

February 16, 2018  
Torii Pharmaceutical Co., Ltd.

Torii receives approval for additional dosage and administration for pediatric indication for MITICURE® House Dust Mite Sublingual Tablets, an Allergen Immunotherapy Tablet for House Dust Mite Allergy

Torii Pharmaceutical Co., Ltd. (TSE:4551) announced today that the Japanese Ministry of Health, Labour and Welfare has approved an additional dosage and administration for pediatric indication for MITICURE® House Dust Mite Sublingual Tablets (Development code: TO-203, “MITICURE” hereinafter), an allergen immunotherapy tablet for house dust mite allergy, for the treatment of allergic rhinitis.

MITICURE has been on the Japanese market since December 2015 with the indication of house dust mite-induced allergic rhinitis (12 years or older). As it is recognized that house dust mite highly affects pediatric allergic diseases, treatment with allergen immunotherapy in earlier age has high medical needs.

Positive results were obtained from the Phase III clinical study in patients with house dust mite-induced allergic rhinitis (5 – 17 years). Furthermore, favorable safety data was obtained in the study. These results were consistent with the data from earlier clinical study involving patients aged 12 years or older. Based on the clinical results, Torii filed an additional dosage and administration for pediatric indication for MITICURE on March 24, 2017. Following the approval, MITICURE is available also for the patients under 12 years of age.

Torii expects that gaining approval for the additional dosage and administration for pediatric indication will serve as a new option for the treatment of pediatric allergic rhinitis, and significantly improve the quality of life of the patients.

The impact of the approval on the business performance is included in forecasts for the fiscal year ending December 2018, announced on February 6, 2018.

Torii holds the exclusive rights to develop and commercialize MITICURE in Japan, which were licensed from ALK-Abelló A/S in January 2011.

<Outline of MITICURE>

Product name: MITICURE® House Dust Mite Sublingual tablets 3,300 JAU

MITICURE® House Dust Mite Sublingual tablets 10,000 JAU

Indication: Hyposensitization therapy for allergic rhinitis induced by house dust mite antigens

Dosage and administration:

The usual dose is one tablet of MITICURE® House Dust Mite Sublingual Tablets 3,300 JAU once a day during the first week of treatment and one tablet of MITICURE® House Dust Mite Sublingual Tablets 10,000 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.

<House dust mite-induced allergic rhinitis>

House dust mite-induced allergic rhinitis is a disease accompanied by nasal symptoms such as sneezing, rhinorrhea, nasal congestion, and nasal itching due to an allergy to house dust mites.

<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.