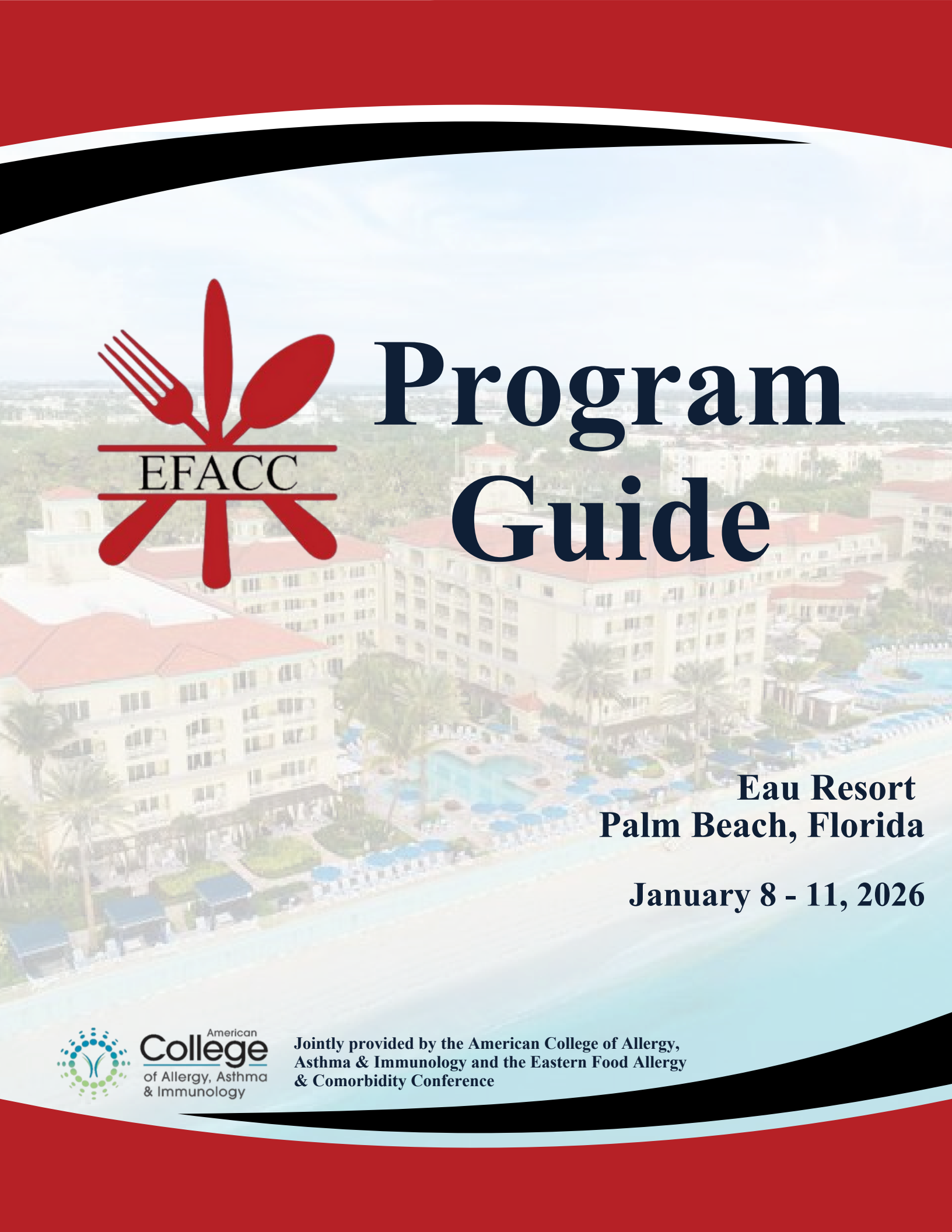

Program Guide

Eau Resort
Palm Beach, Florida

January 8 - 11, 2026

Jointly provided by the American College of Allergy, Asthma & Immunology and the Eastern Food Allergy & Comorbidity Conference

Table of Contents

Welcome to EFACC 2026

The purpose of the Eastern Food Allergy & Comorbidity Conference (EFACC) CME Program is to plan and create educational activities and enduring material that will develop, maintain, update, and enhance the clinical practice of allergy, asthma, and immunology. The overall educational goal is to share clinically relevant information that improves the diagnostic accuracy and the effectiveness of treatments with practitioners who treat food allergies and associated comorbid diseases, including asthma, atopic dermatitis, chronic urticaria, and allergic rhinitis.

