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CHUGAI
Roche Group

Translation

Chronic Hepatitis C Treatment, Pegasys®, Designated for Priority Review by Ministry of Health, Labour and Welfare for the Indication of Chronic Hepatitis B

April 20, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. (hereafter "Chugai") [Head Office: Chuo-ku, Tokyo. President: Osamu Nagayama] announced today that on April 11, the Japanese Ministry of Health, Labour and Welfare designated Pegasys®, trade names: "Pegasys® S.C. 90 μg" and "Pegasys® S.C. 180 μg" (generic name: peginterferon alfa-2a) (genetic recombination) (hereafter "Pegasys®"), a treatment for chronic hepatitis C (CHC), as a priority review subject regarding the application filed on January 27, 2011 seeking additional approval for the indication of "improvement of viraemia associated with chronic hepatitis B."

The application is based on the result of the domestic phase II/III clinical study, which was conducted in patients with chronic hepatitis B, a study comparing Pegasys® monotherapy to conventional natural-type interferon monotherapy.

Chronic hepatitis B is a disease caused by hepatitis B virus (HBV) which infects the liver via blood or body fluid, and causes chronic inflammation of the liver which progresses to liver cirrhosis or hepatocellular carcinoma. Currently available therapeutic agents for chronic hepatitis B in Japan include once-daily nucleic acid analogue administered potentially for long period of time and triweekly conventional interferon. Therefore, a new treatment of once weekly peginterferon for a finite treatment duration has been awaited as a desirable option.

Pegasys® is expected to improve efficacy and convenience for patients compared to conventional interferon treatments, by allowing once-weekly administration for 48-week treatment duration. Furthermore, the aim of Pegasys® therapy is to induce sustained off-treatment response in Chronic hepatitis B patients with a finite treatment duration (48 weeks of therapy).
This application seeks to obtain approval for the treatment of HBe antigen-positive chronic hepatitis B, as well as HBe antigen-negative chronic hepatitis B for which any conventional interferon preparations are not indicated.

Pegasys® obtained approval of "improvement of viraemia associated with CHC" in 2003, and the combination therapy adding antiviral agent “Copegus®” to Pegasys® for some part of the same indication obtained approval in 2007, both by priority review. Also, the indication of "improvement of viraemia associated with compensated cirrhosis related to CHC" was filed on October 25 2010, and has been designated for priority review.

Chugai will make efforts for an early approval of Pegasys® for "the improvement of viraemia associated with chronic hepatitis B," a disease with unmet medical needs, so that the treatment with Pegasys® becomes available for the patients as early as possible.