Press release

Stallergenes Greer Announces the Extension of Staloral® Birch and Staloral® 3 Trees Indications to Children and Adolescents in Germany

- The indication extensions broaden access to established liquid sublingual allergen immunotherapy for children and adolescents in Germany, the largest European allergen immunotherapy market.
- These authorisations are supported by the positive results of the Phase IIIb YOBI study in 553 children and adolescents aged 5 to 17 years.
- Staloral® Birch and Staloral® 3 Trees are the only liquid sublingual allergen immunotherapy treatments with marketing authorisations in Germany for the paediatric population.

Baar (Switzerland), November 26, 2026 – Stallergenes Greer, a global leader in allergy care, today announced that the Paul-Ehrlich-Institut (PEI) has extended the indications for Staloral® Birch and Staloral® 3 Trees to children and adolescents, expanding paediatric allergy treatment options in Germany.

Already authorised and available in Germany for adults, these two liquid sublingual allergen immunotherapy (SLIT liquid) treatments can now be used in children and adolescents, aged from 5 to 17 years old with tree pollen-induced allergic conjunctivitis or rhino conjunctivitis with or without controlled allergic asthma.

The clinical evidence supporting Staloral® Birch is based on the multinational Phase IIIb YOBI (YOung patients and BIrch allergy) study in 553 children and adolescents, aged 5 to 17. YOBI showed significant, clinically relevant and sustained efficacy over two consecutive birch pollen seasons in children and adolescents with allergic rhino conjunctivitis (ARC). The study demonstrated a statistically significant and clinically meaningful 41.7% improvement in the allergic rhino conjunctivitis total combined score with Staloral® Birch versus placebo during the second pollen season, the study's primary endpoint. These data also support the paediatric indication extension for Staloral® 3 Trees (birch, hazel, alder) as part of the homologous group.

"Advancing allergy care for younger patients is central to us and these paediatric indication extensions are an important step forward," said Dr Silvia Scurati, Chief Medical Officer, Stallergenes Greer. *"For young patients with birch-group pollen allergy, symptoms can come back season after season and weigh on everyday life. Based on the YOBI study of Staloral® Birch, these extensions bring Staloral® Birch and Staloral® 3 Trees, liquid sublingual immunotherapies already authorised in adults, to children and adolescents in Germany."*

In children and adolescents, allergic rhino conjunctivitis can disrupt sleep, cause fatigue and missed school days, and limit outdoor activities[1]. Birch is one of the most allergenic trees in northern and central Europe and the allergenic potential of trees in the birch homologous group, such as alder and hazel, is also increasing steadily[2]. Allergic rhino conjunctivitis is a global health burden which affects more than 500 million people worldwide, who are at higher risk of developing rhinitis exacerbation and asthma than the general population[3].

These extensions reflect Stallergenes Greer's commitment to broadening access to evidence-based allergy care across age groups. Staloral® Birch and Staloral® 3 Trees are currently commercialised in 21 countries, in accordance with the applicable regulatory status in each country.

About the YOBI study

YOBI (NCT05668390 and EudraCT 2022-002012-23) is a multinational Phase IIIb, randomised, double-blind, placebo-controlled study evaluating the safety and efficacy of 300 IR Birch SLIT-liquid (Staloral® Birch) in 553 children and adolescents aged 5 to 17 with moderate-to-severe birch pollen-induced ARC, with or without controlled asthma. The study was conducted across 64 sites in 12 European countries. Patients received a daily maintenance dose, pre- and co-seasonally, over two consecutive birch pollen seasons. YOBI is a large double-blind clinical study conducted in paediatric patients receiving sublingual allergen immunotherapy (SLIT). YOBI met its primary endpoint, demonstrating a statistically significant and clinically meaningful 41.7% improvement in the ARC total combined score during the second pollen season versus placebo ($p<0.0001$, between-group difference of -2.62 points). The safety profile was consistent with the established profile of 300 IR Birch SLIT liquid.

About Stallergenes Greer

Headquartered in Baar (Switzerland), Stallergenes Greer is a leading global biopharmaceutical company specialising in allergen immunotherapy for human and veterinary use. Its activities span the full value chain, from product development and commercialisation to allergy diagnosis and treatment. Backed by more than 120 years of expertise and innovation, the company's

[1] Canonica GW, et al. Allergy 2007;62 Suppl 85:17-25 https://doi.org/10.1111/j.1398-9995.2007.01549.x.
[2] Biedermann, T, et al. Allergy 2019; 74(7):1237-1248 https://doi.org/10.1111/all.13758.
[3] Bousquet, J, et al. Allergy 2008; 63 Suppl 86:8-160 https://doi.org/10.1111/j.1398-9995.2007.01620.x.

products reach patients in 46 countries worldwide. For more information, visit www.stallergenesgreer.com

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