Disclaimer
The information provided at this CME activity is for continuing education purposes only and is not meant to substitute for the independent medical judgement of a healthcare provider relative to diagnostic and treatment options of a specific patient's medical condition.

ADA Compliance
In compliance with the Americans with Disabilities Act, EFACC requests that any participant in need of accommodation send an email to jillcourcier@easternmedicalconferences.org.

Instructions for Obtaining a CME Certificate or Certificate of Attendance
In order to receive credit, participants must sign in to the ACAAI College Learning Connection (CLC) at education.acaai.org, complete the evaluation, and download their certificate. Please note, per the American Medical Association (AMA), only physicians are eligible to receive a CME Certificate.

Nursing Professionals, per the California Board of Registered Nurses (provider # CEP17239), may receive a CEU Certificate. Other healthcare professionals will receive a Certificate of Attendance that they may submit to their regulatory body.

A special thank you to our EFACC Co-Directors


Katherine Anagnostou, MD


Russell Settipane, MD

Education Information

Target Audience

- Allergist-immunologists in clinical practice
- Fellows in Training (FIT) A-I programs
- Allied health professionals in the field of allergy-immunology

Learning Objectives

At the conclusion of this activity, participants should be able to:

- Formulate an appropriate treatment strategy for eosinophilic esophagitis
- Compare and contrast the risks and benefits of various forms of food immunotherapy
- Synthesize a treatment plan for intermittent, mild/moderate, and severe persistent asthma as comorbidities of food allergy
- Assess atopic dermatitis as a comorbidity of food allergy
- Utilize and optimally perform shared decision-making in food allergy management
- Integrate anaphylaxis preparedness and treatment in food allergy management

Accreditation

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of American College of Allergy, Asthma & Immunology and Eastern Food Allergy & Comorbidity Conference (EFACC). The American College of Allergy, Asthma & Immunology is accredited by the ACCME to provide continuing medical education for physicians.

Designation

The American College of Allergy, Asthma& Immunology (ACAAI) designates this live activity for a maximum of 16.75 *AMA PRA Category 1 Credits*^{TM}. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CBRN

The American College of Allergy, Asthma& Immunology (ACAAI) is a provider, approved by the California Board of Registered Nursing, Provider Number CEP17239, for 16.75 contact hours.

Claiming CME Credit

- Check your email. You will receive instructions from ACAAI one or two business days after the conclusion of the meeting.
- Go to education.acaai.org and log in with your ACAAI username and password.
- Under “Courses in Progress”, click on **EFACC 2026**.
- Complete the evaluation, claim your credit, and download your CME certificate.

NOTE: Credit must be claimed by the end of the current calendar year.

The College Learning Connection and your certificates are available 24/7 at education.acaai.org

If you need assistance, send an email to katyallen@acaai.org

Disclosure Policy and Disclosures

As required by the Accreditation Council for Continuing Medical Education (ACCME) and in accordance with the American College of Allergy, Asthma and Immunology (ACAAI) policy, all educational planners, presenters, instructors, moderators, authors, reviewer, and other individuals in a position to control or influence the content of an activity must disclose ALL financial relationships with any ineligible company. The ACCME defines an "ineligible company" (formerly commercial interest) as a company whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. (Examples of ineligible companies include: advertising, marketing, or communication firms whose clients are ineligible companies; bio-medical startups that have begun a governmental regulatory approval process; compounding pharmacies that manufacture proprietary compounds; device manufacturers or distributors; diagnostic labs that sell proprietary products; growers, distributors, manufacturers or sellers of medical foods and dietary supplements; manufacturers of health-related wearable products; pharmaceutical companies or distributors; pharmacy benefit managers; reagent manufacturers or sellers). For more information, visit accme.org.

Disclosure in no way implies that the information presented is biased or of lesser quality. It is incumbent upon course participants to be aware of these factors in interpreting the program contents and evaluating recommendations. Moreover, expressed views do not necessarily reflect the opinions of the ACAAI.

