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CHUGAI
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Translation

Chronic Hepatitis C Treatment, Pegasys®, Filed for Additional Indication of Chronic Hepatitis B

January 27, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama (hereafter "Chugai")] announced today that it has submitted an application to the Ministry of Health, Labour and Welfare for the approval of an additional indication of "Pegasys® S.C. 90 μg" and "Pegasys® S.C. 180 μg" (generic name: peginterferon alfa-2a,) (hereafter "Pegasys®") for "the improvement of viraemia associated with chronic hepatitis B." Pegasys® is currently marketed for the indication of "improvement of viraemia associated with chronic hepatitis C."

The application is based on the domestic phase II/III clinical study, 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 hepatic function disorder, and subsequently progress to hepatic cirrhosis or hepatocellular carcinoma. The major therapeutic agents for chronic hepatitis B currently available in Japan include once-daily nucleotide analogue and triweekly interferon, and a new treatment option, a peginterferon, of once-weekly administration for a certain treatment duration has been awaited. Pegasys® is expected to reduce patients' physical and mental burden associated with the treatment comparing with conventional interferon, by allowing once-weekly administration for 48-week treatment duration.
In this application, Pegasys® is intended 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.

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