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Aimmune Therapeutics to Present New Data at ACAAI on the Real-World Burden of Peanut Allergy and Early Physician Experience with PALFORZIA® in Clinical Practice in the U.S.

November 05, 2021

— The Peanut Allergy Burden Study (PABS), demonstrates the need for joint patient-physician decision making to improve peanut allergy management —

— Physician surveys indicate PALFORZIA was readily implemented in clinical practice and highlight real-world experience that may help facilitate adoption in the U.S. —

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 announced it will present new data on the burden of peanut allergy (PA) on patients' and caregivers' Quality of Life. In addition, the company will share results from physician surveys on real-world experiences with PALFORZIA® [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp] that explore treatment adoption in clinical practice in the U.S. The data will be presented at the American College of Asthma, Allergy, and Immunology (ACAAI) Annual Scientific Meeting on November 4-8, 2021, in New Orleans.

PALFORZIA (previously known as AR101) was approved by the U.S. Food and Drug Administration (FDA) in January 2020 as an oral immunotherapy (OIT) for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients aged 4 through 17 years with a confirmed diagnosis of peanut allergy. In December 2020, the European Commission (EC) approved PALFORZIA for patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy in conjunction with a peanut-avoidant diet. PALFORZIA must be used in conjunction with a peanut-avoidant diet and is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

"As we continue to dedicate our research to uncovering the ongoing burden of peanut allergy on children and their families, one factor that consistently rises to the top is the importance of joint decision making to optimize peanut allergy management and help those impacted by this condition," said Mohamed Yassine, MD, SVP Global Medical Affairs at Aimmune. "PALFORZIA offers an important option for many families living with peanut allergy and based on early data from real-world experience with the treatment, we are pleased to see that many allergists are already treating their patients with PALFORZIA."

The Peanut Allergy Burden Study (PABS), sponsored by Aimmune Therapeutics Inc., demonstrates the need for and impact of joint decision making in improving health-related Quality of Life (HRQoL) of both patients and caregivers managing PA. Additional data presented at the meeting demonstrate that PALFORZIA can be readily implemented in clinical settings for the treatment of PA and suggest that information-sharing between physicians is useful to help facilitate treatment adoption. Additionally, results show that PALFORZIA treatment was successfully incorporated in practice by health care providers without prior OIT experience.

"As an allergist who regularly sees a number of patients living with the daily burden of peanut allergy, I have been excited about the opportunity to offer a treatment option to my appropriate patients and also educate other allergists," said Jay Portnoy, MD, Children's Mercy, Kansas. "When adopting novel therapies, it's important to share experiences and tips with other physicians that will help them learn how to incorporate these treatments into their own practices."

The complete list of Aimmune poster presentations at ACAAI is as follows:

- W. McCann, MD. "*Factors Associated with Health-Related Quality of Life in Adolescents with Peanut Allergy: A Multivariate Analysis*." Poster #P106; Friday, Nov. 5, 4:30 p.m. CT; Exhibit Hall B, Monitor 11
  - The Peanut Allergy Burden Study (PABS) assessed the real-world burden of peanut allergy, specifically the factors associated with HRQoL in adolescents with peanut allergy.
    - 102 adolescents aged 13 to 17 years with self-reported, provider-diagnosed PA participated in the online survey, which collected socio-demographic, medical, treatment history and Pediatric Quality of Life Inventory (PedsQL) data and identified potential predictors of PedsQL scores using univariate and multivariate statistics.
    - Results from the survey showed that while some patient characteristics are associated with poor PedsQL scores, the substantial heterogeneity in patient experience indicates the need for shared decision making for PA management to improve HRQoL.

- S. Mustafa, MD. *"Oral Immunotherapy Implementation for Peanut Allergy in Clinical Practice in the United States: Ten Tips."* Poster #P112; Saturday, Nov. 6, 11:35 a.m. CT; Exhibit Hall B, Monitor 11
  - Results from a survey of six experienced PALFORZIA prescribers were also presented and offer guidance from real-world experience to facilitate delivery of the treatment in practice.
    - Physicians participating in interviews and an advisory panel shared key tips for implementation, including preparing facilities, clinicians, and staff to access, administer, and monitor PALFORZIA treatment, supporting shared decision-

making, anticipating AEs, and maintaining flexibility with dosing/treatment consistent with the labeled dosing regimen.

- J. Portnoy, MD. "
  Physician Experience with Prescribing Peanut (Arachis hypogaea) Allergen Powder-dnfp in Pediatric Patients with Peanut Allergy." Poster #P114; Saturday, Nov. 6, 12:05 p.m. CT; Exhibit Hall B, Monitor 11
  - A survey of 48 physicians assessed real-world experience in prescribing and adapting practices to deliver PALFORZIA, showing that the treatment was integrated into practice without difficulty by most physicians surveyed.
    - Results of the survey identified the percent of physicians that were somewhat/extremely likely to prescribe PTAH, including patients with multiple food allergies.
    - Responses indicated that most physicians were more likely to prescribe PTAH for patients with a recent PA reaction (≤12 months).
    - Survey results detailed physician experience prescribing PTAH, identifying the percent of physicians that found prescribing PTAH easy/very easy, moderate, or difficult/very difficult, both overall and at different phases of treatment.

- A. Anagnostou, MD. "
  Real-World Perspectives of Health Care Providers Delivering the First FDA Approved Treatment for Peanut Allergy." Poster #P117; Sunday, Nov. 7, 11:35 a.m. CT; Exhibit Hall B, Monitor 11
  - In interviews with eight allergists and three nurse practitioners around their experiences delivering PALFORZIA, four key themes were explored, including factors influencing adoption, factors related to delivering treatment in everyday practice, learnings and reflections, and delivering PALFORZIA during the COVID-19 pandemic.
    - Responses showed that prior OIT experience was not essential for implementation of PALFORZIA in practice.
    - Learning from others' experiences was suggested to help overcome perceived and actual barriers to implementation.

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

Boxed 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.

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. 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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Source: Aimmune Therapeutics, Inc.

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