All identified relevant financial relationships with ineligible companies have been mitigated:

Katherine Anagnostou, MD - Planner, Speaker
Researcher - ALK, Aquestive, Novartis

Don Bukstein, MD - Facilitator
Speaker - Sanofi and Regeneron

Edmond Chan, MD - Speaker
Advisor - ALK, Novartis, Sanofi, Viatris
Researcher - DBV Technologies, ALK-Abello

Scott Commins, MD - Panelist
Advisor/Speaker - Genentech, Regeneron

Ray Davis, MD - Facilitator
Consultant - Regeneron, Sanofi, Grifols, AstraZeneca

Sandra Gawchik, DO - Moderator
Advisor - AstraZeneca
Speaker - AstraZeneca, Novartis

Disclosure Policy and Disclosures
continued

Matthew Greenhawt, MD - Speaker
Advisor - Nutricia, DBV, Novartis, Aquestive, Bryn, ALK
Speaker - ARS, Genentech

William Greisner, MD - Planner, Moderator
Independent Contractor - GSK, AstraZeneca, TEVA, Regeneron

Shahzad Mustafa, MD - Speaker
Speaker - Genentech, GSK, AstraZeneca, Regeneron/Sanofi, CSL Behring, ARS Pharma

Roxanne Oriel, MD - Speaker
Researcher - ALK, Allergy Therapeutics, DBV
Speaker - ARS Pharma, Genentech

Wanda Phipatanakul, MD - Speaker
Advisor, Speaker - Genentech, Novartis, Regeneron, Sanofi, AstraZeneca

Russell Settipane, MD - Planner, Speaker, Moderator, Reviewer
Advisor - AstraZeneca, GSK
Independent Contractor - AstraZeneca, Genentech, GSK, Regeneron
Speaker - Amgen, AstraZeneca, Genentech, GSK, Grifols, Novartis, Regeneron, Sanofi

Jonathan Tam, MD - Speaker
Researcher - DBV, Novartis
Speaker - ARS Pharma

Julia Upton, MD - Speaker
Advisor - DBV Technologies, ALK Abello, Pfizer, Pharming
Consultant - Viatris
Researcher - DBV Technologies, ALK Abello, Sanofi/Regeneron RAPT, Aquestive, Novartis

Richard Wasserman, MD - Speaker
Consultant, Speaker - Grifols

The following have no relevant financial relationships with ineligible companies to disclose:

Elissa Abrams, MD - Speaker
Sami Bahna, MD - Speaker
Tim Buckey, MD - Speaker
William Corrao, MD - Planner, Moderator
Jill Courcier - Coordinator
Katelyn Keedy, RN - Planner
Ginny Loiselle - Coordinator
Nicholas Rider, DO - Speaker
Robert Settipane, MD - Planner, Moderator, Reviewer

Sponsors

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Events at a Glance

Name badge required for all events.

Thursday, Jan 8	1 PM - 6 PM	Registration / Badge Pick Up	Flagler Hall
	3 PM - 6:30 PM	Plenary*	Grand Ballroom, Salon I
	6:30 PM - 7:15 PM	Product Theater *Sponsored by Genentech*	Grand Ballroom, Salon II
	7:15 PM - 8:15 PM	Reception**	Ocean Ballroom
Friday, Jan 9	6:30 AM - 1:30 PM	Registration / Badge Pick Up	Flagler Hall
	6:55 AM - 7:40 AM	Product Theater *Sponsored by Sanofi and Regeneron*	Grand Ballroom, Salon II
	7:45 AM - 8:55 AM	Plenary*	Grand Ballroom, Salon I
	8:55 AM - 10 AM	PBL Breakouts*	Ocean Ballroom
	10 AM - 10:45 AM	Coffee Break with Exhibits and Posters *Sponsored by DBV Technologies*	Grand Ballroom, Salon III
	10:45 AM - 12:30 PM	Plenary*	Grand Ballroom, Salon I
	12:35 PM - 1:20 PM	Product Theater *Sponsored by Incyte*	Grand Ballroom, Salon II
	1:25 PM - 3 PM	Plenary*	Grand Ballroom, Salon I
	7 PM - 8 PM	Reception**	Flagler Hall
Saturday, Jan 10	6:30 AM - 1:30 PM	Registration / Badge Pick Up	Flagler Hall
	6:55 AM - 7:40 AM	Product Theater *Sponsored by DBV Technologies*	Grand Ballroom, Salon II
	7:45 AM - 8:55 AM	Plenary*	Grand Ballroom, Salon I
	8:55 AM - 10 AM	PBL Breakouts*	Ocean Ballroom
	10 AM - 10:45 AM	Coffee Break with Exhibits and Posters *Sponsored by DBV Technologies*	Grand Ballroom, Salon III
	10:45 AM - 12:40 PM	Plenary*	Grand Ballroom, Salon I
	12:45 PM - 1:30 PM	Product Theater *Sponsored by Genentech*	Grand Ballroom, Salon II
	1:35 PM - 3:10 PM	Plenary*	Grand Ballroom, Salon I
	6:30 PM - 9:30 PM	Dinner Dance - Ticket Required	Grand Ballroom, Salon III
Sunday, Jan 11	7:25 AM - 8:10 AM	Product Theater *Sponsored by Sanofi and Regeneron*	Grand Ballroom, Salon II
	8:15 AM - 10:30 AM	Plenary*	Grand Ballroom, Salon I

