



Press Release 4 March 2014

SVR12 results from a phase IIa study evaluating Simeprevir and Daclatasvir in Hepatitis C patients of genotype 1 have been presented

Stockholm, Sweden — Medivir AB (OMX: MVIR) today announced that study results from a phase IIa trial evaluating simeprevir, a once-daily protease inhibitor jointly developed by Janssen R&D Ireland and Medivir AB, in combination with daclatasvir, an investigational once-daily NS5A inhibitor developed by Bristol-Myers Squibb (NYSE: BMY), with and without ribavirin, in patients with hepatitis C (HCV) genotype 1 infection, have been presented at the 21st Conference on Retroviruses and Opportunistic Infections (CROI) on March 4th in Boston, USA. The study was conducted by Bristol-Myers Squibb.

Data from the study demonstrate that sustained virologic response 12 weeks after the end of treatment (SVR12) was reached in 75 to 85 percent of treatment-naïve patients and 65 to 95 percent of prior null responders with HCV genotype 1b after 12 or 24 weeks of treatment.

“We are pleased to report on the successfully completed exploratory phase IIa clinical trial of simeprevir and daclatasvir. The results are promising, but further studies would be required in order to fully assess the potential of the simeprevir/daclatasvir combination.” says Charlotte Edenius, EVP Development, Medivir AB.

Study Design

In this phase IIa open-label study, HCV genotype 1b treatment-naïve patients (N=104) and prior null responders (N=43) were randomly assigned (1:1) to receive daclatasvir 30mg QD + simeprevir 150mg QD with or without ribavirin. Two treatment durations were evaluated: patients who completed 12 weeks treatment were re-randomized (1:1) to stop at Week 12 or continue treatment through Week 24.

In an exploratory evaluation of HCV genotype 1a patients, treatment naïve (N=12) and prior null responder patients (N=9) received daclatasvir + simeprevir + ribavirin for 24 weeks.

Summary – Efficacy

In treatment-naïve HCV genotype 1b patients SVR12 was achieved by 75% (38/51) and 85% (45/53) when treated with simeprevir and daclatasvir, with or without ribavirin, respectively. In HCV genotype 1b prior null responders SVR12 was achieved by 95% (19/20) and 65% (15/23) with or without ribavirin, respectively. Estimated SVR12 rates in HCV genotype 1b patients (adjusted for pre-Week 12 discontinuations) were similar after 12 or 24 weeks of treatment in naïve patients but higher after 12 than 24 weeks in prior null responders.

In treatment-naïve HCV genotype 1a patients 67% (8/12) achieved SVR12. All HCV genotype 1a prior null responders were offered pegylated interferon alfa-2a in addition to ribavirin + daclatasvir + simeprevir as rescue therapy due to frequent on-treatment breakthroughs and were counted as treatment failures.

Overall, patients were 92% white, 49% male, 21% cirrhotic, and 76% IL28B non-CC genotype and were well-balanced across treatment groups.

Summary - Safety

The all-oral combination of daclatasvir plus simeprevir, with and without ribavirin, was generally well tolerated. There were two treatment-related serious adverse events (neurotoxicity, liver disorder) and one on-treatment death (unrelated trauma-associated intracranial hematoma). Three patients experienced

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.

treatment-related adverse events leading to discontinuation. Seventeen patients experienced grade 3/4 total bilirubin elevations without concurrent transaminase elevations, mostly in patients receiving ribavirin (14/17), consistent with ribavirin-induced hemolysis and known effects of simeprevir on bilirubin transporters.

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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 18.15 CET on 4 March 2014.

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 hepatitis C genotype 1 and 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 and and genotype 4 chronic hepatitis C. To date, more than 3,700 patients have been treated with simeprevir in clinical trials.

About Daclatasvir

Daclatasvir is an investigational NS5A replication complex inhibitor that has been studied in more than 5,500 patients to date as a foundational agent for multiple direct-acting antiviral-based combination therapies and is currently in phase III development. Daclatasvir has shown antiviral potency and pan-genotypic activity across hepatitis C genotypes in vitro. Daclatasvir has a drug-drug interaction profile that supports its continued study in a variety of hepatitis C combination regimens. Daclatasvir-based regimens are currently under review by regulatory authorities in Japan and Europe.

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. 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