STALORAL® BIRCH PHASE III STUDY SUCCESSFULLY MEETS PRIMARY ENDPOINT, DEMONSTRATING EFFICACY IN CHILDREN AND ADOLESCENTS

Baar (Switzerland), October 30, 2025 – Stallergenes Greer, a global leader in allergy therapeutics, announced today that its Phase IIIb clinical study (YOBI, YOung patients and BIrch allergy), designed to confirm the safety and efficacy of Staloral® Birch in children and adolescents with birch pollen-induced allergic rhino-conjunctivitis (ARC), with or without asthma, has successfully achieved its primary endpoint.

The trial enrolled 553 children aged 5 -17 years with moderate to severe birch pollen-induced ARC, with or without asthma, across 64 sites in 12 European countries and assessed the efficacy and safety of Staloral® birch 300IR daily maintenance dose administered pre-and co-seasonally over two consecutive birch pollen seasons.

The YOBI study successfully met its primary endpoint, demonstrating the efficacy of Staloral® Birch in a paediatric population (5-17) with a 41% improvement in the ARC total combined score during the second pollen season compared to placebo. These results were highly statistically significant ($p<0.0001$) and clinically meaningful with a between-group difference of -2.62 points. Moreover, the trial showed a highly statistically significant difference (-0.41, $p<0.0001$) when using the combined symptom and medication score recommended by the European Academy of Allergy and Clinical Immunology (EAACI)[1], which served as a secondary endpoint. Safety and tolerability observed in this study were consistent with the established safety profile of Staloral® Birch. During the first pollen season, similar results were also observed, both statistically significant and clinically relevant.

"The positive results of the YOBI study represent a significant advancement in extending evidence-based allergen immunotherapy to the paediatric population. They highlight the importance of early intervention and broaden treatment options for physicians and their patients," declared Oliver Pfaar, International Coordinator of the YOBI study, Chair of the section of Rhinology and Allergy, Department of Otorhinolaryngology, Philipps-Universität Marburg, Germany.

"The positive outcome of this large clinical study successfully completes our paediatric development of Staloral® Birch in respiratory allergies. The results, which confirm the benefits of treating respiratory allergies with Staloral® Birch from early childhood, mark a significant milestone for Stallergenes Greer. They also further strengthen the body of evidence supporting our sublingual liquid treatments and the company's geographic expansion. This achievement underlines our commitment to offering innovative treatment options that empower physicians to better meet the needs of their patients", stated Dr Elena Rizova, Chief Medical Officer.

Study results will be submitted for presentation at an upcoming major scientific congress meeting.

ABOUT STALORAL®

Staloral® is a sublingual solution of allergen extracts for allergen immunotherapy (AIT). The treatment covers a broad spectrum of allergens, including the most prevalent ones such as pollen, house dust mites, and animal dander.

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 rhino-conjunctivitis 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).

Staloral® Birch is currently commercialised in 21 countries, in accordance with the regulatory status of each country.

Stallergenes Greer thanks the patients, investigators and clinical trial sites who participated in the YOBI trial and remain dedicated to delivering allergy care that serves everyone.

ABOUT ALLERGIC RHINO-CONJUNCTIVITIS

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 population[2]. 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 steadily[3].

In children and adolescents, allergic rhino-conjunctivitis can lead to sleep problems, fatigue, missed school days and can complicate outdoor activities[4]. 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 symptoms. AIT is currently the only available therapeutic treatment that has the potential to uniquely alter the natural course of the disease[5]. In its liquid form, sublingual AIT can provide a needle-free and flexible treatment for children and adolescents.

ABOUT STALLERGENES GREER

Headquartered in Baar (Switzerland), Stallergenes Greer is a global healthcare company specialising in the diagnosis and treatment of allergies through the development and commercialisation of allergen immunotherapy products and services. Supported by more than 100 years of expertise and innovation, our products are available for patients in over 40 countries. For more information, please visit www.stallergenesgreer.com.

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