**Registrants Only*

***Registrants, Paid Guests, and Corporate Sponsors only*

Program

Thursday, January 8

*All **CME sessions** will be held in the Grand Ballroom, Salon I.*

3:00 - 3:15 PM	**Welcome and meeting overview** Russell Settipane, MD, Katherine Anagnostou, MD
3:15 - 3:30 PM	**Journal of Food Allergy: Year-in-review** Katherine Anagnostou, MD
3:30 - 4:00 PM	**The multiple facets of milk allergy in infants** Jonathan Tam, MD
4:00 - 4:30 PM	**The confusing landscape of wheat hypersensitivities: Making the correct diagnosis** Sami Bahna, MD
4:30 - 4:45 PM	**Panel Discussion: Q & A**
4:45 - 5:15 PM	**A review of the 2025 food allergy literature: What can new evidence do for my practice?** Elissa Abrams, MD
5:15 - 5:45 PM	**All about food allergy therapies: What options should I be offering my patients in 2026?** Julia Upton, MD
5:45 - 6:15 PM	**Atopic Dermatitis: Quantifying patient suffering** Jonathan Tam, MD
6:15 - 6:30 PM	**Panel Discussion: Q & A**
6:30 - 7:15 PM	Product Theater *Not for CME / Grand Ballroom, Salon II*
7:15 - 8:15 PM	Reception *Not for CME / Ocean Ballroom*

Program

Friday, January 9

*All **CME sessions** will be held in the Grand Ballroom, Salon I.*

6:55 - 7:40 AM	Product Theater - Breakfast Served *Not for CME / Grand Ballroom, Salon II*
7:45 - 8:15 AM	**The role of AI in food allergy: How to navigate novel tools** Nicholas Rider, DO
8:15 - 8:45 AM	**Practical SLIT in food allergy: What is happening in the real world?** Edmond Chan, MD
8:45 - 8:55 AM	**Panel Discussion: Q & A**
8:55 - 10:00 AM	**PBL: A 7-year-old with food allergies and comorbid asthma** Ray Davis, MD, Don Bukstein, MD, Russell Settipane, MD
10:00 - 10:45 AM	Coffee Break - Visit exhibits and posters *Not for CME / Grand Ballroom, Salon III*
10:45 - 11:15 AM	**Eosinophilia and food allergy: A practical approach** Richard Wasserman, MD
11:15 - 11:45 AM	**When and how to address significantly elevated IgE levels in food allergy** Julia Upton, MD
11:45 AM - 12:15 PM	**Food allergy and asthma: Management overview** Wanda Phipatanakul, MD
12:15 - 12:30 PM	**Panel Discussion: Q & A**
12:35 - 1:20 PM	Product Theater - Lunch Served *Not for CME / Grand Ballroom, Salon II*
1:25 - 1:55 PM	**Oral food challenges: A practical approach** Roxanne Oriel, MD
1:55 - 2:20 PM	**Biologics for asthma: What to use and when?** Wanda Phipatanakul, MD
2:20 - 2:50 PM	**Safety of biologics in food allergy: What our patients need to know** Shahzad Mustafa, MD
2:50 - 3:00 PM	**Panel Discussion: Q & A**
7:00 - 8:00 PM	Reception *Not for CME / Flagler Hall*

