

STALLERGENES GREER ANNOUNCES SUBMISSION OF NEW DRUG APPLICATION FOR PEDIATRIC USE OF ACTAIR[®] IN JAPAN

DATE: 28 March 2017

London (UK) - Stallergenes Greer (the “Company”) (Euronext Paris: STAGR), a biopharmaceutical company specializing in treatments for respiratory allergies, today announced that its commercialization partner in Japan, Shionogi & Co. Ltd. (Shionogi), submitted its New Drug Application (NDA) for ACTAIR[®], an investigational allergy immunotherapy sublingual tablet for the treatment of house dust mite (HDM) induced allergic rhinitis in children 5 to 11 years old. ACTAIR is already approved for the treatment of HDM-induced allergic rhinitis in patients 12 years of age and older in Japan.

The NDA submission is 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. Having achieved the study’s primary efficacy endpoint, the active group demonstrated a statistically significant difference ($p=0.0005$) on the Average Adjusted Symptom Score (AAdSS) after one year of treatment versus placebo.

“Now on the cusp of providing access to this therapy for children living with HDM-induced allergies in Japan, we are pleased with the progress our partner, Shionogi, has made to bring this NDA filing to fruition,” said Fereydoun Firouz, Chairman and CEO of Stallergenes Greer. “If approved, ACTAIR will be a valuable new treatment option for this pediatric patient population and their families.”

In September 2010, Stallergenes SA signed exclusive partnership agreements with Shionogi for the clinical development, registration and commercialization of sublingual HDM and Japanese cedar pollen immunotherapy tablets. As part of this, the Company is eligible for development, regulatory and sales milestones, as well as royalty payments on net sales.

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 this country. From early childhood, house dust mites can trigger allergic rhinitis, which worsens over time with a natural 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 where sublingual allergy immunotherapy tablets have not been available.

Trading Information

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

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

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