir plus ribavirin for 12 weeks in treatment-naïve HCV-infected patients. Subsequently, the companies plan to evaluate a three-DAA combination of IDX719, simeprevir, TMC647055/r, with or without ribavirin. The clinical trials will be conducted by Idenix. Both companies retain all rights to their respective compounds under this agreement.

"This collaboration agreement underscores our strong commitment to develop interferon-free treatment options with simeprevir as a base for hepatitis C patients", says Charlotte Edenius, EVP of Research and Development, Medivir AB. "We are committed to develop these new treatments, where already four different interferon-free combinations with simeprevir are under investigation, with the potential to achieve high viral cure rates after only 12 weeks of total treatment, and we look forward to start this new collaboration with Idenix."

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About Simeprevir (TMC435)

Simeprevir is a once-daily potent investigational hepatitis C protease inhibitor in late phase III clinical development being jointly developed by Janssen R&D Ireland and Medivir AB 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 four other phase II interferon-free combinations both with and without ribavirin (RBV).

Global phase III studies of simeprevir in combination with PegIFN/RBV include the following studies:

- QUEST-1 and QUEST-2 in treatment-naïve patients.
- PROMISE in patients who have relapsed after prior interferon-based treatment.
- ATTAIN in prior null-responder patients and studies in Japanese HCV genotype 1 patients.

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.

In parallel to these trials, phase III studies for simeprevir are ongoing in treatment-naïve and treatment-experienced HIV-HCV co-infected patients and in HCV genotype 4 patients.

Simeprevir is also being studied in phase II interferon-free trials both with and without ribavirin:

- Simeprevir in combination with Gilead Sciences' sofosbuvir (GS7977) in hepatitis C genotype 1 treatment-naïve or prior null responder patients.
- Simeprevir in combination with BMS's, daclatasvir in hepatitis C genotype 1 treatment-naïve or prior null responder patients.
- Simeprevir in combination with Janssen's TMC647055 and low dose ritonavir in hepatitis C genotype 1 treatment-naïve, prior relapser or null responder patients.
- Simeprevir in combination with Vertex's VX-135 in hepatitis C genotype 1 treatment-naïve patients to commence in 2013.

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

About IDX719

IDX719 is an NS5A inhibitor with low picomolar, pan-genotypic antiviral activity *in vitro*. To date, IDX719 has been safe and well tolerated after single and multiple doses of up to 100 mg in healthy volunteers (n=36; up to 7 days duration) and HCV-infected patients (n=69; up to 3 days duration). There have been no treatment-emergent serious adverse events reported in the program. IDX719 has demonstrated potent pan-genotypic antiviral activity in HCV-infected patients with mean maximal viral load reductions up to approximately 4.0 log₁₀ IU/ML across HCV genotypes 1-4 in a proof-of-concept, three-day monotherapy study. **For more information about IDX719, please visit www.idenix.com.**

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 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 late phase III clinical development for 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, please visit the Company's website: www.medivir.com