

PRESS RELEASE

STALLERGENES GREER SUBMITS A MARKETING AUTHORISATION APPLICATION IN EUROPE FOR ITS SUBLINGUAL HOUSE DUST MITE ALLERGEN IMMUNOTHERAPY TABLET

London (UK), May 4, 2020– Stallergenes Greer, a biopharmaceutical company specialising in treatments for respiratory allergies, announces the submission of a marketing authorisation application for STAGR320, its sublingual house dust mite (HDM) immunotherapy (SLIT) tablet, via a European decentralized procedure.

“By further developing its portfolio of allergen immunotherapy solutions, Stallergenes Greer enables physicians and patients to determine the treatment alternative that best meets the clinical and immunological profile and the lifestyle needs of each individual. This significant milestone demonstrates our determination to offer patients and the medical community an extensive portfolio of personalised treatment options including injectable and sublingual therapies such as drops and tablets,” stated Michele Antonelli, CEO of Stallergenes Greer.

The STAGR320 phase III clinical trial, which included 1,600 patients from 231 participating investigative sites in 13 countries, assessed the treatment of HDM-induced allergic rhinitis in adult and adolescent patients. The trial achieved both its primary efficacy endpoint and key secondary endpoints and showed a comparable safety profile to that observed in other clinical studies with STAGR320. The randomized, double-blind, placebo-controlled trial was the largest phase III clinical trial conducted to evaluate the treatment of house dust mite allergy.

Allergic rhinitis affects more than 500 million people worldwide, who are at higher risk of developing rhinitis exacerbation and asthma than the general population. Allergic rhinitis can include symptoms such as sneezing, a runny or itchy nose, nasal congestion and watery or itchy eyes, among others^{1,2}. Symptoms may be severe and can worsen over time and have a significant impact on quality of life^{1-3,4-5}.

ABOUT STAGR320

STAGR320 is Stallergenes Greer’s investigational sublingual allergen immunotherapy (AIT) tablet for the treatment of HDM-induced allergic rhinitis, with or without intermittent asthma. Allergen immunotherapy uniquely alters the natural course of respiratory allergies. It is the only therapeutic class capable of modifying disease progression and potentially preventing the onset of the disease by inducing tolerance in the immune system. STAGR320 is registered under the brand name Actair® in Australia, Japan, New Zealand and South Korea for the treatment of HDM-induced allergic rhinitis in adults and adolescents. The indication is extended in Japan for use in children below 12 years of age.

The review by Health Canada of the New Drug Submission for STAGR320 is underway.

Stallergenes Greer’s STAGR320 HDM sublingual immunotherapy tablet strengthens the company’s tablet portfolio, which already includes Oralair® for the treatment of grass pollen allergies. STAGR320 contains the same active ingredient as the company’s Staloral® HDM sublingual solution formulation. Stallergenes Greer’s wide range of treatment options provides physicians with solutions tailored to the needs of each patient: sublingual tablet formulation for ease of use and convenience, and sublingual solution for flexible dosing according to each individual profile.

PRESS RELEASE

ABOUT STALLERGENES GREER Ltd

Headquartered in London (UK), Stallergenes Greer Ltd is a global healthcare company specialising in the diagnosis and treatment of allergies through the development and commercialisation of allergen immunotherapy products and services. Stallergenes Greer Ltd is the parent company of Greer Laboratories, Inc. (whose registered office is in the United States) and Stallergenes SAS (whose registered office is in France).

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

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. 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.
5. 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 Jan;104(1):79-85.

CONTACTS

Communications

Catherine Kress
Tel: +33 01 55 59 26 05
Email: catherine.kress@stallergenesgreer.com