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Japanese Health Authority Approves Sovriad™ for the Treatment of Genotype-1 Chronic HCV Infection

Japan is the first country in the world where SOVRIAD™ is approved

TOKYO, Japan, 27 September 2013 - Janssen Pharmaceutical K.K. (Headquarters: Chiyoda-ku, Tokyo, President: Bruce Goodwin; henceforth "Janssen") announced today that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved SOVRIAD™ (simeprevir sodium) for the treatment of genotype-1 chronic hepatitis C virus (HCV) infection.*

SOVRIAD™ is a new direct-acting antiviral agent (DAA) and a second-generation protease inhibitor¹, which is administered as once-daily capsules for 12 weeks in combination with pegylated interferon and ribavirin for 24 or 48 weeks.

"We submitted SOVRIAD™ for regulatory approval in February of this year before any other country in the world," said Bruce Goodwin, President, Janssen Pharmaceutical K.K. "Data from the four Japanese phase 3 CONCERTO studies that supported the new drug application were presented in June at the Japan Society of Hepatology's 49th Annual Meeting in Tokyo."

As part of a combination therapy with pegylated interferon and ribavirin in clinical trials, SOVRIAD™ has demonstrated strong efficacy, with 89 percent² of patients with previously untreated genotype-1 HCV achieving a sustained virological response (SVR). The primary endpoint in all clinical studies for SOVRIAD™ was an SVR 12 weeks after the last dose of treatment. In studies that included patients who had relapsed after stopping previous HCV treatment, results showed an SVR-12 of 96 percent.²

In clinical trials, there were no significant additional adverse events observed when SOVRIAD™ was added to traditional treatment with pegylated interferon and ribavirin compared to treatment with pegylated interferon and ribavirin alone. The most common side effects observed were decreased white blood cell count, fever, anemia, malaise, headache and rash.

In Japan, an estimated 1.5 to 2 million people are infected with chronic HCV infection³. Approximately 70 percent of Japanese patients who have HCV are infected by genotype-1 HCV.³ After initial infection with HCV, the infection may persist in about 70 percent of cases, leading to the development of chronic hepatitis.³ Continued inflammation causes liver fibrosis to develop and progress, potentially leading to liver cirrhosis and liver cancer.³ Approximately 30,000 people die from liver cancer each year in Japan,⁴ and HCV is said to be the cause of liver cancer in about 80 percent of cases.³

"SOVRIAD™ has the potential to offer a new standard treatment option for people infected with chronic hepatitis C in Japan and around the world," Mr. Goodwin said. "Janssen is committed to working with the HCV community and will continue to engage with healthcare professionals, government officials and patient advocates around the world to contribute to the elimination of HCV."

Product Outline of SOVRIAD™

Trade Name: SOVRIAD™

Generic Name: Simeprevir Sodium

Formulation: Capsule

Indication: Treatment of chronic hepatitis C genotype-1 infection in patients:
1) who are treatment-naïve with high HCV RNA levels or,
2) who failed previous interferon-based therapy

Dosage and Administration:

For adults, 100 mg of SOVRIAD™ is administered orally once daily for 12 weeks. SOVRIAD™ must be used in combination with pegylated interferon alfa (2a or 2b recombinant) and ribavirin.

**For full prescribing information, please refer to the package insert.*

About SOVRIAD™²

SOVRIAD™, a new direct-acting antiviral agent (DAA), is a second-generation protease inhibitor jointly developed by Janssen Research & Development LLC and Medivir AB for the treatment of genotype-1 chronic HCV infection. SOVRIAD™ works by blocking the protease enzyme that enables the hepatitis C virus to replicate in host cells.

About the CONCERTO Studies

Janssen's phase 3 clinical program for simeprevir in Japan consists of four studies in patients with genotype-1 HCV: CONCERTO-1 in treatment-naïve patients, CONCERTO-2 and -3 in prior non-responders or patients who relapsed after prior interferon-based treatment, and CONCERTO-4 using different pegylated interferon treatments (pegylated interferon alfa-2b) in a broad patient population.

SVR-12 in the CONCERTO Trials			
Trial	Patient Type	Treatment + pegylated interferon and ribavirin	Proportion of Patients Achieving SVR-12 (%)
CONCERTO-1	Treatment-naïve	Simeprevir (12 weeks)	89
		Placebo (12 weeks)	62
CONCERTO-2	Prior Non-responder	Simeprevir (12 weeks)	53
CONCERTO-3	Prior Relapser	Simeprevir (12 weeks)	96
CONCERTO-4	Treatment-naïve	Simeprevir (12 weeks)	92
	Prior Relapser	Simeprevir (12 weeks)	100
	Prior Non-responder	Simeprevir (12 weeks)	39

The most common adverse events seen in patients receiving simeprevir plus pegylated interferon and ribavirin in CONCERTO-1 were similar to those observed with pegylated interferon and ribavirin alone and were also similar in the other CONCERTO studies (decreased white blood cell count, fever, anemia, malaise, headache and rash). Treatment discontinuation rates due to an adverse event in CONCERTO-1 were five percent in the simeprevir arm and eight percent in the placebo arm, four percent in CONCERTO-2, four percent in CONCERTO-3 and one percent in CONCERTO-4.

For additional information about SOVRIAD™ (simeprevir) clinical trials, please visit www.clinicaltrials.gov.

About Janssen Pharmaceutical K.K.

Janssen Pharmaceutical K.K. is dedicated to addressing and solving the most important unmet medical needs in oncology, immunology, neuroscience (central nervous system and pain management), infectious diseases/vaccines and metabolic/cardiovascular diseases. Driven by the passionate pursuit of science for the benefit of patients, we are committed to bringing innovative solutions to unmet medical needs. Janssen Pharmaceutical K.K. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Pharmaceutical K.K. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Janssen Pharmaceutical K.K. nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.

References

- ¹ Treatment Guidelines of Hepatitis C in 2012. The Committee for Hepatitis Clinical Guidelines, Japan Society of Hepatology.
- ² Data on file: phase 3 clinical program for simeprevir in Japan.
- ³ Hepatitis Information Center, Research Institute, National Center for Global Health and Medicine.
- ⁴ Population Survey Report 2010, Japanese Ministry of Health, Labour and Welfare (MHLW).

Media Contacts:

Jennifer Tear (Asia Pacific)
Office: +61 2 9815 3349

Mobile: +61 4 2992 0517

Daniel De Schryver (outside Asia Pacific)

Office: +32 1460 3030

Mobile: +49 17 3768 9149

Investor Contacts:

Louise Mehrotra (US)

Johnson & Johnson

Office: +1 732-524-6491

Stan Panasewicz (US)

Johnson & Johnson

Office: +1 732-524-2524