

# STALLERGENES GREER ANNOUNCES COMPLETION OF ENROLLMENT IN LARGEST PHASE III STUDY TO TREAT HOUSE DUST MITES ALLERGY

- STG320 is an investigational sublingual immunotherapy tablet designed to treat patients with allergic rhinitis induced by house dust mites.
- With more than 1,600 patients enrolled, this study is the largest conducted study to assess the efficacy and safety of a sublingual immunotherapy tablet treatment.
- Allergic rhinitis is a common, chronic, and often debilitating condition that impacts approximately 500 million people globally, putting these patients at greater risk for developing allergic asthma<sup>1-3</sup>

**London (United Kingdom) – 27 July 2017** - Stallergenes Greer, a biopharmaceutical company specialising in treatments for respiratory allergies, announced today that it completed enrollment in a pivotal Phase III clinical study to evaluate the safety and efficacy of its investigational sublingual immunotherapy tablet STG320 for the treatment of house dust mite (HDM) induced allergic rhinitis. The study recruited over 1,600 patients from 13 countries with 231 participating investigative sites, and is the largest study of its kind. Principal investigators are Pascal Demoly, MD, from University Hospital of Montpellier, France, and the President of the French Allergy Federation, and Thomas Casale, MD, Professor of Medicine and Pediatrics at the University of South Florida.

"This is the largest study undertaken to measure the efficacy of sublingual immunotherapy (SLIT) treatment against HDM-induced allergic rhinitis and this study has the potential to bring more options for patients," said Professor Casale. "In the United States, subcutaneous immunotherapy treatment for patients with allergic rhinitis is administered through injections at the doctor's office; the tablet formulation offers an effective alternative treatment option for patients that may prefer oral administration at home."

"Our aim is to bring innovation to patients suffering from HDM-induced allergic rhinitis, one of the most prevalent allergies in the world." Completion of patient enrollment in this pivotal study is a significant milestone for Stallergenes Greer towards achieving this goal," said Fereydoun Firouz, CEO of Stallergenes Greer. "We are committed to our purpose – to enable people with allergies to live normal lives – and continue to focus on developing evidence based solutions to prevent and treat all allergies."

This Phase III study, together with other clinical data, will form the company's submission for a Biologics License Application (BLA) in the United States planned for 2019 and for additional marketing authorizations in European and international markets. To date, the product is already approved for commercialisation in Japan, Australia and South Korea.

# **ABOUT THE STG320 STUDY**

The study is global, multi-center, randomized, double-blind and placebo controlled. It evaluates the safety and efficacy of STG320 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 are sensitized to D. pteronyssinus and/or D. farinae mites as defined on a skin prick test and HDM-specific serum immunoglobulin E, were eligible for participation.

# ABOUT HOUSE-DUST MITE INDUCED ALLERGIC RHINITIS

Allergic rhinitis is a worldwide disease affecting over 500 million people and the risk of developing asthma is about six times higher in patients with allergy to House Dust Mites (HDM) than those allergic to pollens<sup>1-4</sup>. Allergic rhinitis can

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include symptoms such as sneezing, runny nose, wheezing, cough, itching, and watery/itchy eyes, among others<sup>1,2</sup>. Symptoms may be severe and significantly impact the patient's quality of life, as well as worsen over time with progression towards asthma<sup>1-3,5-8</sup>.

Symptomatic treatments such as antihistamines and **nasal corticosteroids** provide only temporary relief to patients<sup>1,8</sup>. The primary therapeutic goals of allergy immunotherapy (AIT) include reducing symptoms, reducing symptomatic medication use, and improving allergy-related quality of life. The evidence is strong that AIT achieves these goals and can alter the course of the disease, with benefits persisting in many patients for several years after treatment discontinuation<sup>1,2,10-16</sup>.

#### 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

Market: Euronext Paris regulated market

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

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#### **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.
- 9. Nathan R. A. The burden of allergic rhinitis. Allergy and asthma proceedings: the official journal of regional and state allergy societies. 2007 Jan-Feb;28(1):3-9.
- 10. Abramson M., Puy R., Weiner J. Immunotherapy in asthma: an updated systematic review. Allergy. 1999 1999 Oct;54(10):1022-1041.
- 11. Durham S. R., Walker S. M., Varga E. M., et al. Long-term clinical efficacy of grass-pollen immunotherapy. The New England journal of medicine. 1999 Aug 12;341(7):468-475.
- 12. Abramson M. J., Puy R. M., Weiner J. M. Allergen immunotherapy for asthma. Cochrane database of systematic reviews. 2003(4):CD001186.
- 13. Calderon M. A., Alves B., Jacobson M., et al. Allergen injection immunotherapy for seasonal allergic rhinitis. Cochrane database of systematic reviews. 2007 2007(1):CD001936.
- 14. Nelson H. S. Allergen immunotherapy: where is it now? The Journal of allergy and clinical immunology. 2007 Apr;119(4):769-779.
- 15. Radulovic S., Calderon M. A., Wilson D., Durham S. Sublingual immunotherapy for allergic rhinitis. Cochrane database of systematic reviews. 2010(12):CD002893.
- 16. Lin S. Y., Erekosima N., Suarez-Cuervo C., Ramanathan M., Kim J. M., Ward D., Chelladurai Y., Segal J. B. Allergen-Specific Immunotherapy for the Treatment of Allergic Rhinoconjunctivitis and/or Asthma: Comparative Effectiveness Review. Rockville (MD)2013.

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