

Torii files an additional pediatric indication for TO-203 (MITICURE<sup>®</sup> House Dust Mite Sublingual Tablets), an Allergen Immunotherapy Tablet for House Dust Mite Allergy

Torii Pharmaceutical Co., Ltd. (TSE:4551) announced today that it has filed an additional indication for TO-203 (MITICURE<sup>®</sup> House Dust Mite Sublingual Tablets), an allergen immunotherapy tablet for house dust mite allergy, for the treatment of pediatric allergic rhinitis patients to the Japanese Ministry of Health, Labour and Welfare.

MITICURE<sup>®</sup> House Dust Mite Sublingual Tablets 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. Considering the situation, Torii initiated a Phase III clinical study of TO-203 for the pediatric indication of house dust mite-induced allergic rhinitis in 2015.

This is a randomized, multicenter, placebo-controlled, double-blind, comparative study to evaluate the efficacy and safety of TO-203 in patients with house dust mite-induced allergic rhinitis (5 – 17 years). The study met its primary endpoint, providing statistically significant improvement in “Total Combined Rhinitis Score (TCRS)” compared to placebo as shown in the study for the current indication in patients aged 12 years or older, proving that sublingually administered TO-203 reduced symptoms of house dust mite-induced allergic rhinitis. Furthermore, favorable safety data was obtained in the study.

Torii expects that gaining approval for the additional 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.

Torii holds the exclusive rights to develop and commercialize TO-203 in Japan, which were licensed from ALK-Abelló A/S in January 2011.

<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, and alleviation of allergy symptoms and long-term remission are expected.

<Total Combined Rhinitis Score>

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