



Press Release 22 October 2013

The regulatory process for Simeprevir in the U.S.

Stockholm, Sweden — Medivir AB (OMX: MVIR) In March 2013, Medivir's partner Janssen Pharmaceuticals, Inc. (Janssen) filed a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) seeking approval for simeprevir for a triple combination treatment of simeprevir combined with pegylated interferon and ribavirin in patients infected with chronic genotype 1 hepatitis C. In May 2013, the FDA granted Priority Review to the new drug application for simeprevir.

Next step in the regulatory process is scheduled to be on 24 October 2013 when the FDA's Antiviral Drugs Advisory Committee is scheduled to meet to review the application for simeprevir.

The Committee is scheduled to meet from 8am to 5pm Eastern Standard Time (EST), ending with a voting session. The outcome is typically announced by the FDA after the meeting. Medivir will issue a press release about FDA's announcement. The FDA is then expected to make its final decision by end of November 2013. That decision will also be announced through a press release.

A Briefing Book, which contains information about simeprevir and its clinical studies, is available on the FDA website.

There is no planned trading halt in the Medivir share on 24 October 2013.

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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

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.