Program

Saturday, January 10

*All **CME sessions** will be held in the Grand Ballroom, Salon I.*

6:55 - 7:40 AM	Product Theater - Breakfast Served *Not for CME / Grand Ballroom, Salon II*
7:45 - 8:15 AM	**Adult food allergy** Shahzad Mustafa, MD
8:15 - 8:45 AM	**Food pollen syndrome: An overview** Edmond Chan, MD
8:45 - 8:55 AM	**Panel Discussion: Q & A**
8:55 - 10:00 AM	**PBL: A 26-year-old with food allergy and recurrent anaphylaxis** Ray Davis, MD, Don Bukstein, MD, Russell Settipane, MD
10:00 - 10:45 AM	Coffee Break - Visit exhibits and posters *Not for CME / Grand Ballroom, Salon III*
10:45 - 11:15 AM	**Anaphylaxis case management** Elissa Abrams, MD
11:15 - 11:30 AM	**Benefits of "watching and waiting" after epinephrine is administered** Richard Wasserman, MD
11:30 - 11:45 AM	**Risks of "watching and waiting" after epinephrine is administered** Sami Bahna, MD
11:45 AM - 12:15 PM	**Choosing the right epinephrine device for the right food-allergic patient** Matthew Greenhawt, MD
12:15 - 12:40 PM	**Panel Discussion: Q & A *(with Abrams, Wasserman, Bahna, Greenhawt, and Scott Commins, MD)***
12:45 - 1:30 PM	Product Theater - Lunch Served *Not for CME / Grand Ballroom, Salon II*
1:35 - 2:05 PM	**An updated action plan for anaphylaxis** Katherine Anagnostou, MD
2:05 - 2:30 PM	**Discussing the omalizumab option in a shared decision-making conversation with your food allergy patients** Jonathan Tam, MD
2:30 - 3:00 PM	**Navigating EoE therapies: A practical approach** Matthew Greenhawt, MD
3:00 - 3:10 PM	**Panel Discussion: Q & A**
6:30 - 9:30 PM	Dinner Dance - Ticket Required *Not for CME / Grand Ballroom, Salon III*

Program

Sunday, January 11

*All **CME sessions** will be held in the Grand Ballroom, Salon I.*

7:25 - 8:10 AM	Product Theater - Breakfast Served *Not for CME / Grand Ballroom, Salon II*
8:15 - 8:45 AM	**Addressing food allergy misconceptions** Tim Buckey, MD
8:45 - 9:15 AM	**Food allergy OIT: What happens 5 and 10 years down the line?** Katherine Anagnostou, MD
9:15 - 9:45 AM	**Mild food allergy and thresholds** Roxanne Oriel, MD
9:45 - 10:15 AM	**EoE: Managing challenging cases** Tim Buckey, MD
10:15 - 10:30 AM	**Panel Discussion: Q & A**

Product Theaters / Non-CME Program

For full conference registrants only. Not for CME credit. Entrance requires scanning your name badge. By attending, you consent to the sharing of your contact information.

All product theaters will be held in the Grand Ballroom, Salon II.

Thursday, January 8

6:30 PM - 7:15 PM
Clinical Food Allergy Exchange: Perspectives on Diagnosis, Treatment, and Transitions
Speakers: Douglas Mack, MD: Katherine Anagnostou, MD; Shahzad Mustafa, MD
Sponsored by: Genentech

Friday, January 9

6:55 AM - 7:40 AM
Eosinophilic Esophagitis: Clinical Implications of Disease Progression
Speaker: John Leung, MD
Sponsored by: Sanofi and Regeneron
Breakfast served

12:35 PM - 1:20 PM
Mild to Moderate Atopic Dermatitis in your Practice; Burden of Disease and a Topical Pathway for JAK Inhibition
Speaker: Ellen Sher, MD
Sponsored by: Incyte
Lunch served

Saturday, January 10

6:55 AM - 7:40 AM
Exploring the Potential of Epicutaneous Immunotherapy (EPIT) to Re-educate the Immune System in Food Allergy
Speakers: Jay Lieberman, MD; Julia Upton, MD; Travis Miller, MD
Sponsored by: DBV Technologies
Breakfast served

12:45 PM - 1:30 PM
A Therapeutic Option For IgE-Mediated Food Allergy
Speaker: Scott Commins, MD
Sponsored by: Genentech
Lunch served

Sunday, January 11

7:25 AM - 8:10 AM
Transform the Way You Manage Eosinophilic Esophagitis (EoE)
Speaker: Scott Commins, MD
Sponsored by: Sanofi and Regeneron
Breakfast served

Abstract Directory

Posters will be on display in the Grand Ballroom, Salon III.
Not for CME credit.

