



Press Release 18 April 2012

## Medivir announces TMC435 in an expanded clinical collaboration

- **Expanded clinical study program evaluating a combination of TMC435 and daclatasvir (BMS-790052)**
- **TMC435 and BMS-986094 (formerly INX-189), two direct-acting antivirals in combination, will be evaluated in clinical trial**

**Stockholm, Sweden** - Medivir AB (OMX:MVIR), the research-based speciality pharmaceutical company focused on the development of high-value treatments for infectious diseases, announces that its development partner, Janssen R&D Ireland has broadened its clinical collaboration agreement with Bristol-Myers Squibb Company (NYSE:BMJ).

- This announcement concerns an expansion of the clinical collaboration agreement between Tibotec Pharmaceuticals (now Janssen R&D Ireland) and Bristol-Myers Squibb (NYSE:BMJ) announced by Bristol-Myers Squibb on 2<sup>nd</sup> December 2011
- Bristol-Myers Squibb and Janssen have agreed, pending the outcome of the upcoming phase II study, to further study daclatasvir (BMS-790052) and TMC435 in a phase III trial.
- Bristol-Myers Squibb and Janssen have agreed to conduct a drug-drug interaction study with TMC435 and BMS-986094. Results from the DDI study will guide the further evaluation of the use of TMC435 and BMS-986094 in HCV patients.

### **TMC435 and daclatasvir (BMS-790052)**

In the agreement announced on 2<sup>nd</sup> December 2011, TMC435, a once daily potent NS3/4A protease inhibitor (PI) in phase III development for the treatment of genotype-1 chronic hepatitis C virus (HCV) infection will be investigated in a combination in a phase II trial with Bristol-Myers Squibb's investigational NS5A replication complex inhibitor, daclatasvir (BMS-790052), also in phase III development.

In the upcoming phase II study the companies will evaluate the potential to achieve sustained viral response 12 and 24 weeks post treatment in null responder and interferon intolerant patients with HCV genotype 1. This study is planned to start later in 2012.

### **TMC435 and BMS-986094 (INX-189)**

The expanded clinical agreement also includes clinical evaluation of a combination of TMC435 and the nucleotide polymerase NS5B inhibitor BMS-986094, formerly known as INX-189. A drug-drug interaction (DDI) study with TMC435 and BMS-986094 will be conducted. Results from the DDI study will guide the further evaluation of the use of TMC435 and BMS-986094 in HCV patients.

**Charlotte Edenius, Executive VP Research & Development, of Medivir commented:** "We are very excited to see this expanded collaboration between Janssen and Bristol-Myers Squibb and to be investigating TMC435 with the nucleotide BMS-986094 and to expand the clinical collaboration evaluating TMC435 with daclatasvir. This represents one of several strategies to explore TMC435 in interferon free regimens; a development we believe will be an important advancement in the HCV field for patients."

### **About TMC435**

TMC435 is a highly potent once-daily (q.d.) investigational drug that is being jointly developed by Janssen R&D Ireland and Medivir to treat chronic hepatitis C virus infections in genotype 1 patients.

### **TMC435 - On-going global phase III program in brief:**

- TMC435-C208 or QUEST-1 in 375 treatment-naïve genotype-1 patients
- TMC435-C216 or QUEST-2 in 375 treatment-naïve genotype-1 patients
- TMC435-C3007 or PROMISE in 375 genotype-1 patients who have relapsed after prior interferon-based treatment
- Phase III program in Japan, includes 417 genotype-1 treatment naïve and treatment experienced patients
- TMC435-C3001 is a phase III efficacy, safety and tolerability study comparing TMC435 versus telaprevir, each in combination with Pegylated Interferon  $\alpha$ -2a (PegIFN) and ribavirin (RBV), in hepatitis C genotype-1 infected patients who were null or partial responders to prior PegIFN/RBV therapy
- TMC435-C3011 is an open label, single arm phase III trial to explore the efficacy, safety and tolerability of TMC435 150 mg once daily, in combination with PegIFN/RBV in 100 treatment naïve or treatment experienced, hepatitis C genotype-4 infected patients

For additional information from these studies, please see [www.medivir.com](http://www.medivir.com) and [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

### **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 180 million people worldwide, or approximately 3% of the world's population, are infected with hepatitis C virus (HCV). The CDC has reported that almost three million people in the United States are chronically infected with HCV.

### **For more information about Medivir, please contact:**

#### **Medivir**

Rein Piir, EVP Corporate Affairs & IR

#### **M:Communications**

Europe: Mary-Jane Elliott, Amber Bielecka, Hollie Vile

Mobile: +46 708 537 292

[medivir@mcomgroup.com](mailto:medivir@mcomgroup.com)

+44(0)20 7920 2330

### **About Medivir**

Medivir is an emerging research-based specialty pharmaceutical company focused on the development of high-value treatments for 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 TMC435, a novel protease inhibitor in phase III clinical development for hepatitis C that is being developed in collaboration with Janssen Pharmaceuticals.

In June 2011, Medivir acquired the specialty pharmaceutical company BioPhausia to ensure timely commercialisation of TMC435 in the Nordic markets, once approved.

Medivir's first product, the unique cold sore product Xerese<sup>®</sup>/Xerclear<sup>®</sup>, was launched on the US market in 2011. Xerese<sup>®</sup>/Xerclear<sup>®</sup>, which has been approved in both the US and Europe, is being launched in collaboration with GlaxoSmithKline to be sold OTC in Europe, Japan and Russia. Rights in North America, Canada and Mexico were sold to Meda AB in June 2011. Medivir has retained the Rx rights for Xerclear<sup>®</sup> in Sweden and Finland.

**For more information about Medivir, please visit the Company's website: [www.medivir.com](http://www.medivir.com)**