

Translation

License Agreement with Romark Laboratories and Development of Nitazoxanide in Japan

February 18, 2009 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama] (hereafter, “Chugai”) announced that Chugai has concluded a license agreement with Romark Laboratories [Head Office: Tampa, Florida, USA; Chairman: Jean-F. Rossignol] (hereafter, “Romark”) obtaining exclusive rights in Japan to develop, manufacture and distribute nitazoxanide, a therapeutic agent that Romark has been developing overseas for chronic hepatitis C, and that Chugai has decided to develop nitazoxanide in Japan.

Nitazoxanide is an oral thiazolide compound with a wide spectrum of activity for protozoa, bacteria and viruses and was approved by the FDA (US Food and Drug Administration) in 2002 for the indication of diarrhea caused by parasitic diseases [trade name: Alinia[®]]¹⁾.

An overseas phase II study conducted for hepatitis C genotype 4 patients, has reported that when nitazoxanide added to pegylated interferon α -2a, one of the current standard treatments, and ribavirin, the SVR (sustained virus response) rate at 24 weeks after the end of administration was about 30% higher than that of the standard treatment²⁾. Phase II studies are ongoing in the United States for genotype 1 patients.

In addition, nitazoxanide was selected as one of the new research agents of future potential in the 7-year strategy of hepatitis study compiled by the Ministry of Health, Labour and Welfare (MHLW) in the fiscal 2008.

Chugai released Japan's first pegylated interferon agent “Pegasys[®]”³⁾ as a therapeutic agent for chronic hepatitis C in December 2003 and an antiviral agent “Copegus[®]”³⁾ to be used in combination with “Pegasys[®]” in March 2007.

By introducing nitazoxanide in Japan, Chugai can not only present a new treatment option for patients with chronic hepatitis C in Japan but also strengthen its franchise for hepatitis region.

About Romark Laboratories

Romark Laboratories (www.romark.com), a privately held biopharmaceutical company, has discovered and developed a new class of small molecule anti-infectives known as thiazolides. The company is developing nitazoxanide, the first of the thiazolide class, for the treatment of chronic hepatitis C, and is developing other new thiazolides for treating viral diseases including chronic hepatitis B, herpes and influenza.

[Reference]

1) "Alinia[®]" is registered in the United States by Romark as a trademark.

2) Rossignol *et al*, EASL 2008, oral, Gastroenterology, in press

3) About "Pegasys[®]"

- Indicated in Japan for "1. Improvement of viremia in patients with chronic hepatitis C and 2. Improvement of viremia in either of the following patients with chronic hepatitis C in combination with ribavirin
 - (1) Patients of Serogroup 1 (genotypes I (1a) or II (1b)) with a high level of HCV-RNA)
 - (2) Patients who had no effect of interferon monotherapy or who had a repetition after the end of interferon monotherapy."

About "Copegus[®]"

- Indicated in Japan for improvement of viremia in either of the following patients with chronic hepatitis C in combination with pegylated interferon α -2a (genetical recombination)
 - (1) Patients with Serogroup 1 (genotype I (1a) or II (1b)) with a high level of HCV-RNA)
 - (2) Patients who had no effect of interferon monotherapy or who had a repetition after the end of interferon monotherapy."

"Pegasys[®]" and "Copegus[®]" are registered by F. Hoffmann-La Roche Ltd. (Switzerland) as trademarks.