

Translation

Chronic Hepatitis C Treatment, Pegasys[®], and Antiviral Drug, Copegus[®], Filed for Additional Indication of Compensated Liver Cirrhosis Related to Hepatitis C

October 26, 2010 (Tokyo) - Chugai Pharmaceutical Co., Ltd. ("Chugai") [Head Office: Chuo-ku, Tokyo. President: Osamu Nagayama] announced today that it has submitted an application to the Ministry of Health, Labour and Welfare for the approval of an additional indication, "improvement of viraemia associated with compensated cirrhosis related to hepatitis C" for the combination therapy of Pegasys[®] and Copegus[®]. Pegasys[®], trade names: "Pegasys[®] S.C. 90 µg" and "Pegasys[®] S.C. 180 µg" (generic name: peginterferon alfa-2a) (hereafter "Pegasys[®]") and Copegus[®], trade name: "Copegus[®] 200 mg tablets" (generic name: ribavirin) (hereafter "Copegus[®]") are currently marketed for the indication of "improvement of viraemia associated with chronic hepatitis C (CHC)."

The application was made based on the domestic phase II/III clinical study, which was conducted as a partial-blind comparative study, which randomized patients with compensated cirrhosis related to hepatitis C to two parallel groups, combination therapy of Pegasys[®] and Copegus[®] vs. treatment-free group,, in order to compare the efficacy and safety of the combination therapy of Pegasys[®] and Copegus[®] against the treatment-free group.

In patients with chronic HCV infection, 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 single-agent therapy with interferon. Therefore, a once weekly combination therapy of peginterferon and ribavirin is desirable as a new option, as it was in the case of improvement of viraemia associated with chronic hepatitis C.

Chugai will make best efforts for the early approval of the combination therapy of Pegasys[®] and Copegus[®] for "improvement of viraemia in CHC patients with compensated cirrhosis," an area with a high unmet medical need, so that the therapy becomes available for the patients as early as possible.