STALLERGENES GREER RECEIVES MARKET APPROVAL IN AUSTRIA FOR ITS SUBLINGUAL ALLERGEN IMMUNOTHERAPY TABLET FOR HOUSEHOLD MITE ALLERGY

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VIENNA - (BUSINESS WIRE) - Stallergenes Greer announced today that the sublingual allergen immunotherapy (SLIT) tablet developed by the company for house dust mite allergy, Actair ® , has received national marketing approval from the Federal Office for Safety in Health Care (AGES).

House dust mites are the second most common cause of allergies in Austria after pollen. Many thousands of patients in Austria suffer from a house dust mite allergy [1] .

Actair ® is used in adolescents (12 years and older) and adults to treat moderate to severe house dust mite-induced allergic rhinitis or rhinoconjunctivitis that has been diagnosed based on history and evidence of sensitization to house dust mite allergens.

The regulatory filing for Actair ® was based, among other things, on the largest Phase III clinical trial conducted to evaluate the treatment of house dust mite allergy [2] . In total, more than 5,000 patients worldwide participated in the Actair ® development and testing study program [2-7] .

Andy Möckel, Vice President Stallergenes Greer DACH, is convinced: " This is a milestone in the treatment of house dust mite allergies, because with Actair ®we offer doctors and patients an effective, well-documented, recognized sublingual tablet for the causal treatment of house dust mite allergies. In addition, this innovation strengthens and completes the already established allergen immunotherapy portfolio of Stallergenes Greer, which in Austria includes Oralair ® for grass pollen allergies and Staloral ® individual formulations in drop form for allergies to birch / early blooming pollen, grass pollen, house dust mites and various herb pollen. "

" For many house dust mite allergy sufferers, Actair ® is a relevant and simple treatment option that can improve their quality of life and treat the underlying cause of their illness by making Actair ® more tolerant to house dust mites," explains Dr. med. Ursula Kreuzberg, Medical Director DACH.

At the end of a decentralized European approval process, Stallergenes Greer's SLIT tablet received national approval for house dust mite allergy in Austria. In other European countries, the approval process is about to be completed or has already been completed. The tablet has been used outside of Europe since 2015; in Germany, it has been available to doctors and patients under the Orylmyte brand since September 2021.

About the STAGR320 (Actair ®) clinical studies

The Phase III clinical study [2], which enrolled 1,607 patients from 231 study sites in 13 countries, studied the treatment of house dust mite-induced allergic rhinitis in adult and adolescent patients. The study met both its primary efficacy endpoint and secondary endpoints and demonstrated a similar safety profile to that seen in other clinical trials with STAGR320. The study results provide the medical community with convincing evidence that STAGR320 (whole-body extracts from Dermatophagoides pteronyssinus and Dermatophagoides farinae in equal parts) brings about a clinically relevant improvement in rhinitis symptoms in patients with house dust mite allergy, which ultimately has a positive effect on all parameters of quality of life. The randomized, double-blind,[2] .

About Stallergenes Greer Ltd

Stallergenes Greer Ltd. headquartered in London (UK) is a global healthcare company specializing in the diagnosis and treatment of allergies through the development and marketing of allergen immunotherapy products and services. Stallergenes Greer Ltd. is the parent company of Greer Laboratories, Inc. (based in the United States) and Stallergenes SAS (based in France). Further information can be found at https://www.stallergenesgreer.com/

1. https://www.gesundheit.gv.at/krankheiten/allergie/hausstaubmilbenallergie/inhalt
2. Demoly P et al. *J Allergy Clin Immunol.* 2021; 147: 1020-1030
3. Roux M et al. *J Allergy Clin Immunol.* 2016; 138: 451-458
4. Bergmann KC et al. *J Allergy Clin Immunol.* 2014; 133: 1608-1614
5. Okamoto Y et al. *Allergy.* 2017; 72: 435-443
6. Okamoto Y et al. *Pediatr Allergy Immunol.* 2019; 30: 66-73
7. Stallergenes Greer, data on file

BRIEF INFORMATION according to the Specialized Information Ordinance *.

Name: STALORAL ®. Qualitative and quantitative composition: STALORAL® is a sublingual solution of allergen extracts. List of excipients: mannitol (E421), sodium chloride, glycerin and purified water. Areas of application: STALORAL® is used for the treatment of allergies with rhinitis, rhinoconjunctivitis or mild to moderate asthma with seasonal or year-round character in adults and children from 5 years. Contraindications: Hypersensitivity to any of the other ingredients, severe and / or unstable asthma, immunodeficiency or illness that attacks the own immune system, use of immunosuppressants, malignant disease or malignant tumor (e.g. cancer), inflammation in the oral cavity. Delivery: Prescription and pharmacy only. Registration holder: STALLERGENES, 6 rue Alexis de Tocqueville, 92160 ANTONY, France. Information as of September 2018

[Special warnings and precautionary measures for use, interactions with other drugs and other forms of interaction, pregnancy and breastfeeding and side effects can be found in the package insert *.]

* For NPPs, the authorities do not approve any technical information or instructions for use, as NPPs are approved under simplified conditions in accordance with Section 7a AMG.

SPECIALIST INFORMATION:

Name: ORALAIR ® 100 IR + 300 IR sublingual tablets ORALAIR® 300 IR sublingual tablets Qualitative and quantitative composition: Grass pollen allergen extract from: common ball grass (Dactylis glomerata L.), common stork (Anthoxanthum odoratum L.), German ryegrass (Lolium perenne L.), Meadow bluegrass (Poa pratensis L.) and timothy grass (Phleum pratense L.) 100 IR * or 300 IR * per sublingual tablet. * IR (reactivity index): The unit IR was defined to measure the allergenicity of an allergen extract. The allergen extract contains 100 IR / ml if, in the skin prick test with a Stallerpoint® needle, a wheal 7 mm in diameter (geometric mean) is induced in 30 patients sensitized to this allergen. the

Skin reactivity of these patients is shown simultaneously with 9% codeine phosphate or 10 mg / ml histamine as a positive control. The IR unit used by Stallergenes is not comparable with the units given by other allergen manufacturers. List of excipients: Mannitol (E421, Ph.Eur.), Microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silicon dioxide, magnesium stearate, lactose monohydrate. Areas of application: Treatment of allergic rhinitis caused by grass pollen with or without conjunctivitis in adults, adolescents and children (from 5 years of age) with clinically relevant symptoms, which was confirmed by a positive skin test and / or a positive titer of the specific IgE against grass pollen. Contraindications: Hypersensitivity to any of the excipients (see “List of excipients”), severe and / or unstable asthma (FEV1 <70% of the predictive value), severe immunodeficiency or autoimmune disease, malignancies (e.g. cancer), oral inflammation (e.g. B. oral lichen planus, oral ulceration or oral mycosis). Pharmacotherapeutic group: Allergen extract, grass pollen, ATC code: V01AA02 Authorization holder: STALLERGENES, 6 rue Alexis de Tocqueville, 92160 Antony, France Prescription / pharmacy requirement: Prescription and pharmacy only. Information as of February 2020. Special warnings and precautionary measures for use, interactions with other medicinal products and other forms of interaction,

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