PRESS RELEASE

STALLERGENES GREER

First real-world evidence shows long term benefits of sublingual immunotherapy to control allergic rhinitis and potentially prevent allergic asthma

- Allergic rhinitis is a common, chronic, and often debilitating condition that impacts approximately 500 million people globally[1], putting these patients at greater risk for developing allergic asthma.[2,3,4,5]
- A retrospective analysis conducted with over 74,000 patients in Germany and recently published in the peer-reviewed journal *Allergy*[6] showed that grass pollen SLIT (sublingual immunotherapy) treatment can help control allergic rhinitis and may reduce the risk of the onset and progression of allergic asthma.
- The data also showed that patients whose treatment included Stallergenes Greer's tablet ORALAIR®, for allergic rhinitis induced by grass pollen, experienced better relief up to six years after treatment cessation compared to patients treated with symptomatic treatments.

London (United Kingdom) – 19 June 2017 - Stallergenes Greer, a biopharmaceutical company specialising in treatments for respiratory allergies, announced positive results from a real-world evidence (RWE) study on the long-term effectiveness of grass pollen sublingual immunotherapy (SLIT) treatment vs. symptomatic drugs. This is the first study that is based on eight years' worth of data to demonstrate the long-term effectiveness of SLIT tablets including Stallergenes Greer's tablet ORALAIR®. Study results showed that grass pollen SLIT tablets significantly improved control of allergic rhinitis and may have a preventive effect on allergic asthma onset and worsening compared to symptomatic treatments. Notably, SLIT treatment was associated with a ~30 percent relative reduction in the risk of developing asthma throughout the treatment period, and a ~40 percent relative risk reduction in the follow-up period.

The data were published in the peer-reviewed journal *Allergy* in May 2017 and presented this week at the annual European Academy of Allergy and Clinical Immunology (EAACI) Congress, held in Helsinki, Finland. The study, a retrospective analysis of a database of 74,126 patients in Germany, is the first of its kind in the SLIT grass therapeutic area, and adds to the body of evidence about the benefits of Allergy Immunotherapy (AIT) in controlling allergic rhinitis and potentially preventing allergic asthma. AIT is a disease-modifying allergy treatment that acts on the immune system by increasing tolerance to allergens, and can be administered by physicians through injection (subcutaneous) or taken at home through liquid formulation or tablets (sublingual).

"The study data further confirm the long-term benefits of allergy immunotherapy over symptomatic treatments such as antihistamines and corticosteroids that provide temporary relief for patients suffering from allergies," said Professor Ulrich Wahn, Department for Pediatric Pneumology and Immunology, Charité Medical University, Berlin, who presented the data during the EAACI Congress. "The health impact of allergic rhinitis is often underestimated and can lead to allergic asthma. Taking the right course of treatment upfront can potentially prevent the onset and the development of the disease."

"The study data provide further evidence that the tablet formulation is an effective allergy immunotherapy treatment option for the patients who may prefer oral administration over injections," said Fereydoun Firouz, Chairman and CEO of Stallergenes Greer. "As a global leader, we are engaged in a comprehensive program to gather real world data from diverse countries to deepen our knowledge and understand how real life practices may impact patient outcomes."

"With over 74,000 patients in the data set, the design of this retrospective analysis is powered enough to drive meaningful conclusions about the use of allergy immunotherapy treatment over symptomatic treatments," said Professor Stefan Zielen, Department for Children and Adolescents, Division of Allergology, Pulmonology and Cystic Fibrosis, Goethe University Hospital, Frankfurt, who co-presented the data with Professor Wahn during the EAACI Congress. "Germany is ahead of many other countries in the use of allergy immunotherapy and patient access. We look forward to additional data from other countries to further review the findings."

STUDY RESULTS

After SLIT cessation, allergic rhinitis medication use in the SLIT group vs. the control group was 18.8 percentage points lower compared to before SLIT treatment ($p<0.001$). While the study was not designed to assess efficacy difference between the tablets (a five-grass pollen SLIT tablet and a timothy SLIT tablet), a subgroup sensitivity analysis showed that Stallergenes Greer's ORALAIR® SLIT tablets controlled allergic rhinitis by 20 percent up to six years after treatment cessation, compared to the symptomatic treatment group ($p<0.001$).

Overall, SLIT tablets were associated with a lower risk of developing asthma in non-asthmatic patients by about 30 percentage points during treatment ($p=0.013$), and by about 40 percent after treatment cessation ($p=0.013$). In the ORALAIR® subgroup (1,466 patients), the risk of developing asthma in non-asthmatic allergic rhinitis patients was reduced by about 32 percent during the treatment period ($p=0.033$), and by about 44 percent following the cessation of treatment ($p=0.051$). In patients who already had asthma at the onset of the study, SLIT tablets were also associated with lower use of asthma medication by about 21 percentage points during treatment ($p=0.005$) and by about 17 percentage points after treatment cessation ($p=0.004$). For the ORALAIR® subgroup, the treatment was associated with lower use of asthma medication by 24.6 percentage points during treatment ($p=0.013$) and by 15.2 percentage points after treatment cessation ($p=0.05$), compared to the control group.

