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Translation

Peginterferon alfa-2a "Pegasys®" Approved for Additional Indication of "Chronic Active Hepatitis B"

September 26, 2011 - Chugai Pharmaceutical Co., Ltd. (hereafter "Chugai") [Head Office: Chuo-ku, Tokyo. President: Osamu Nagayama] announced today that on September 26, 2011, it obtained approval by the Ministry of Health, Labour and Welfare for the additional indication of "improvement of viraemia associated with chronic active hepatitis B" for peginterferon alfa-2a "Pegasys®." "Pegasys®" is currently marketed for the indication of "improvement of viraemia associated with chronic hepatitis C (CHC) and compensated cirrhosis related to CHC."

The application was made based on the result of the domestic phase II/III clinical study, a study comparing Pegasys® monotherapy to conventional natural-type interferon monotherapy, and was filed on January 27, 2011, and designated as a priority review subject on April 11.

Chronic active 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 active hepatitis B in Japan include once-daily nucleic acid analogue administered potentially for long period of time and conventional interferon which is administered three times a week. Therefore, a new treatment of once weekly peginterferon for a finite treatment duration had been awaited as a desirable option.
The efficacy for both HBe antigen-positive and -negative chronic active hepatitis B was confirmed, and this approval makes a new treatment of peginterferon available for all types of chronic active hepatitis B including HBe antigen-negative chronic hepatitis B for which no conventional interferon preparation is indicated. In addition, once-weekly administration for 48-week treatment duration is expected not only to improve efficacy but also to reduce patients' burden comparing with conventional interferon treatments.

"Pegasys®" obtained approval for the indication 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. The indication of "improvement of viraemia associated with compensated cirrhosis related to CHC" for the combination with "Copegus®" was added on July 1, 2011. Both indications were reviewed under priority designation.

Chugai strongly believes that "Pegasys®" can greatly contribute to patients as a treatment for "improvement of viraemia associated with chronic active hepatitis B," an indication with high unmet medical needs, and will continue its effort to contribute to the hepatitis therapies through provision of new treatment options.