1	**VIASKIN® Peanut Patch for Treatment of Peanut Allergy in Toddlers Aged 1 Through 3 Years: EPITOPE Open-Label Extension and COMFORT Toddlers Studies** *Funded by: DBV Technologies*
2	**VITESSE Phase 3 Study of Epicutaneous Immunotherapy for the Treatment of Peanut Allergy in Children** *Funded by: DBV Technologies*
3	**Dupilumab Efficacy in Adolescents and Adults with Eosinophilic Esophagitis with and Without Concurrent Elimination Diet: Post Hoc Analysis of LIBERTY EoE TREET at 52 Weeks** *Funded by: Sanofi and Regeneron*
4	**Dupilumab is Efficacious in Children with Eosinophilic Esophagitis Weighing ≥15kg Independent of Individual Atopic Comorbidity History: 16-Week Results from the Phase 3 EoE KIDS Study** *Funded by: Sanofi and Regeneron*
5	**Epinephrine Delivered via Sublingual Film (Anaphylm™) Elicits Rapid and Consistent Pharmacokinetic and Pharmacodynamic Responses** *Funded by: Aquestive Therapeutics, Inc.*
6	**The Physicochemical Properties of Anaphylm™ Under Extreme Temperatures and Real-World Conditions** *Funded by: Aquestive Therapeutics, Inc.*
7	**Process Optimization to Improve Total Protein Yield of Peanut Extract for Skin Prick Testing** *Funded by: ALK Abello, Inc.*
8	**Health-related quality of life in patients with food allergy – analysis of associated factors** *Funded by: ARS Pharmaceuticals Operations, Inc.*
9	**Ease of use demonstrated in real world use of epinephrine nasal spray** *Funded by: ARS Pharmaceuticals Operations, Inc.*
10	**Stability of epinephrine nasal spray under freeze, thaw and extreme temperatures** *Funded by: ARS Pharmaceuticals Operations, Inc.*

Abstracts

Not for CME credit.

1

VIASKIN® Peanut Patch for Treatment of Peanut Allergy in Toddlers Aged 1 Through 3 Years: EPITOPE Open-Label Extension and COMFORT Toddlers Studies

Authors: Matthew Greenhawt, MD; Julie Wang, MD; George Du Toit, MBBCh; Michael O'Sullivan, MD; Terri Brown-Whitehorn, MD; Timothée Bois, MSc; Katharine J. Bee, PhD; Todd D. Green, MD; Hugh A. Sampson, MD; A. Wesley Burks, MD

Introduction:
The VIASKIN® peanut patch (VP250) is currently being studied as a potential treatment option for peanut-allergic toddlers aged 1 through 3 years, with efficacy and safety data from the completed EPITOPE study and ongoing COMFORT Toddlers study. The 12-month, phase 3 EPITOPE study of epicutaneous immunotherapy with VP250 demonstrated a statistically significant treatment effect with a favorable safety profile in children aged 1 through 3 years. Here we report end-of-study results, after 36 months of treatment, from the open-label extension (OLE).

Methods:
After 12 months of VP250 or placebo in EPITOPE, participants were eligible to enroll in the OLE for up to 3 years of total active treatment, with annual double-blind, placebo-controlled food challenges (DBPCFCs) and safety assessments. The phase 3 COMFORT Toddlers safety study is randomizing ~480 participants 3:1 to receive 6 months of VP250 or placebo, followed by an optional 18-month OLE study.

Results:
In the EPITOPE OLE, 204 participants completed 3 years of active treatment. Increases were observed at Month (M) 36 vs M12 in the percentage of participants reaching an eliciting dose (ED) ≥1000 mg (83.5% vs 64.2%), ED ≥2000 mg (72.7% vs 37.0%), and those completing the DBPCFC without meeting stopping criteria (68.2% vs 30.7%). Similar increases were observed in those initially randomized to placebo, though the treatment effect was lower in magnitude. Additionally, continued reduction in DBPCFC reaction severity occurred, with 66.6% having no/mild symptoms at M36 vs 36.5% at M12. No treatment-related anaphylaxis or serious treatment-related adverse events occurred during year 3.

Conclusions:
Three years of VP250 in peanut-allergic toddlers showed continued accumulated treatment benefit and a consistent safety profile. Together with the anticipated supplemental safety data from COMFORT Toddlers, these results contribute to a robust clinical dataset to support VP250 as a potential treatment option for young children with peanut allergy, if approved.

Funded by: DBV Technologies

2

VITESSE Phase 3 Study of Epicutaneous Immunotherapy for the Treatment of Peanut Allergy in Children

Authors: David M. Fleischer; Julie Wang; Jeffrey Leflein; Michael O'Sullivan; Juan Trujillo; Anne-Sophie Chhim; Katharine J. Bee; Douglas P. Mack

Background:
Epicutaneous immunotherapy (EPIT) with VIASKIN® peanut patch containing 250 µg peanut protein (VP250) demonstrated statistically significant desensitization in peanut-allergic children aged 4 through 11 years in the phase 3 PEPITES trial. Post hoc analysis revealed a greater treatment effect in younger ages; thus, the efficacy and safety of VP250 is being investigated in children aged 4 through 7 years in the ongoing double-blind, placebo-controlled (DBPC) phase 3 VITESSE study. Here, we present VITESSE baseline demographics and patient characteristics.

