

PRESS RELEASE**STALLERGENES GREER INITIATES A EUROPEAN PAEDIATRIC PHASE III STUDY WITH STALORAL® BIRCH**

Baar (Switzerland), May 25, 2023 – Stallergenes Greer, a biopharmaceutical company specialising in the diagnosis and treatment of respiratory allergies, announced today the initiation of a Phase III clinical study (YOBI, YOung patients and BIrch allergy) to confirm the safety and efficacy of Staloral® Birch in children and adolescents with birch pollen-induced allergic rhino-conjunctivitis with or without asthma. The randomised, double-blind placebo-controlled Phase III study will involve approximately 80 sites in 12 European countries.

Allergic rhino-conjunctivitis is a worldwide disease and a global health burden affecting more than 500 million people, who are at higher risk of developing rhinitis exacerbation and asthma than the general population¹. Birch is among the strongest allergy-producing trees in northern Europe. The allergic potential of other trees belonging to the birch homologous group, such as alder and hazel, is also increasing steadily².

In children and adolescents, allergic rhino-conjunctivitis can lead to sleep problems, fatigue, missed school days and can complicate outdoor activities³. Individuals sensitised at a young age are also more at risk of developing asthma. The younger the children are, the higher their risk of developing asthma, which highlights the relevance of early causal treatment in paediatric patients to slow the worsening of allergy symptoms⁴. Allergen immunotherapy (AIT) is currently the only available therapeutic treatment that has the potential to uniquely alter the natural course of the disease⁵. In its liquid form, sublingual AIT can provide a needle-free and flexible treatment for children and adolescents.

“Allergic rhino-conjunctivitis induced by birch and related trees can lead to a spiraling of respiratory symptoms and conditions in the paediatric population. The YOBI study will contribute to addressing a global health burden, while deepening our knowledge of AIT with the aim of improving patient outcomes for children and adolescents with birch-induced allergies,” said Professor Oliver Pfaar, International Coordinator of the YOBI study, Head of Rhinology and Allergy, Department of Otorhinolaryngology, Philipps-Universität Marburg, Germany.

“Stallergenes Greer’s AIT treatments have proven their efficacy and safety in both clinical trials and the real world,” stated Michele Antonelli, CEO of Stallergenes Greer. *“This paediatric Phase III study, illustrates our determination to further develop evidence-based solutions and build on robust datasets and cutting-edge research technologies to advance precision medicine combined with dose adaptation for the benefit of patients with allergies, the medical community, and health systems.”*

ABOUT STALORAL®

Staloral® is a sublingual solution of allergen extracts for AIT. It is indicated in the treatment of seasonal or perennial allergic rhinitis, rhino-conjunctivitis and mild to moderate allergic asthma in adults and, in certain territories, in the paediatric population (children over 5 years of age).

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Clinical evidence of the efficacy of Staloral® is globally consistent over the clinical studies Stallergenes Greer conducted versus placebo. The effectiveness of Staloral® as a causal treatment for allergic rhinoconjunctivitis beyond clinical trials was also assessed by Stallergenes Greer's real-world studies EfficAPSI and BREATH (Bringing Real-World Evidence to Allergy Treatment for Health).

ABOUT ALLERGIC RHINITIS/ALLERGIC RHINO-CONJUNCTIVITIS

Allergic rhinitis/allergic rhinoconjunctivitis (AR/ARC) is a chronic disorder of the upper airways that is caused by allergen exposure and the resulting IgE-mediated inflammation of the nose and, to a less extent, the eyes. Allergic rhinitis can notably include symptoms such as sneezing, a runny nose, wheezing, cough, itching, and watery/itchy eyes. Symptoms may be severe and significantly impact the patient's quality of life, as well as worsen over time with progression towards asthma⁴.

First intention symptomatic treatments such as antihistamines and nasal corticosteroids provide temporary relief to patients. The primary therapeutic goals of AIT include reducing symptoms, reducing symptomatic medication use, and improving allergy-related quality of life. AIT achieves these goals and can alter the course of the disease, with benefits persisting in many patients for several years after treatment discontinuation⁶.

ABOUT STALLERGENES GREER INTERNATIONAL AG

Headquartered in Baar (Switzerland), Stallergenes Greer International AG is a global healthcare company specialising in the diagnosis and treatment of allergies through the research, development and commercialisation of allergen immunotherapy products and services. Stallergenes Greer International AG 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). For more information, visit www.stallergenesgreer.com.

CONTACT

Stallergenes Greer Communications

Catherine Kress
Tel: +33 (0)1 55 50 26 05
Email: catherine.kress@stallergenesgreer.com

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