

## STALLERGENES GREER ANNOUNCES U.S. FDA APPROVAL OF PEDIATRIC INDICATION EXTENSION FOR ORALAIR® SUBLINGUAL IMMUNOTHERAPY TABLET FOR THE TREATMENT OF GRASS POLLEN ALLERGY

**London (UK), November 14, 2018** – Stallergenes Greer, a biopharmaceutical company specializing in treatments for respiratory allergies, today announced that it has received approval from the U.S. Food and Drug Administration (FDA) for the extension of the indication for Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract), an allergy immunotherapy sublingual tablet, to treat patients ages five to nine with grass pollen-induced allergic rhinitis. Oralair is the only allergy immunotherapy tablet that contains grass pollens from five of the most common grasses in the United States and received FDA approval in patients ages ten to 65 in 2014.

“We are very pleased to be able to make this effective and convenient treatment option with a demonstrated safety profile available for children ages five and over as well as adults,” said Fereydoun Firouz, Chairman and CEO of Stallergenes Greer. “AIT can offer a valuable benefit to patients to help treat the underlying cause of allergies. Oralair provides an important option to patients who seek the relief of AIT but want the convenience of taking a tablet at home. We are committed to enabling physicians to determine the treatment method that best meets the disease and lifestyle needs of the patient.”

Allergic rhinitis affects approximately 40 to 60 million people in the U.S.<sup>1</sup> and treatment options include allergy immunotherapy, a disease-modifying treatment that treats the underlying cause of allergy and can provide long-lasting improvements of allergy symptoms. In the U.S. AIT can be administered sublingually as a tablet, such as Oralair, or as an injectable formulation. Today, fewer than 3 million allergy sufferers (i.e., 5% of the U.S. allergic population), are treated with allergy immunotherapy.

### **ABOUT ORALAIR**

Oralair is a sublingual tablet administration of allergy immunotherapy that contains a mix of five grass pollens: Kentucky Blue, Orchard, Perennial Rye, Sweet Vernal and Timothy. The five grass pollens contained in Oralair represent those to which most patients in the U.S. are exposed.

Oralair is indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis for any of the five grass species contained in this product. Oralair has been approved based on results from an extensive clinical development program and has been studied in double-blind, placebo-controlled trials in Europe and the United States in over 2,500 adults and children. The results of these trials demonstrated that pre-seasonal and co-seasonal treatment reduces patients’ allergy symptoms and their need for symptom-relieving medication (Oralair is not indicated for immediate relief of allergy symptoms). In the clinical development program, the most common adverse reactions for Oralair (reported in ≥5% of patients) were oral pruritus, throat irritation, ear pruritus, mouth edema, tongue pruritus, cough and oropharyngeal pain.

<sup>1</sup> <https://acaai.org/allergies/types/hay-fever-rhinitis>

To support administration of Oralair in the pediatric population, an open-label study was conducted to evaluate the 30-day safety profile of Oralair in 307 children five through nine years of age. Adverse reactions reported at an incidence of  $\geq 2\%$  were: throat irritation (22.1%), oral pruritus (11.7%), oral paresthesia (11.1%), tongue pruritus (8.1%), mouth edema (6.2%), cough (6.2%), oropharyngeal pain (4.2%), ear pruritus (5.2%), eye pruritus (4.6%), lip edema (3.3%), vomiting (2.6%), tongue edema (2.3%), abdominal pain (2.3%), oral discomfort (2.3%), and ocular hyperemia (2.0%).

## ABOUT STALLERGENES GREER PLC

Headquartered in London (UK), Stallergenes Greer plc is a global healthcare company specialising in the diagnosis and treatment of allergies through the development and commercialisation 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).

## TRADING INFORMATION

Name: Stallergenes Greer

ISIN: GB00BZ21RF93 1 - Ticker: STAGR

ICB Classification: 4577

LEI: 213800CYVZA7GJQEME86

Market: Euronext Paris regulated market

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

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