STUDY DESIGN

The objective of the study was to evaluate the real-world effectiveness of grass-pollen SLIT tablets in controlling allergic rhinitis, and their impact on asthma onset and progression, following a minimum treatment period of two years. The study was based on a real-world, retrospective analysis of data from a prescription database in Germany, which is the first European country to have authorized the marketing of grass pollen SLIT tablet formulations and therefore provided the longest time for the analysis. The study analyzed a data set related to 74,126 adult and pediatric patients with allergic rhinitis induced by grass pollen. Two groups of patients were compared. One group received grass pollen allergy immunotherapy treatment, either in the form of a five-grass pollen SLIT tablet (1,466 patients) or a timothy grass SLIT tablet (1,385 patients), and the other group received symptomatic treatments only (71,275 patients). The overall analysis period ran from January 2008 to February 2016. Changes in the use of symptomatic allergic rhinitis medication, asthma medication and time to asthma onset were compared between the two groups using multiple regression and logistic regression. The study, commissioned by Stallergenes Greer, was conducted by Quintiles IMS, a 3rd party clinical research organization (CRO) and designed by an independent Scientific Committee. The committee included Hartmut Richter (Quintiles IMS); Stefan Zielen, MD; Philippe Devillier, MD, PhD; Joachim Heinrich, PhD, Karel Kostev, MD, and Ulrich Wahn, MD. The study was published online in the May 2017 edition of *Allergy*.

There were some limitations to the study. The database only included reimbursed prescriptions and lacked direct clinical information, such as the diagnostic methodology and the patient's sensitisation status. However, the sensitisation status would not impact the results of the study, as both the timothy grass tablet and the five-grass tablet showed a similar treatment effect regardless of the patient's sensitisation status. To eliminate the risk of including patients without allergic rhinitis in the study, the researchers looked at INS prescription (nasal corticosteroids that are only indicated for the treatment of allergic rhinitis) data. The SLIT tablet formulations used in the study differed in

composition and recommended regimen. The study was not designed to assess the efficacy difference between the SLIT tablets included in the study.

ABOUT ORALAIR®

ORALAIR® is a sublingual allergy immunotherapy tablet with a mix of five grass allergen extracts (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract).

ORALAIR® is a treatment for grass pollen allergic rhinitis with or without conjunctivitis in adults, adolescents, and children (above the age of five except in the United States, where it is approved for use in persons 10 through 65 years of age) with clinically relevant symptoms, confirmed by a positive cutaneous test and/or a positive titre of the specific IgE to the grass pollen. ORALAIR® is not indicated for the immediate relief of allergy symptoms. ORALAIR® is not indicated for allergic asthma treatment.

ORALAIR® was originally approved in Europe in 2008 and is currently authorized in over 30 countries around the world, including most European countries, the United States, Canada, Australia, and Russia for the treatment of grass pollen allergic rhinitis. In United States, ORALAIR® was launched in May 2014, making it the first allergy immunotherapy tablet to be registered and marketed in United States. Worldwide post-marketing experience with ORALAIR® includes more than 50 million doses given to more than 290,000 patients.

ORALAIR® has been approved based on results from an extensive clinical development program. ORALAIR® has been studied in double-blind, placebo-controlled trials, in both Europe and the United States in over 2,800 adults and children.

ABOUT STALLERGENES GREER PLC

Headquartered in London (UK), Stallergenes Greer plc is a global healthcare company specialising in the diagnosis and treatment of allergies through the development and commercialisation 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). Additional information is available at http://www.stallergenesgreer.com.

Trading information

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

DISCLAIMER

This document (including information incorporated by reference in this document), oral statements made and other information published by the Company contain statements that are or may be forward-looking with respect to the financial condition and/or results of operations and businesses of the Company. These statements can be identified by the use of forward-looking terminology such as "believe," "expects," "project," "estimated," "forecast," "should," "plan," "may" or the negative of any of these, or other variations thereof, or comparable terminology indicating expectations or beliefs concerning future events. These forward-looking statements include risk and uncertainty because they relate to events and depend on circumstances that will occur in the future. Without being exhaustive, such factors include economic situations and business conditions, including legal and product evaluation issues, fluctuations in currencies and demand, and changes in competitive factors. These and other factors are more fully described in the Company's 2016 annual report published on 28 April 2017 on the Company's website www.stallergenesgreer.com. Actual results may differ from those set forth in the forward-looking statements, due to

various factors. Save as required by applicable law, neither the Company nor any other person assumes any obligation to update these forward-looking statements or to notify any person of any such update.

REFERENCES

1. Ozdoganoglu T, Songu M. The burden of allergic rhinitis and asthma. Ther Adv Respir Dis. 2012;6(1):11-23.
2. Simons FE. Allergic rhinobronchitis: the asthma-allergic rhinitis link. J Allergy Clin Immunol. 1999;104(3 Pt 1):534-40.
3. Greiner AN, Hellings PW, Rotiroti G, Scadding GK. Allergic rhinitis. Lancet. 2011;378:2112-22.
4. Van Bever HP, Samuel ST, Lee BW. Halting the allergic march. World Allergy Organ J. 2008;1:57-62.
5. Shaker M. New insights into the allergic march. Curr Opin Pediatr. 2014;26:516-20.
6. Zielen, S., Devillier, P., Heinrich, J., Richter, H. and Wahn, U. Sublingual immunotherapy provides long-term relief in allergic rhinitis and reduces the risk of asthma: a retrospective, real-world database analysis. Allergy. May 2017. doi:10.1111/all.13213

CONTACTS

Communications and Investor Relations
Natacha Gassenbach
Tel: +1 (617) 225 8013
Email: natacha.gassenbach@stallergenesgreer.com

Media
Bloom
Serra Sariderelis
Tel: +1 (212) 715 1604
Sariderelis@bloompr.com

Havas Worldwide Paris
Samuel Rousseau
Tel: +33 (0) 6 51 03 51 43
Email: samuel.rousseau@havas.com