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## Translation

### Chronic Hepatitis C Treatment, Pegasys<sup>®</sup>, and Antiviral Drug, Copegus<sup>®</sup>, Obtained Approval for Additional Indication of Compensated Liver Cirrhosis Related to Hepatitis C

July 1, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. ("Chugai") [Head Office: Chuo-ku, Tokyo. President: Osamu Nagayama] announced today that it obtained approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the additional indication of "improvement of viraemia associated with compensated cirrhosis related to hepatitis C" for the combination therapy of Pegasys<sup>®</sup> and Copegus<sup>®</sup>.

Pegasys<sup>®</sup> (generic name: peginterferon alfa-2a) (genetic recombination) and Copegus<sup>®</sup> (generic name: ribavirin) are currently marketed for the indication of "improvement of viraemia associated with chronic hepatitis C (CHC)."

The additional application was made based on the domestic phase II/III clinical study, which was conducted in patients with compensated cirrhosis related to CHC. In the partial-blind comparative study which randomized patients to two parallel groups, the efficacy and safety of the combination therapy of Pegasys<sup>®</sup> and Copegus<sup>®</sup> was confirmed in comparison to the treatment-free group. Chugai submitted an application to the MHLW for the approval of the additional indication in October 2010.

In patients with compensated liver cirrhosis related to CHC, chronic inflammation of the liver progresses finally leading to a serious outcome of hepatic failure or hepatocellular carcinoma. In Japan, the current medical treatment for improvement of viraemia in CHC patients with compensated cirrhosis is limited to a single-agent therapy with interferon which is administered three times a week. No anti-viral therapy has been approved for treatment of genotype I CHC with a high viral load (500 KIU/mL or more), and new therapeutic options had been awaited. The efficacy of once weekly combination therapy of peginterferon and ribavirin was confirmed irrespective of genotype and viral load, and this approval makes the combination therapy clinically available to patients, with expectation to reduce patients' physical and mental burden.

Chugai strongly believes that combination therapy of Pegasys<sup>®</sup> and Copegus<sup>®</sup> will make a contribution to patients as a treatment for "improvement of viraemia associated with compensated cirrhosis related to CHC," an indication with high unmet medical needs. Through development of new treatment options, Chugai will continue its effort to contribute to the advancement of hepatitis therapies.