

STALLERGENES GREER ANNOUNCES APPROVAL IN JAPAN OF PEDIATRIC USE FOR ACTAIR®, SUBLINGUAL IMMUNOTHERAPY TABLET FOR THE TREATMENT OF HOUSE DUST MITE ALLERGY

London (UK), February 16, 2018 – Stallergenes Greer, a biopharmaceutical company specializing in treatments for respiratory allergies, today announced that its partner in Japan, Shionogi & Co. Ltd., received approval for the extension of the indication for ACTAIR®, an allergy immunotherapy sublingual tablet for the treatment of house dust mite (HDM) induced allergic rhinitis, to treat patients under the age of 12. ACTAIR is already approved for the treatment of HDM-induced allergic rhinitis in patients 12 years of age and older in Japan since March 2015.

“The approval of ACTAIR for pediatric use in Japan will provide a valuable treatment option for patients under the age of 12 suffering from allergic rhinitis caused by an allergy to house dust mites. We are very pleased that this product will be available to even more patients in Japan,” said Fereydoun Firouz, Chairman and CEO of Stallergenes Greer.

The New Drug Application submission was supported by data from Shionogi’s positive Phase III trial, which was announced in January 2017. The multi-center, randomized, double-blind, placebo-controlled study evaluated the efficacy of ACTAIR at a daily maintenance dose of 300IR administered for 12 months to children between 5 and 16 years old with HDM-associated allergic rhinitis. The active group demonstrated a statistically significant difference ($p=0.0005$) versus placebo on the Average Adjusted Symptom Score after one year of treatment, achieving the primary efficacy endpoint.

In addition to Japan, Stallergenes Greer’s HDM tablet is registered in Australia, New Zealand and South Korea under the brand name ACTAIR for the treatment of HDM-induced allergic rhinitis in patients 12 years of age and older.

Stallergenes Greer has exclusive partnership agreements with Shionogi for the clinical development, registration and commercialization of HDM and Japanese cedar pollen sublingual immunotherapy tablets in Japan.

ABOUT SHIONOGI’S PHASE 3 TRIAL IN CHILDREN 5 TO 11 YEARS OLD

The primary endpoint was the AAdSS over the last month of the one-year treatment period. The AAdSS is the average of the total score of four rhinitis symptoms (sneezing, rhinorrhea, nasal congestion and nasal pruritus) adjusted for rescue medication use. This was a multi-center, randomized, double-blind, placebo-controlled study to assess the efficacy of HDM sublingual immunotherapy tablets for the treatment of allergic rhinitis. Patients aged 5 to 16 years old with medical history consistent with HDM-induced allergic rhinitis were eligible. A total of 438 patients were randomized to receive 12 months of treatment with HDM sublingual immunotherapy tablets or placebo. The active group showed statistically significant difference ($p=0.0005$) compared to placebo. Local adverse reactions were observed, with most of them mild in nature with no marked safety concerns.

ABOUT RESPIRATORY ALLERGIES IN JAPAN IN PEDIATRIC PATIENTS

Allergic rhinitis affects 25% of Japan’s population. House dust mites and Japanese cedar pollen are the two main causes of respiratory allergies in the country. From early childhood, house dust mites can trigger

allergic rhinitis, which worsens over time with a potential progression towards asthma. The symptoms may be severe, significantly impairing patients' quality of life. With 32 million respiratory allergy sufferers, there is a strong, and as yet unmet, demand for allergy treatment in Japan.

ABOUT STALLERGENES GREER PLC

Headquartered in London (UK), Stallergenes Greer plc is a global healthcare company specializing in the diagnosis and treatment of allergies through the development and commercialization of allergy immunotherapy products and services. Stallergenes Greer plc is the parent company of GREER Laboratories, Inc. (whose registered office is in the US) and Stallergenes SAS (whose registered office is in France).

TRADING INFORMATION

Name: Stallergenes Greer
 ISIN: GB00BZ21RF93 1 - Ticker: STAGR
 ICB Classification: 4577
 LEI: 213800CYVZA7GJQEME86
 Market: Euronext Paris regulated market

Additional information is available at <http://www.stallergenesgreer.com>.

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