Methods:
Participants were randomized 2:1 to VP250 or placebo for 12 months, followed by an open-label extension. Eligibility criteria included peanut-specific immunoglobulin E (PNsIgE) >0.7 kUA/L, peanut skin prick test (SPT) >6 mm, and eliciting dose (ED) of ≤100 mg peanut protein. The primary efficacy endpoint is the proportion of treatment responders in the VP250 group vs placebo, as defined by prespecified increases in ED between DBPC food challenges at baseline and Month 12. Safety is being assessed throughout the study.

Results:
654 children (57% 4- to 5-year-olds; 43% 6- to 7-year-olds; 62% male; 66% Caucasian [self-reported]) were randomized. At baseline, median ED was 30 mg, median PNsIgE was 39.7 kUA/L, and median peanut SPT was 11 mm. Allergic comorbidities were common (618/654, 94%): 68% other food allergies, 77% eczema/atopic dermatitis, 51% allergic rhinitis, and 36% asthma. The median age at diagnosis of peanut allergy was 12 months. 566 participants (87%) had a history of reactions to peanut consumption, and 146 (22%) reported prior epinephrine use.

Conclusions:
The VITESSE study cohort reflects the general population of peanut-allergic children aged 4 through 7 years, including a high frequency of allergic comorbidities. The DBPC period of the VITESSE trial was recently completed and topline data will be presented at upcoming scientific meetings.

Funded by: DBV Technologies

3

Dupilumab Efficacy in Adolescents and Adults with Eosinophilic Esophagitis with and Without Concurrent Elimination Diet: Post Hoc Analysis of LIBERTY EoE TREET at 52 Weeks

Authors: Antonella Cianferoni, MD, PhD; Kathryn Peterson, MD, MS; Eric E. Low, MD; Changming Xia, PhD; Sherif Zaghloul, MD; Bram Raphael, MD; James Angello, PharmaD; Amr Radwan, MD, FFPM

Introduction:
Eosinophilic esophagitis (EoE) is a chronic, progressive, non-Immunoglobulin E (IgE) immune/antigen-mediated type 2 inflammatory disease. Food elimination diets (FEDs) are an established EoE treatment, but it is not known whether concurrent FED impacts medication efficacy. This analysis assessed the efficacy of dupilumab in patients with EoE with/without concurrent FED during LIBERTY EoE TREET (NCT03633617).

Methods:
In Part B, patients received dupilumab 300 mg or placebo weekly until Week (W) 24. Patients entering Part C received dupilumab 300 mg weekly until W52. Patients on FED at screening were instructed to continue FED throughout the study. Endpoints analyzed with/without concurrent FED at W24 and W52 included proportion of patients achieving ≤6 eosinophils per high-power field (eos/hpf) and absolute mean change from baseline in Dysphagia Symptom Questionnaire (DSQ) score, Endoscopic Reference Score (EREFS), and EoE Histologic Scoring System (EoE-HSS) grade/stage.

Results:
At screening, 89 (37.1%) patients were on an FED. At W24, the proportion of patients achieving ≤6 eos/hpf (95% CI) with concurrent FED (dupilumab vs placebo: 61.3% [42.2, 78.2] vs 3.4% [0.1, 17.8]) was comparable to those without concurrent FED (57.1% [42.2, 71.2] vs 8.0% [2.2, 19.2]). Absolute mean change in DSQ score (Standard Error [SE]) with concurrent FED (–26.25 [2.93] vs –18.27[3.13]) was comparable to without concurrent FED (–21.43 [2.37] vs –10.39 [2.50]). Results were similar for EREFS and EoE-HSS grade/stage. At W52, improvements in EoE endpoints were maintained in patients continuing dupilumab independent of FED status, and those switching to dupilumab demonstrated similar improvements.

Conclusions:
Dupilumab improved histologic, symptomatic, and endoscopic features of EoE in adolescents and adults independent of concurrent FED.

