

Translation

Approval of Antiviral Drug, Copegus® for Additional Indication -First All-Oral Treatment Regimen for Patients with Serogroup 2 HCV in Japan-

March 26, 2015 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama] (hereafter, "Chugai") announced today that it obtained approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the additional indication of Copegus® (ribavirin) for "improvement of viraemia associated with chronic hepatitis C (CHC) and compensated cirrhosis related to hepatitis C," when administered in combination with Sovaldi® (sofosbuvir), developed by Gilead Sciences K.K. [Head Office: Tokyo, Japan President and Representative Director: Yuji Orihara] (hereafter, "Gilead"). The combination therapy of Copegus and Sovaldi is the first all-oral treatment regimen for patients with serogroup 2 (genotype 2) hepatitis C virus (HCV) in Japan.

This approval was mainly based on the result of a Japanese Phase 3 clinical study (GS-US-334-0118) managed by Gilead. This study was conducted as an open-label study to confirm the efficacy and safety of the combination therapy of Copegus and Sovaldi administered for 12 weeks in patients with serogroup 2 (genotype 2) CHC including those with cirrhosis. The result showed that 96.4 percent of the patients (n=135/140) achieved Sustained Virologic Response after 12 weeks of treatment (SVR12; a therapeutic indication for cure of HCV). During the study, side effects were observed in 43.6 percent of patients and common symptoms included anemia and headache. While cases of dose modification or interruption of any drug were recorded, no patients prematurely discontinued treatment with Copegus and/or Sovaldi in the study. With these data, Chugai submitted an application to the MHLW for the approval for the additional indication in September 2014.

CHC is a liver disease caused by persistent infection by HCV. Approximately 70 percent of HCV carriers develop chronic hepatitis, which gradually progresses to cirrhosis and then liver cancer. It is reported that about 1.5 to 2 million people are infected with HCV, and 20 to 30 percent of those are estimated to be categorized in serogroup 2 (genotype 2) in Japan. As many of them are latent patients, promoting HCV testing and urging the right treatment at the right time are crucial. Currently, the standard treatment for the patients with serogroup 2 (genotype 2) HCV is an interferon monotherapy such as Chugai's peginterferon alfa-2a agent, Pegasys® and the combination therapy of interferon and ribavirin such as Copegus.

Chugai strongly believes that the combination therapy of Copegus and Sovaldi will deliver great contribution to patients as a treatment for "improvement of viraemia associated with CHC and cirrhosis." Under its business philosophy "Innovation all for the patients," Chugai will

continue its effort to contribute to the advancement of hepatitis therapies through novel treatment options.

Note

Copegus® and PEGASYS® are registered trademarks of F. Hoffmann-La Roche, Ltd. In Japan, Chugai marketed these two products.