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Aimmune Therapeutics Presents New PALFORZIA® [Peanut (Arachis hypogaea) Allergen Powder-dnfp] Data on Immunological Outcomes of Long-Term Daily Oral Immunotherapy at the EAACI PAAM Digital Meeting

November 12, 2021

— Pooled, Longitudinal Analyses Showed Treatment with PALFORZIA for up to 6 Years Resulted in Long-Term Immunomodulation —

— Additional Data Presented Reported a Gain in Utility Measures for Quality of Life for Both Patients Treated with PALFORZIA and Caregivers —

BRISBANE, Calif.--(BUSINESS WIRE)-- Aimmune Therapeutics, Inc., a Nestlé Health Science company developing and commercializing pharmaceutical therapies to prevent, manage, and treat food and metabolic-related diseases, today presented results from longitudinal analyses evaluating immunological outcomes of long-term daily oral immunotherapy (OIT) with PALFORZIA® [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp] in patients with peanut allergy (PA) for up to 6 years, as well as new data on the utility benefits for Quality of Life (QoL) between pre- and post-OIT health states in children and adolescents with PA who received PALFORZIA and their caregivers in the United Kingdom (U.K.). The data will be presented at the European Academy of Allergy and Clinical Immunology (EAACI) Pediatric Allergy and Asthma Meeting (PAAM) Digital Event, November 12-13, 2021.

PALFORZIA was approved as an oral immunotherapy (OIT) for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut for patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy on January 31, 2020 by the U.S. Food and Drug Administration (FDA), on December 17, 2020 by the European Commission (EC), on April 7, 2021 by the Medicines and Healthcare products Regulatory Agency (MHRA) in the U.K., and on May 4, 2021 by Swissmedic. Use of PALFORZIA may be continued in patients 18 years of age and older. PALFORZIA is not indicated for the emergency treatment of allergic reactions, including anaphylaxis and must always be used in conjunction with a peanut-avoidant diet.

Please see U.S. Important Safety Information below and the full Prescribing Information, including Boxed WARNING, and Medication Guide at www.PALFORZIA.com.

“We have followed more than 650 participants from PALFORZIA clinical trials, in an uncontrolled, open-label extension study, to continue evaluating the long-term effects of PALFORZIA treatment on certain immunological parameters,” said Mohamed Yassine, MD, SVP Global Medical Affairs at Aimmune. “Now, we are proud to share these data of up to 6 years, that suggest continued immunomodulation in PA patients.”

Data presented at the meeting suggest that continued long-term treatment (median treatment duration at the time of the data analysis was 3.21 years, with a maximum duration of 6 years) with PALFORZIA induced long-term immunomodulation, indicating a continued shift away from pretreatment sensitivity to peanut. Key highlights from this data presentation include:

- Median Peanut-Specific IgE levels (psIgE) declined initially in Year 2 from baseline, further lowering with continued treatment over time.
- The median Peanut-Specific IgG4 levels (psIgG4) increased to a peak around Years 2 and 3 from baseline.
- Additionally, median peanut Skin Prick Test (SPT) decreased over time hitting its lowest at Year 5 and plateauing in Year 6.
- Results indicate that median Peanut-Specific IgE to Peanut-Specific IgG4 Ratio (psIgE/psIgG4) declined substantially in Year 1 from baseline and remained lower up to Year 6.

Additionally, results from a cross-sectional, observational study using different data collection methods, conducted in the U.K., provided the first-ever estimates of QoL utility measures for patients and caregivers across different health states relating to OIT in PA. The data showed a gain in utility related to QoL among patients treated with PALFORZIA and their caregivers between untreated PA and post-treated PA OIT health states.

“We know there is a significant daily burden for both patients and caregivers living with peanut allergy, so I’m hopeful to see these new data that indicate a gain in utility measures for QoL after PA OIT treatment with PALFORZIA,” said George du Toit, pediatric allergist, U.K. and an investigator in PALFORZIA clinical trials.

The following abstracts are now available for on-demand viewing on the PAAM scientific program website:

- Poster #P17: Nilsson, C, et al.
  “Immunological Outcomes of Daily Oral Immunotherapy for Peanut Allergy in Children and Adolescents: Longitudinal Analyses Up to 6 Years.”
- Poster #P20: Gallop, K, et al.
  “Exploring health-related quality of life burden in peanut allergy and the potential benefit of oral immunotherapy.”

INDICATION

PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older.

PALFORZIA is to be used in conjunction with a peanut-avoidant diet.

Limitations of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

IMPORTANT SAFETY INFORMATION

WARNING:

PALFORZIA can cause anaphylaxis, which may be life threatening and can occur at any time during PALFORZIA therapy.

