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Press Release

Vevey, December 21, 2020

European Commission approves Aimmune's PALFORZIA® as first-ever treatment for peanut allergy in the EU

The European Commission (EC) has approved the use of PALFORZIA® [defatted powder of Arachis hypogaea L., semen (peanuts)] for the treatment of peanut allergy in the European Union (EU). Developed by Aimmune Therapeutics, Inc., a Nestlé Health Science Company, PALFORZIA is an oral immunotherapy indicated in patients aged 4 to 17 years, who have a confirmed diagnosis of peanut allergy. PALFORZIA may be continued in patients 18 years and older and must be used in conjunction with a peanut-avoidant diet.

"Today's news of the EC approval represents the first-ever treatment option approved for peanut allergy in the EU and underscores our vision of providing end-to-end solutions as a driver of wellness and treatment, in the key growth areas of nutrition, metabolism, healthy aging and food allergy," said Greg Behar, CEO of Nestlé Health Science.

Food allergies affect around 17 million people across Europe,[1] with peanut allergy being one of the most common of those. In fact, peanut allergy doubled among children between 2005 and 2015,[1,2,3] and the number of hospital admissions due to severe allergic reactions increased seven-fold.[1] Severe reactions combined with the difficulty of avoiding peanut protein create an urgent need for treatment.[4]

Andrew Oxtoby, President and CEO of Aimmune Therapeutics, said, "Now we turn our efforts toward working with health authorities to ensure access to this first-of-kind treatment for those children with peanut allergy for whom our product is appropriate as we prepare to launch in Germany and the UK in May 2021."

The approval was based on a package of data, including from two phase 3 clinical trials PALISADE and ARTEMIS.[5,6,7] In both studies, PALFORZIA treatment resulted in a significant increase in the amount of peanut protein tolerated, compared to placebo.[6,7]

In Switzerland, a Marketing Authorization Application for PALFORZIA has been filed with Swissmedic and review is currently ongoing.

About PALFORZIA [defatted powder of Arachis hypogaea L., semen (peanuts)]

PALFORZIA is a complex biologic drug used with a structured dosing approach that builds on a century of oral immunotherapy (OIT) research. With OIT, the specific allergenic proteins are ingested initially in very small quantities, followed by incrementally increasing amounts, that can result in the ability to mitigate allergic reactions to the allergen over time.

Results from the two phase 3 clinical trials PALISADE and ARTEMIS showed that more than half of patients treated with PALFORZIA were able to tolerate the equivalent of seven to eight peanut kernels after nine to twelve months of treatment. This data highlights PALFORZIA's potential to mitigate against allergic reactions, including anaphylaxis in the event of unintended exposure to peanut protein.[6,7] PALFORZIA is not intended for, and does not provide, immediate relief of allergic symptoms.

The safety profile was as expected for an oral desensitization therapy. The most common adverse reactions (of any severity) were abdominal pain (49.4%), throat irritation (40.7%), pruritus (33.7%), nausea (33.2%), vomiting (28.5%), urticaria (28.5%), oral pruritus (26.0%), abdominal discomfort (22.9%), and abdominal pain upper (22.8%).[5]

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