

TWO NEW REAL-WORLD EVIDENCE STUDIES SHOW LONG-TERM BENEFITS OF SUBLINGUAL ALLERGY IMMUNOTHERAPY

- Two retrospective analyses showed that sublingual grass pollen and birch tree pollen allergy immunotherapy treatments can reduce the long term need of both rhinitis and asthma symptomatic medications as well as reduce asthma medication initiation in allergic patients
- The studies are part of Stallergenes Greer's BREATH real-world evidence program and were presented today at the 2018 European Academy of Allergy and Clinical Immunology Congress in Munich, Germany
- Allergic rhinitis is a common, chronic and often debilitating condition that impacts approximately 500 million people globally¹, putting these patients at greater risk for developing allergic asthma^{2,3,4,5}

London (UK), May 29, 2018 – Stallergenes Greer, a biopharmaceutical company specializing in treatments for respiratory allergies, announced positive results from two real-world evidence studies regarding the use of allergy immunotherapy (AIT) compared to the use of only symptomatic treatments to treat patients with respiratory allergies. These studies were retrospective longitudinal analyses of French and German prescription databases and further substantiated the long-term benefits of AIT to significantly reduce the need for allergic rhinitis and asthma medication in patients suffering from grass pollen- and birch tree pollen-induced allergies. These studies are part of the BREATH real-world evidence program, which is designed to understand the real-world benefits of allergy immunotherapy outside of a clinical trial setting.

"As a global leader in allergy immunotherapy, we are pleased to be able to provide further evidence into the real-world effectiveness of allergy immunotherapy for patients across Europe," said Fereydoun Firouz, Chairman and CEO of Stallergenes Greer. "The BREATH program has allowed us to deepen our knowledge and understanding of real-life patient outcomes. We look forward to bringing these outcomes to international forums to provide further evidence on the benefits that AIT can offer to a broader range of patients suffering from respiratory allergies. Today, less than 1% of patients are treated with allergy immunotherapy."¹

Grass pollen tablets demonstrate effectiveness in reducing allergic rhinitis and asthma medication intake for allergic rhinitis patients in France^{6,7,8}

This retrospective analysis is based on four years' worth of prescription data from 28,574 patients in France and demonstrated the statistically significant long-term benefit of grass pollen AIT sublingual tablets, including Stallergenes Greer's Oralair®, on grass pollen-induced allergic rhinitis compared to only symptomatic treatments. The study included 1,099 patients treated with AIT sublingual tablets as well as symptomatic medications, and a non-AIT control group of 27,475 patients receiving only symptomatic medications. Study results showed that the number of symptomatic medication prescriptions per patient per year decreased by 50 percent in the post-treatment follow-up in the AIT group, compared to an increase of prescriptions (30 percent) for patients in the non-AIT group who were using only symptomatic treatments. In addition, the risk of new asthma medication onset in the AIT group during the follow-up period was 63 percent lower when compared to the non-AIT group ($p=0.0025$). Among patients who were already taking asthma medications at the onset of the study, AIT was associated with a 40 percent decrease in asthma medication prescriptions during post-treatment follow-up versus baseline, compared to a 20 percent increase of asthma medication prescriptions among the non-AIT group.

"The results from this study are significant and further demonstrate the positive impact allergy immunotherapy can bring to allergic patients," said Professor Pascal Demoly, from Montpellier University's Pneumology and Addiction Department and a member of the study's scientific committee. "First, there is a clear benefit to AIT, showing that AIT reduced symptomatic medication prescriptions where patients who received only symptomatic treatments saw their need for medication increase. Second, these results are consistent with those obtained in Germany, confirming the scientific solidity of the methodology and suggesting transferability to other countries."

Birch tree AIT demonstrates effectiveness in reducing allergic rhinitis and asthma medication intake for allergic patients in Germany^{9,10,11}

The retrospective analysis based on eight years' worth of prescription data from 54,006 patients in Germany demonstrated the statistically significant long-term benefit of birch tree pollen AIT treatments, including Stallergenes Greer's Staloral® sublingual drops, on birch tree-induced allergic rhinitis and asthma compared to only symptomatic treatments. The study included 9,001 patients treated with AIT (administered as either a sublingual or subcutaneous formulation) as well as symptomatic treatments, and a non-AIT control group of 45,005 patients receiving only symptomatic treatments. During the follow-up period, significantly more patients in the AIT group (65 percent) were free of allergic rhinitis symptomatic medications compared to the non-AIT group (47 percent). In addition, during the follow-up period, 49 percent of AIT patients using asthma therapy at baseline were asthma medication free compared to 35 percent of non-AIT patients. Finally, during treatment, new onset of asthma medication was significantly reduced in the AIT group compared to the non-AIT group (p=0.001)

"This data provides new insight on allergy immunotherapy benefits for asthmatic patients," said Professor Ulrich Wahn, Department for Pediatric Pneumology and Immunology, Charité Medical University, Berlin and a member of the study's scientific committee. "This study builds upon our understanding of AIT and will help health care providers around the globe to make more informed decisions about how to treat patients suffering from respiratory allergies."

Data from both studies were presented this week at the annual European Academy of Allergy and Clinical Immunology (EAACI) Congress, held in Munich, Germany. The studies are part of the BREATH real-world evidence program. The first BREATH study to be released, Zielen, et. al¹², followed a similar study design and analyzed prescription data from patients with grass pollen-induced allergic rhinitis in Germany. The study was published in the peer-reviewed journal *Allergy* in May 2017 and its results were consistent with those released today. The three studies, funded by Stallergenes Greer, were conducted in collaboration with IQVIA (formerly Quintiles IMS), a 3rd party clinical research organization, and designed by independent scientific committees.

ABOUT BREATH

The BREATH (Bringing Real-World Evidence to Allergy Treatment for Health) real-world evidence program, sponsored by Stallergenes Greer, is designed to gather real-world data about the benefits of allergy immunotherapy (AIT). Allergy Immunotherapy is a disease-modifying treatment that treats the underlying cause of allergy and can provide long-lasting improvements of allergy symptoms. AIT can be administered sublingually (oral drop, tablet) or as an injectable formulation. Real world data has the potential to supplement randomized controlled trial data by providing additional information about how AIT performs in routine medical practice, nevertheless, they have several limitations and cannot be used as stand-alone evidence to validate the efficacy and/or safety of a treatment.

The BREATH studies reviewed prescription data for a variety of AIT products, including Stallergenes Greer's Oralair and Staloral. Oralair is a sublingual allergy immunotherapy tablet with a mix of five grass allergen extracts (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) currently authorized in more than 30 countries around the world, including most European countries, the United States, Canada, Australia, and Russia for the treatment of grass pollen allergic rhinitis. Staloral is a sublingual immunotherapy oral drop, currently available in more than 40 countries, including most European countries for the treatment of allergy involving rhinitis, conjunctivitis, rhino-conjunctivitis or asthma (mild to moderate) of a seasonal or perennial nature, in adults and children (from the age of 5 year). Staloral is not approved in the U.S.

ABOUT STALLERGENES GREER

Headquartered in London (UK), Stallergenes Greer plc is a global healthcare company specializing in the diagnosis and treatment of allergies through the development and commercialization of allergy immunotherapy products and services. Stallergenes Greer plc is the parent company of GREER Laboratories, Inc. (whose registered office is in the US) and Stallergenes SAS (whose registered office is in France).

PRESS RELEASE

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

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