

STALLERGENES GREER ANNOUNCES THAT THE PHASE III TRIAL FOR ITS SUBLINGUAL ALLERGY IMMUNOTHERAPY TABLET STAGR320 TO TREAT HOUSE DUST MITE-INDUCED ALLERGIC RHINITIS ACHIEVED ITS PRIMARY ENDPOINT

- The study achieved its primary efficacy endpoint ($p < 0.0001$)
- The study also achieved all key secondary endpoints, and showed a comparable safety profile to that observed in other clinical studies with STAGR320
- The results support a path for regulatory submissions in Europe and the United States
- The randomized, double-blind, placebo controlled study, which recruited more than 1,600 patients from 231 participating investigative sites in 13 countries, was the largest phase III clinical trial conducted to evaluate the treatment of house dust mite allergy

London (UK), November 20, 2018 – Stallergenes Greer, a biopharmaceutical company specializing in treatments for respiratory allergies, today announced topline results for its phase III clinical trial to evaluate the efficacy and safety of its sublingual allergy immunotherapy tablet STAGR320 for the treatment of house dust mite (HDM)-induced allergic rhinitis. The study met its primary endpoint. Results indicated a statistically significant reduction of the Total Combined Score, the sum of the Rhinitis Total Symptom Score and the Rescue Medication Score, in patients treated with STAGR320 compared to patients on placebo. The study also reached key secondary endpoints, including overall quality of life, and showed that the treatment was generally well tolerated, confirming the favorable safety profile observed in previous studies.

This was the largest phase III study to evaluate the treatment of HDM-induced allergic rhinitis in adult and adolescent patients, recruiting more than 1,600 patients from 231 participating investigative sites in 13 countries.

“We are very pleased that the results from this confirmatory, double-blind and placebo controlled trial met its efficacy endpoints, demonstrated a favorable safety profile and validated previous clinical studies which showed that STAGR320 can bring relief to patients suffering from house dust mite-induced allergies,” said Fereydown Firouz, Chairman and CEO of Stallergenes Greer. “House dust mite allergy is one of the most common allergies, impacting the quality of life for patients across ages and geographies. The results of this study provide us with the confidence to seek further market registrations, including in Europe and the United States. We look forward to working with regulatory authorities around the world to make this therapy available to patients as part of our comprehensive portfolio of allergy immunotherapy products.”

Allergic rhinitis is a worldwide disease affecting more than 500 million people and the risk of developing asthma is about six times higher in patients with an allergy to house dust mites than those allergic to pollens¹⁻⁴. Allergic rhinitis can include symptoms such as sneezing, runny or itchy nose, nasal congestion and watery or itchy eyes, among others^{1,2}. Symptoms may be severe and can worsen over time with progression towards asthma, as well as have a significant impact patients' quality of life^{1-3,5-8}.

“Meeting the primary endpoint of this important study confirms the clinical value that STAGR320 is effective for the treatment of house dust mite allergies,” said Pascal Demoly, Professor at the Department of Pneumology and Addiction Heart Poumons Center at the University Hospital of Montpellier, France, President of the College of Allergology Teachers, President of the French Allergy Federation and a coordinating investigator. “In addition, these study results provide the physician community with compelling evidence that STAGR320 can address some of the most severe symptoms that patients experience, which ultimately has an impact on quality of life.”

“More than 500 million people globally are affected by allergic rhinitis, a condition that can be a factor of asthma onset and progress,” said Thomas Casale, MD, Professor of Medicine and Pediatrics at the University of South Florida and a coordinating investigator. “These study results demonstrate the clinical benefit that STAGR320 can offer to patients. By changing the immune response to the allergen and addressing the underlying cause of the allergy, patients have an alternative to treatment options that only affect the symptoms of the disease.”

The multi-center, randomized, double-blind and placebo-controlled study evaluated the efficacy and safety of STAGR320 at a daily dose of 300IR administered for approximately 12 months to adult and adolescent patients aged 12-65 with HDM-associated allergic rhinitis.

The study met its primary efficacy endpoint and demonstrated a statistically significant difference ($p < 0.0001$) on the Total Combined Score (TCS) after one year of treatment in the treated group versus placebo. The TCS combined the Rhinitis Total Symptom Score (RTSS) and the Rescue Medication Score (RMS). In addition, all key secondary endpoints achieved statistical significance and, overall, the product was well tolerated.

