

New Drug Application Approval of “CEDARCURE[®] Japanese Cedar Pollen Sublingual Tablets”, an Allergen Immunotherapy Tablet for Japanese Cedar Pollinosis

Torii Pharmaceutical Co., Ltd. (TSE:4551) announced today that the Japanese Ministry of Health, Labour and Welfare has approved the New Drug Application of “CEDARCURE[®] Japanese Cedar Pollen Sublingual Tablets” (Development code: TO-206, “CEDARCURE” hereinafter), an Allergen Immunotherapy Tablet for Japanese Cedar Pollinosis.

Torii has been pursuing clinical development of CEDARCURE which is expected wider range of treatment age, higher dosage and improved convenience of use as compared to “CEDARTOLEN[®] SUBLINGUAL DROP - Japanese Cedar Pollen” (“CEDARTOLEN” hereinafter), an Allergen Immunotherapy Drop for Japanese Cedar Pollinosis, launched in October 2014.

CEDARCURE is the first regulatory approved sublingual tablet available for adult and pediatric patients in Japan. CEDARCURE has characteristics such as higher dosage and improved convenience of use with storage at room temperature compared to CEDARTOLEN.

Positive results were obtained from the Phase II/III clinical study of CEDARCURE in Japanese patients with Japanese cedar pollinosis (5-64 years), proving that sublingually administered CEDARCURE reduced symptoms of the Japanese cedar pollinosis, providing statistically significant improvement in “Total Combined Rhinitis Score (TCRS)” compared to placebo as shown in the study. Furthermore, no specific finding was observed in safety.

Torii expects that expanded therapeutic option can contribute to the treatment of Japanese cedar pollinosis with CEDARCURE in addition to CEDARTOLEN. Furthermore, Torii expects to contribute to improve the quality of life of the patients with allergy, through marketing “MITICURE[®] House Dust Mite Sublingual Tablets” an Allergen Immunotherapy Tablet for house dust mite-induced allergic rhinitis, injectable products and diagnostic products.

The timing of the launch of CEDARCURE will be announced after a decision is made following the National Health Insurance price listing.

<Outline of CEDARCURE >

Product name: CEDARCURE[®] Japanese Cedar Pollen Sublingual Tablets 2,000 JAU
CEDARCURE[®] Japanese Cedar Pollen Sublingual Tablets 5,000 JAU

Indication: Japanese Cedar Pollinosis (Hyposensitization therapy)

Dosage and administration:

The usual dose is one tablet of CEDARCURE[®] Japanese Cedar Pollen Sublingual Tablets 2,000 JAU once a day during the first week of treatment and one tablet of CEDARCURE[®] Japanese Cedar Pollen Sublingual Tablets 5,000 JAU once a day from the second week. Patients should keep the tablet under the tongue for 1 minute and then swallow it. Patients should avoid gargling, eating, and drinking for 5 minutes after swallowing the tablet.

Approval conditions:

Necessary measures should be taken for manufacturing and marketing so that this drug will be prescribed and used only by physicians with adequate knowledge and experience regarding sublingual immunotherapy, will be used only under the supervision of physicians and medical

institutions that can manage and explain the risks, etc. of this drug, and will be dispensed at pharmacies only after the pertinent physicians and medical institutions have been confirmed.

<Japanese cedar pollinosis>

Japanese cedar pollinosis collectively refers to an allergic disease caused by Japanese cedar pollen. Patients with Japanese cedar pollinosis have excessive immunological reaction to Japanese cedar pollen and develop sneezing, nasal discharge, nasal occlusion, itchiness of the eyes, and runny eyes among other symptoms.

According to a nationwide survey, about 25% of Japanese people have pollinosis and about 70% of them have Japanese cedar pollinosis ^(ref. 1). Japanese cedar pollinosis is widely observed from youth to middle age group but it has been pointed out that onset age is becoming younger in recent years ^(ref. 2) ^(ref. 3).

(ref. 1) A FY 2010 MHLW-subsidized research program for prophylaxis/treatment of immunological allergic diseases, "Research for Correct Treatment of Pollinosis"

(ref. 2) "Rheumatism and Allergy Countermeasure Committee Report", Welfare Science Council Disease Control Committee, Rheumatism and Allergy Countermeasure Committee August 2011

(ref. 3) "Allergic Rhinitis Epidemiology in Japan 2008 (compared to 1998)", BABA Kohtaro, NAKAE Kimihiro, Progress in Medicine 2008; 28 (8):2001-2012.

<Allergen immunotherapy>

Allergen immunotherapy is a therapeutic method of administering the causative allergen of an allergic disease at a low dose at first and then an increased dose in order to reduce hypersensitivity to the allergen. It is expected curing allergy symptoms and long-term remission.

<Total Combined Rhinitis Score>

The Total Combined Rhinitis Score (TCRS) is a total overall score of the Nasal Symptom Score (sum of the scores allocated as appropriate, depending on the severity of three symptoms: sneezing, nasal discharge and nasal obstruction) and the Medication Score (sum of the scores allocated as appropriate, depending on the number of antihistaminic doses used to alleviate the symptoms of Japanese cedar pollinosis), and is used to measure the degree of improvement of allergic symptoms such as rhinitis.