STALLERGENES GREER

PRESS RELEASE

FDA APPROVES U.S. PEDIATRIC INDICATION EXTENSION FOR PALFORZIA® ORAL IMMUNOTHERAPY FOR THE TREATMENT OF PEANUT ALLERGY

Baar (Switzerland), July 30, 2024 – Stallergenes Greer, a leading global healthcare company specialising in allergen immunotherapy, today announced that the U.S Food and Drug Administration (FDA) has approved Palforzia® *[Peanut (Arachis hypogaea) Allergen Powder-dnfp],* for the treatment of toddlers (ages 1-3 years) with a confirmed diagnosis of a peanut allergy. This approval expands the January 2020 FDA approval for patients ages 4-17 years. Palforzia® is to date the first and only approved oral immunotherapy treatment (OIT) for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut.

Peanut allergy currently affects approximately 2% of the general population of Western nations[1], and the prevalence of peanut allergy doubled among children between 2005 and 2015[2]. Compared with other food allergies, peanut allergy is associated with higher rates of accidental exposure, severe reactions and potentially fatal anaphylaxis[1]. The difficulty in avoiding peanuts, combined with the severity of allergic reactions, shows the need for effective treatment[3].

"We are delighted that Palforzia® has received regulatory approval in the U.S. for toddlers as there is a high unmet medical need for this age group and we are confident that this indication extension will alleviate the burden of peanut allergy for younger patients and their families," says Elena Rizova, MD, PHD, Chief Medical Officer of Stallergenes Greer.

The FDA approval in toddlers 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.

Stallergenes Greer acquired the rights to Palforzia® in September 2023. As part of our ongoing commitment to delivering innovative solutions in allergen immunotherapy, our focus in the U.S has been on establishing a specialised Food Allergy business unit and transitioning the product into our AIT portfolio.

ABOUT PALFORZIA®

Palforzia® is in the U.S an oral immunotherapy treatment indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut for patients. The treatment is approved for use in patients with a confirmed diagnosis of peanut allergy and in conjunction with a peanut-avoidant diet. Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

Palforzia® is approved by the U.S. Food and Drug Administration (FDA) for ages 1-17 years and for ages 4-17 years by the European Medicine Agency (EMA), by the Medicines and Healthcare products Regulatory Agency (MHRA) in the U.K., and by Swissmedic in Switzerland. Pediatric indication extension submissions are currently under review by the EMA and Swissmedic.

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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] The global burden of illness of peanut allergy: A comprehensive literature review. Jay A. Lieberman, Ruchi S Gupta, Rebecca C. Knibb, Tmirah Haselkorn, Stephen Tilles, Douglas P. Mack, and Guillaume Pouessel. Online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8247890/. Accessed August 31, 2023
[2] Du Toit G, et al. Randomized Trial of Peanut Consumption in Infants at Risk for Peanut Allergy. N Engl J Med 2015; 372: 803-13. Accessed August 31, 2023.
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