Launch of “Allergen Scratch Extract Positive control (Torii) Histamine Dihydrochloride” in Japan

Japan Tobacco Inc. (JT) (TSE:2914) and Torii Pharmaceutical Co., Ltd. (Torii) (TSE:4551) announced that Torii would launch “Allergen Scratch Extract Positive control (Torii) Histamine Dihydrochloride” in Japan on January 18, 2016, following the National Health Insurance price listing as of today. JT received manufacturing and marketing approval of this medical product from the Japanese Ministry of Health, Labour and Welfare on September 28, 2015.

The product is used as a positive control in skin tests to identify allergens that cause allergic reactions.

Histamine dihydrochloride solution used to be prepared from reagent by healthcare practitioners in Japan, as no positive control for allergy skin tests existed as a medical product. Solving the complicated preparation method and the instability of the solution have been concerns in daily medical practice. In this circumstance, a histamine dihydrochloride was publicly offered for a development company by the Evaluation Committee on Unapproved or Off-labeled Drugs with High Medical Needs*1. JT and Torii acquired exclusive rights to develop and commercialize the histamine dihydrochloride preparation in Japan from ALK-Abelló A/S in 2013, and jointly developed this medical product with a grant funding from the Pharmaceutical Development Support Center.

JT and Torii expect to contribute to treating allergies, through marketing “Allergen Scratch Extract Positive control (Torii) Histamine Dihydrochloride” in Japan.

*1 A committee set up by the Ministry of Health, Labour and Welfare, to facilitate development of unapproved and off-label drugs which have been available outside Japan.

**Product outline**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Allergen Scratch Extract Positive control (Torii) Histamine Dihydrochloride</th>
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</thead>
<tbody>
<tr>
<td>Generic Name</td>
<td>Histamine Dihydrochloride</td>
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<tr>
<td>Indication</td>
<td>Diagnosis</td>
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<tr>
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<td>Positive control of skin tests for allergens</td>
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</tbody>
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Dosage and Administration: Diagnosis

Usually, the product is used as a positive control for allergen screening. The superficial layer of the skin is pierced in such a way as to avoid bleeding by scarification (prick method) or incision (scratch method), and one drop of the product is applied onto the site of skin.

Package: 2mL bottle (with a dropper cap)
NHI Drug Price: ¥7,966 per bottle
Approval Date: September 28, 2015
NHI Pricing Date: November 26, 2015
Launch Date: January 18, 2016
Manufacturing and Distributor: Japan Tobacco Inc.
Distributor: Torii Pharmaceutical Co., Ltd.

Japan Tobacco Inc. is a leading international tobacco company. Its products are sold in over 120 countries and its internationally recognized brands include Winston, Camel, Mevius and LD. With diversified operations, JT is also actively present in pharmaceuticals and processed foods. The company’s revenue was ¥2,154 trillion (US$17,867 million(*)) in the fiscal year ended December 31, 2014(**).
*Translated at the rate of ¥120.55 per $1, as of December 31, 2014

**Due to a change in the accounting period from March 31 to December 31, the fiscal year 2014 covered nine months for Japanese domestic businesses and 12 months for the consolidated subsidiaries which operate the Group’s international tobacco business. On a comparable full calendar year basis, revenue was ¥2.433 trillion (US$20,186 million(*)).

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