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Chugai Pharmaceutical Co. Ltd. has obtained approval from 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.

Chugai claims that 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 per cent 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 per cent 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.

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.