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BMS seeks Hep C therapy approval in Japan

November 7, 2013 | News | By BioSpectrum Bureau



Singapore: Bristol-Myers Squibb has submitted a New Drug Application (NDA) to Japan's Pharmaceutical and Medical Devices Agency seeking the world's first interferon-free and ribavirin-free treatment regimen for patients with chronic hepatitis C.

Globally, there are 170 million people who are infected with HCV. Of the 1.2 million people living with HCV in Japan, approximately 70 percent of these patients have genotype 1b, which has one of the lowest response rates to current treatments. Further, a significant number of patients with HCV in Japan are over the age of 65, leading to more disease-related complications and a decreased likelihood of tolerating interferon-based therapies, the standard for treating HCV.

"With our submission in Japan, we are pleased to be one step closer to bringing a potential new treatment option to the many people living with HCV in that country," said Dr. Brian Daniels, senior vice president, Global Development and Medical Affairs, Research and Development, Bristol-Myers Squibb.