STALLERGENES GREER

PRESS RELEASE

EUROPEAN COMMISSION APPROVES THE EXTENSION OF THE INDICATION OF PALFORZIA® TO THE TREATMENT OF TODDLERS WITH CONFIRMED PEANUT ALLERGY

Baar (Switzerland), January 9th, 2025 - Stallergenes Greer, a biopharmaceutical company specialising in allergen immunotherapy (AIT), announces that the European Commission (EC) has approved the extension of indication of Palforzia® (defatted powder of *Arachis hypogaea* L., semen (peanut)) for the treatment of toddlers (ages 1 through 3) with a confirmed diagnosis of peanut allergy. The marketing authorisation covers all 27 European member states and the three European Economic Area states (Iceland, Liechtenstein and Norway).

This approval of the extension of indication of Palforzia® to toddlers, follows the July 2024 approval by the U.S. Food and Drug Administration (FDA). Palforzia® is the first and only EMA and FDA approved oral immunotherapy for toddlers with a confirmed diagnosis of peanut allergy.

"*Peanut allergy is one of the most frequent food allergies. Early intervention is crucial to reduce the risks of accidental exposure and may be very important in improving long-term outcomes. The approval of Palforzia for toddlers represents for the medical community a meaningful advancement in managing allergy at a pivotal stage in a child's development,"* stated Dr Katharina Blümchen, Professor at the University of Medicine of Frankfurt, Clinic for Pediatric and Adolescent Medicine, Department of Pneumology, Allergology, Infectiology, and Gastroenterology.

"*The approval of Palforzia® by the European Commission highlights the need for a treatment to help alleviate the burden of peanut allergy for young patients and their family,"* said Michele Antonelli, CEO of Stallergenes Greer. "*In addition to the risk of severe reactions from accidental exposure, peanut allergy can have significant psychological consequences on disease sufferers and their families while negatively impacting quality of life. We are proud of this milestone which highlights Stallergenes Greer's commitment to the patients and healthcare professionals we serve."*

Palforzia® is designed to gradually increase the body's ability to tolerate small amounts of peanut (desensitisation) through carefully controlled and supervised initial dose escalation, up-dosing and maintenance. The extension of the indication enables treatment to be initiated at an earlier age, thus offering young children and their families the opportunity to reduce the risk of severe allergic reactions from accidental exposure to peanut allergens, with adjustment of contraindications.[1]

The approval is based on data from the Phase 3 POSEIDON (**P**eanut **O**ral Immunotherapy **S**tudy of **E**arly **I**ntervention for **D**esensitizati**on**) study that was published in the New England Journal of Medicine Evidence in 2023. The study evaluated the efficacy and safety of Palforzia® in peanut-allergic children aged 1 to 3 years old, meeting all its primary and secondary efficacy endpoints and demonstrating a favourable safety profile.[2]

Palforzia®'s broader accessibility highlights Stallergenes Greer's mission to bring innovative therapies to patients across all stages of life. Beyond food allergy treatments, the company offers

a diverse portfolio, including sublingual and subcutaneous immunotherapies for respiratory and insect venom allergies.

ABOUT PALFORZIA®

Palforzia® is indicated by the European Medicine Agency (EMA) in all 27 European member states, Iceland, Liechtenstein and Norway, for the treatment of patients aged 1 to 17 years with a confirmed diagnosis of peanut allergy. It is indicated by the Medicines and Healthcare products Regulatory Agency (MHRA) in the U.K., and by Swissmedic in Switzerland for the treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy. Palforzia® may be continued in patients 18 years of age and older. Palforzia® should be used in conjunction with a peanut-avoidant diet.

Palforzia® is also approved by the U.S. Food and Drug Administration (FDA) for ages 1-17 years for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. The treatment is approved for use in patients with a confirmed diagnosis of peanut allergy; Initial Dose Escalation may be administered to patients aged 1 through 17 years. Up-Dosing and Maintenance may be continued in patients 1 year of age and older. Palforzia® is to be used in conjunction with a peanut-avoidant diet. Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

ABOUT POSEIDON PHASE 3 STUDY

POSEIDON (Peanut Oral Immunotherapy Study of Early Intervention for Desensitization, clinicaltrials.gov number NCT03736447) is an international, randomized (2:1), double-blind, placebo-controlled Phase 3 study that evaluated the efficacy and safety of Palforzia® in peanut-allergic children aged 1 to 3 years of age in North America and Europe.

The POSEIDON study was completed by Aimmune Therapeutics, part of Nestlé Health Science before Nestlé divested Palforzia® to Stallergenes Greer in September 2023.

Enrollment was based on several entry criteria, including a documented clinical history of peanut allergy, positive skin prick tests and/or elevated blood levels of peanut antibodies, and dose-limiting symptoms after consuming single doses of peanut protein >3 to ≤300 mg in a positive double-blind, placebo-controlled food challenge.

In POSEIDON, patients underwent a dose-escalation period of approximately 22 weeks to reach a dose of 300 mg per day of Palforzia® or placebo, then continued that dose for approximately six months. At the end of the trial, patients underwent an exit double-blind, placebo-controlled food challenge (DBPCFC).

ABOUT STALLERGENES GREER INTERNATIONAL AG

Headquartered in Baar (Switzerland), Stallergenes Greer International AG is a global healthcare company specialising in the diagnosis and treatment of respiratory, food and venom allergies through the development and commercialisation of allergen immunotherapy products and services. Stallergenes Greer International AG is the parent company of Greer Laboratories, Inc.

(whose registered office is in the United States) and Stallergenes SAS (whose registered office is in France). For more information, visit www.stallergenesgreer.com.

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[1] Summary of Product Characteristics. Rev 19 dec 2024
[2] https://evidence.nejm.org/doi/full/10.1056/EVIDoa2300145