A full assessment of the data is ongoing, with detailed results expected to be presented at future scientific congresses, including the annual European Academy of Allergy and Clinical Immunology (EAACI) Congress.

ABOUT THE STAGR320 PHASE III CLINICAL TRIAL

The phase III trial was a global, multi-center, randomized, double-blind and placebo controlled study. It evaluated the efficacy and safety of STAGR320 at a daily dose of 300IR administered to adult and adolescent patients aged 12-65 with HDM-induced allergic rhinitis. Patients who experienced HDM-associated allergic rhinitis for at least one year, who were sensitized to *D. pteronyssinus* and/or *D. farinae* mites as determined by a skin prick test and HDM-specific serum immunoglobulin E, were eligible for participation.

This was the largest phase III clinical trial conducted to evaluate the treatment of house dust mite allergy in adult and adolescent patients. The study recruited more than 1,600 patients from 231 participating investigative sites in 13 countries. International coordinating investigators were Pascal Demoly, Professor at the Department of Pneumology and Addiction Heart Poumons Center at the University Hospital of Montpellier, France, President of the College of Allergology Teachers and President of the French Allergy Federation, and Thomas Casale, MD, Professor of Medicine and Pediatrics at the University of South Florida.

ABOUT STAGR320

STAGR320 is Stallergenes Greer's investigational sublingual allergy immunotherapy (AIT) tablet for the treatment of HDM-induced allergic rhinitis. AIT is a disease-modifying treatment that treats the underlying cause of allergy and can provide long-lasting reduction of allergy symptoms. STAGR320 is registered in Australia, Japan, New Zealand and South Korea. Results from the recent phase III trial, together with other clinical data, will form the clinical basis for the company's potential submission of a Biologics License Application (BLA) in the United States, as well as for additional marketing authorizations in European and international markets.

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

This announcement contains inside information for the purposes of Article 7 of the Market Abuse Regulation (EU) 596/2014.

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

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," "will" 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 2017 annual report published on 16 April 2018 on the Company's website www.stallergenesgreer.com. Actual results may differ materially from those set forth in the forward-looking statements, due to these and other 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. Bousquet J, Khaltaev N, Cruz A, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) 2008 update (in collaboration with the World Health Organization, GA(2)LEN and AllerGen). Allergy. 2008 Apr;63 Suppl 86:8-160.
2. Brożek JL, Bousquet J, Agache I, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) Guidelines – 2016 Revision, Journal of Allergy and Clinical Immunology (2017), doi: 10.1016/j.jaci.2017.03.050.
3. Linneberg A., Henrik Nielsen N., Frolund L, et al. The link between allergic rhinitis and allergic asthma: a prospective population-based study. The Copenhagen Allergy Study. Allergy. 2002 Nov;57(11):1048-1052.
4. Calderon M. A., Linneberg A., Kleine-Tebbe J., De Blay F., Hernandez Fernandez de Rojas D., Virchow J. C., Demoly P. Respiratory allergy caused by house dust mites: What do we really know? J Allergy Clin Immunol. 2015 Jul;136(1):38-48.
5. Shin J-W, Sue J-H, Song T-W, et al. Atopy and house dust mite sensitization as risk factors for asthma in children. Yonsei Med J.2005;46:629-634
6. Leger D., Annesi-Maesano I., Carat F., et al. Allergic rhinitis and its consequences on quality of sleep: An unexplored area. Arch Intern Med. 2006 Sep 18;166(16):1744-1748.
7. Meltzer E. O. Quality of life in adults and children with allergic rhinitis. J Allergy Clin Immunol. 2001 Jul;108(1 Suppl):S45-53
8. Hankin C. S., Cox L., Lang D., et al. Allergen immunotherapy and health care cost benefits for children with allergic rhinitis: a large-scale, retrospective, matched cohort study. Ann Allergy Asthma Immunol. 2010 2010 Jan;104(1):79-85.

CONTACTS

Communications and Investor Relations

Caitlin Stefanik
 Tel: +1 (857) 331 4117
 Email: caitlin.stefanik@stallergenesgreer.com

Media Relations Agency

Havas Paris (Europe)
 Samuel Rousseau
 +33 6 77 88 32 43
 E-mail : samuel.rousseau@havas.com

Investor Relations Agency

FTI Consulting
 Arnaud de Cheffontaines
 Tel: +33 1 47 03 68 10
 Email: stalleregenesgreer@fticonsulting.com