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## POSITIVE OUTCOME OF EUROPEAN DECENTRALISED REGISTRATION PROCEDURE FOR STALLERGENES GREER'S SUBLINGUAL HOUSE DUST MITE ALLERGEN IMMUNOTHERAPY TABLET

**London (UK), May 31, 2021** - Stallergenes Greer, a biopharmaceutical company specialising in treatments for respiratory allergies, announces the positive outcome of the European decentralised registration procedure for its sublingual house dust mite (HDM) allergen immunotherapy tablet Actair®. The Paul-Ehrlich-Institut (PEI), Germany, acted as reference member state on behalf of 21 European countries. Each member state involved in the procedure will now issue individual national marketing authorisations at the end of their national phase.

*"We are pleased to have achieved this significant milestone which demonstrates our commitment to patients and marks a major step forward for the company's further development in the European market. Stallergenes Greer's sublingual allergen immunotherapy tablet is an important option for people suffering from house dust mite-induced allergic rhinitis or rhinoconjunctivitis and illustrates our engagement to provide patients with a range of administration modes tailored to individual needs and profiles,"* declares Michele Antonelli, Chief Executive Officer.

Stallergenes Greer offers a wide range of treatment options and is paving the way for personalised precision medicine-based allergen immunotherapy: tablet and liquid sublingual solutions as well as subcutaneous formulations.

The tablet is already registered in Australia, Japan, New Zealand and South Korea under the brand name Actair® for treatment of moderate to severe house dust mite-induced allergic rhinitis or rhinoconjunctivitis.

This sublingual allergen immunotherapy (SLIT) tablet will strengthen the company's tablet portfolio in Europe which already includes Oralair®.

### About the STAGR320 Clinical Trial

The STAGR320 Phase III clinical trial, which included 1,607 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[1]. The study results provide the medical community with compelling evidence that STAGR320 induces clinically relevant improvement of rhinitis symptoms in patients with HDM allergy, which ultimately has an impact on all parameters relating to quality of life.

The randomised, double-blind, placebo-controlled trial was the largest Phase III clinical trial conducted to evaluate the treatment of house dust mite allergy[1].

### About Allergic Rhinitis and STAGR320

Allergic rhinitis is a worldwide disease affecting more than 500 million people, 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

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itchy eyes, among others[2,3]. Symptoms may be severe and can worsen over time and have a significant impact on quality of life[2,3,4,5,6].

STAGR320 is Stallergenes Greer's sublingual allergen immunotherapy (AIT) tablet for the treatment of HDM-induced allergic rhinitis. Allergen immunotherapy uniquely alters the natural course of respiratory allergies by inducing tolerance in the immune system.

STAGR320 will be marketed under the brand names Actair®, Orylmyte® or Aitmyte® in selected European countries.

## 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/

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