

October 16, 2009

Toray Industries, Inc.
Daiichi Sankyo Company, Limited
Toray Medical Co., Ltd

**Additional indication for the natural-type interferon beta preparation Feron[®] against
“chronic hepatitis C on concomitant use with ribavirin”**

Toray Industries, Inc. (Headquarters: Chuo-ku, Tokyo, President: Sadayuki Sakakibara, hereinafter abbreviated as “Toray”) has obtained approval in Japan to add a new indication to its natural-type interferon beta preparation Feron[®], jointly developed and marketed with Daiichi Sankyo Company, Limited (Headquarters: Chuo-ku, Tokyo; President: Takashi Shoda, hereinafter abbreviated as “Daiichi Sankyo”), for the “improvement of viraemia in chronic hepatitis C on concomitant administration with ribavirin.” Feron[®] is the first interferon beta preparation indicated for concomitant administration with ribavirin. The approval of Feron[®] for use with the newly added indication is effective as of today.

There is estimated to be approximately 1.5 to 2 million patients with hepatitis C virus infection in Japan. In addition, approximately 80% of patients with hepatocellular carcinoma have been shown to be infected with hepatitis C virus. Interferon preparations are commonly used for radical treatment of chronic hepatitis C. For using the preparations, the Ministry of Health, Labour and Welfare of Japan has issued the “2009 Guideline for Standardization of Therapies against Viral Liver Diseases including Liver Cirrhosis,” recommending a combination therapy of pegylated interferon alpha preparations and ribavirin in intractable cases.

Approval for combination therapy with an interferon beta preparation Feron[®] and ribavirin against chronic hepatitis C may add a new treatment option for patients.

Feron[®], a natural-type interferon beta preparation, was the first interferon preparation marketed in Japan since 1985 for treatment of glioblastoma (brain tumor) and malignant melanoma of the skin (skin cancer). Over subsequent years chronic active hepatitis B, chronic hepatitis C, and compensated cirrhosis type C among other indications were added for the product. Toray and Daiichi Sankyo continue to make important contributions in the treatment of chronic viral liver diseases.

Feron[®] is distributed by Daiichi Sankyo and Toray Medical Co., Ltd. (Headquarters: Urayasu, Chiba).

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Outline of the Natural-type Interferon Beta Preparation Feron[®]

1. Trade name: Feron[®] (1 million for injection, 3 million for injection, 6 million for injection)
2. Nonproprietary name: interferon beta
3. Indications: Glioblastoma, medulloblastoma, astrocytoma, malignant melanoma, improvement of viraemia in chronic active hepatitis B patients positive for HBe antigen and DNA polymerase, improvement of viraemia in chronic hepatitis C, improvement of viraemia by concomitant administration with ribavirin in chronic hepatitis C patients matching any of the following descriptions: (1) patients with high blood HCV-RNA levels, or (2) patients for whom a monotherapy with an interferon preparation has failed to show efficacy, or patients who present with recurrence of hepatitis C after improvement obtained by a monotherapy with an interferon preparation, improvement of viraemia in compensated cirrhosis type C (excluding patients with HCV serogroup 1 and high blood HCV-RNA levels). (The underline indicates the newly added indication.)
4. Dosage and administration: (taken from the dosage and administration of the latest approval)
Intravenous injection or intravenous drip infusion
Feron[®] should be administered after confirming that the patient is positive for HCV-RNA. Feron[®] should be dissolved in isotonic sodium chloride solution or 5% glucose solution for injection. Generally, a dose of 6 million IU per day is given to adults by intravenous injection or intravenous drip infusion every day for up to 4 weeks and three times a week subsequently.
5. Manufacturer and distributor: Toray Industries, Inc.
6. Distributor: Daiichi Sankyo Company, Limited, Toray Medical Co., Ltd.

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