Prescribe injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.

Do not administer PALFORZIA to patients with uncontrolled asthma.

Dose modifications may be necessary following an anaphylactic reaction.

Observe patients during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes.

In the US, PALFORZIA is available only through a restricted program called the PALFORZIA REMS.

CONTRAINDICATIONS

PALFORZIA is contraindicated in patients with uncontrolled asthma, or with a history of eosinophilic esophagitis and other eosinophilic gastrointestinal disease.

WARNINGS AND PRECAUTIONS

Anaphylaxis

PALFORZIA can cause anaphylaxis, which may be life threatening. In the US, PALFORZIA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the PALFORZIA REMS because of the risk of anaphylaxis. Only prescribers, healthcare settings, pharmacies, and patients certified and enrolled in the REMS Program can prescribe, receive, dispense or administer PALFORZIA.

Anaphylaxis has been reported during all phases of PALFORZIA dosing, including Maintenance and in subjects who have undergone recommended Up-Dosing and dose modification procedures.

Do not initiate PALFORZIA treatment in a patient who has had severe or life-threatening anaphylaxis within the previous 60 days. PALFORZIA may not be suitable for patients with certain medical conditions that may reduce the ability to survive anaphylaxis, including but not limited to markedly compromised lung function, severe mast cell disorder, or cardiovascular disease. In addition, PALFORZIA may not be suitable for patients taking medications that can inhibit or potentiate the effects of epinephrine.

All Initial Dose Escalation doses and the first dose of each Up-Dosing level must be administered in a certified health care setting.

Patients may be more likely to experience allergic reactions following PALFORZIA administration in the presence of cofactors such as exercise, hot water exposure, intercurrent illness (e.g., viral infection), or fasting. Other potential cofactors may include menstruation, sleep deprivation, nonsteroidal anti-inflammatory drug use, or uncontrolled asthma. Patients should be proactively counseled about the potential for the increased risk of anaphylaxis in the presence of these cofactors. If possible, adjust the time of dosing to avoid these cofactors. If it is not possible to avoid these cofactors, consider withholding PALFORZIA temporarily.

Asthma

Uncontrolled asthma is a risk factor for a serious outcome, including death, in anaphylaxis. Ensure patients with asthma have their asthma under control prior to initiation of PALFORZIA.

PALFORZIA should be temporarily withheld if the patient is experiencing an acute asthma exacerbation. Following resolution of the exacerbation, resumption of PALFORZIA should be undertaken cautiously. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of PALFORZIA.

Eosinophilic Gastrointestinal Disease

Discontinue PALFORZIA and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastrointestinal symptoms, including dysphagia, vomiting, nausea, gastroesophageal reflux, chest pain, or abdominal pain.

Gastrointestinal Adverse Reactions

Gastrointestinal adverse reactions were commonly reported in PALFORZIA-treated subjects, and dose modification should be considered for patients who report these reactions. For severe or persistent gastrointestinal symptoms consider a diagnosis of eosinophilic esophagitis.

ADVERSE REACTIONS

The most common adverse events reported in subjects treated with PALFORZIA (incidence ≥ 5% and ≥ 5% than placebo) are abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, and ear pruritus.

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide at www.PALFORZIA.com.

For more information about PALFORZIA, please call 1-844-PALFORZ (1-844-725-3679) or visit www.PALFORZIA.com.

About Aimmune

Aimmune Therapeutics, Inc., a Nestlé Health Science Company, is a biopharmaceutical company developing and commercializing pharmaceutical therapies to prevent, manage, and treat food and metabolic-related diseases, including gastrointestinal conditions. Aimmune has one FDA- and EU-approved medicine for peanut allergy and other investigational therapies in development. For more information, please visit www.aimmune.com.

About Nestlé Health Science

Nestlé Health Science (NHSc), a wholly owned subsidiary of Nestlé, is a globally recognized leader in the field of nutritional science. At NHSc we are committed to empowering healthier lives through nutrition for consumers, patients and their healthcare partners. We offer an extensive consumer health portfolio of industry-leading medical nutrition, consumer and vitamins, minerals and supplements (VMS) brands that are science-based solutions covering all facets of health from prevention to maintenance, all the way through to treatment. NHSc is redefining the way we approach the management of health in several key areas such as pediatric health, allergy, acute care, oncology, metabolic health, healthy aging, gastrointestinal health, and inborn errors of metabolism. Headquartered in Switzerland, NHSc employs over 5,000 people around the world who are committed to making a difference in people's lives, for a healthier today and tomorrow. www.nestlehealthscience.com.

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