Innovation all for the patients

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Approval of Antiviral Drug, COPEGUS® for Additional Indication for Improvement of Viraemia in Patients with neither Serogroup 1 nor 2 Chronic Hepatitis C or Compensated Cirrhosis Related to Hepatitis C

TOKYO, March 24, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained approval by the Japanese Ministry of Health, Labour and Welfare for the additional indication of Copegus® (ribavirin) for "Improvement of viraemia in patients with neither serogroup 1 (genotype 1) nor serogroup 2 (genotype 2) chronic hepatitis C or compensated cirrhosis related to hepatitis C," when administered in the combination with Sovaldi® (sofosbuvir), developed by Gilead Sciences K.K. With the approval, the combination therapy of Copegus and sofosbuvir is available for all patients except serogroup 1 (genotype 1) with chronic hepatitis C or compensated cirrhosis related to hepatitis C.

The "28th Review Committee on Unapproved Drugs and Indications with High Medical Needs"* held on August 3, 2016, requested the company to develop Copegus regarding this indication. Given that decision, Chugai filed for Copegus through a partial amendment application on November 18, 2016, and obtained this supplemental approval. This approval was granted based on the results of six overseas clinical studies conducted by Gilead to investigate the safety and efficacy of the 24 weeks combination therapy of sofosbuvir and ribavirin in patients with genotype 3 and genotype 4 chronic hepatitis C or compensated cirrhosis related to hepatitis C.

Chronic hepatitis C is a liver disease caused by persistent infection by Hepatitis C Virus (HCV). Approximately 70 percent of HCV carriers develop chronic hepatitis, which gradually progresses to cirrhosis and then liver cancer. HCV is classified into genotype 1 to 6 based on genetic types. Especially, genotype 3 is recognized among patients with chronic diseases such as HCV/ Human Immunodeficiency Virus (HIV) superinfection and coagulation defect. In case of HCV/HIV superinfection, early treatment intervention is required because a liver disease proceed at a rapid rate compared with the HIV non-infected case.

Chugai strongly believes that the combination therapy of Copegus and sofosbuvir will deliver the contribution to patients as a treatment for "all patients except serogroup 1 (genotype 1) with chronic hepatitis C or compensated cirrhosis related to hepatitis C." 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.

* The "Review Committee on Unapproved Drugs and Indications with High Medical Needs" was established for the purpose of enhancing development by the pharmaceutical companies of drugs and indications that have been approved for use in western countries but not yet approved in Japan, through activities such as evaluating medical needs and confirming the applicability of "public knowledge-based application" and investigating the need for studies that should be

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additionally conducted. The additional indication was requested by The Japanese Society for AIDS Research, Japanese Society of Hematology, The Japan Society of Hepatology, The Japanese Society on Thrombosis and Hemostasis, Tokyo and Osaka HIV Litigation Plaintiffs, and Social Welfare Corporation Habataki Welfare Project.

Copegus® is a registered trademark of F. Hoffmann-La Roche, Ltd. (Switzerland)

[Drug Information] Indication with underlined is newly added.
Brand name: Copegus® 200mg

Generic name: ribavirin

Indications:
1. Improvement of viraemia in either of the following groups of chronic hepatitis C patients when administered in combination with peginterferon alfa-2a (genetical recombination)
   (1) Serogroup 1 (genotype I [1a] or II [1b]) patients with high HCV-RNA levels
   (2) Patients who have not responded to interferon monotherapy or who have relapsed after interferon monotherapy
2. Improvement of viraemia associated with compensated cirrhosis related to hepatitis C, when administered in combination with peginterferon alfa-2a (genetical recombination)
3. Improvement of viraemia in either of the following groups of patients with chronic hepatitis C or compensated cirrhosis related to hepatitis C when administered in combination with sofosbuvir
   (1) Serogroup 2 (genotype 2) patients
   (2) Patients with neither serogroup 1 (genotype 1) nor serogroup 2 (genotype 2)

Dosage and Administration:
Copegus should be coadministered with peginterferon alfa-2a (genetical recombination) or sofosbuvir.
The usual oral dosage for adults is shown below. When Copegus is administered, the patient's condition should be monitored, and measures such as dose reduction or discontinuation should be taken when appropriate.

Body weight	Dosage	After breakfast	After evening meal
≤60 kg	600 mg/d	200 mg	400 mg
>60 kg to 80 kg	800 mg/d	400 mg	400 mg
>80 kg	1000 mg/d	400 mg	600 mg

Drug price: JPY 789.20/Tablet