Funded by: Sanofi and Regeneron

4

Dupilumab is Efficacious in Children with Eosinophilic Esophagitis Weighing ≥15kg Independent of Individual Atopic Comorbidity History: 16-Week Results from the Phase 3 EoE KIDS Study

Authors: Antonella Cianferoni, MD, PhD; Mirna Chehade, MD; Benjamin David Gold, MD, FAAP, FACG; Seema Aceves, MD, PhD; Changming Xia, PhD; Sherif Zaghloul, MD; Bram Raphael, MD; James Angello, Pharma D; Amr Radwan, MD

Introduction:
Eosinophilic esophagitis (EoE) is a chronic disease characterized by type 2 inflammation. Many patients with EoE experience atopic comorbidities due to shared etiologic mechanisms. This analysis aimed to assess the efficacy of weight-tiered dupilumab vs placebo in children aged 1–11 years weighing ≥15kg with EoE from the phase 3 EoE KIDS trial, according to baseline history of individual atopic comorbidities which included atopic dermatitis (AD), asthma, allergic rhinitis (AR), and food allergy (FA).

Methods:
Endpoints included proportions of patients achieving peak eosinophil count (PEC) ≤6 and <15 eosinophils per high-power field (eos/hpf), mean change in Endoscopic Reference Score (EREFS); and mean change in Histology Scoring System (HSS) grade and stage scores (Week 16). Rate differences are based on the Cochran-Mantel-Haenszel method.

Results:
At baseline, 84/87 (96.6%) patients in the ≥15kg subgroup had ≥1 atopic comorbidity. At Week 16, dupilumab led to greater proportions achieving PEC ≤6 eos/hpf regardless of individual atopic comorbidities when analyzed separately (rate difference vs placebo [95% CI]: AD: yes- 73.7% [53.9–93.5], no-45.5% [14.2–76.8]; asthma: yes-53.7% [29.7–77.8], no-77.8% [50.6–100.0]; AR: yes-60.1% [39.3–81.0], no-66.7% [29.0–100.0]; FA: yes-61.0% [40.9–81.1], no-66.7% [29.0–100.0]). Dupilumab treatment also led to greater proportions achieving PEC <15 eos/hpf and improved EREFS and HSS grade and stage scores vs placebo in all subgroups.

Conclusions:
Dupilumab improved features of EoE vs placebo in children aged 1–11 years weighing ≥15kg, regardless of baseline history of individual atopic comorbidities when analyzed separately.

Funded by: Sanofi and Regeneron

Abstracts

Not for CME credit.

5

Epinephrine Delivered via Sublingual Film (Anaphylm™) Elicits Rapid and Consistent Pharmacokinetic and Pharmacodynamic Responses

Authors: Carl Kraus, MD; Nils Confer, PhD; David Golden, MD; David Bernstein, MD; Matthew Greenhawt, MD

Introduction:
Epinephrine is the first-line treatment for severe allergic reactions, including anaphylaxis. Prompt, reliable treatment is critical for patient outcomes. Anaphylm is a sublingual film containing a novel prodrug of epinephrine in development for the treatment of Type I allergic reactions, including anaphylaxis.

Methods:
A phase 3 cross-over trial (AQ109301) was conducted in 64 healthy adults evaluating the pharmacokinetics (PK, including time to peak plasma concentration [T_{max}]) and pharmacodynamics (PD, heart rate [HR], systolic [SBP] and diastolic blood pressure [DBP]) of Anaphylm compared to epinephrine autoinjectors (EAI) and manual intramuscular epinephrine injection (IM).

Results:
After single dose administration, the T_{max} variability as reflected by interquartile range (IQR) was 5.0 minutes (min) for Anaphylm (median T_{max} 12 min), 23.5 min for EpiPen (median T_{max} 20 min), 32.0 min for Auvi-Q (median T_{max} 30 min), and 15.0 min for manual IM injection (median T_{max} 50 min). After Anaphylm administration, clinically meaningful changes in median SBP, DBP, and HR were seen in 5 minutes (>10mmHg), 5 minutes (>10mmHg), and 8 minutes (>10bpm), respectively.

Conclusion:
Anaphylm data demonstrates a more rapid and consistent PK profile in comparison to EAIs and IM. Moreover, Anaphylm's PD profile showed clinically relevant increases in SBP, DBP, and HR. These results further support the development of sublingual epinephrine film as a reliable needle-free alternative for the treatment of Type I allergic reactions, including anaphylaxis.

Funded by: Aquestive Therapeutics, Inc.

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The Physicochemical Properties of Anaphylm™ Under Extreme Temperatures and Real-World Conditions

Authors: Nils Confer, PhD; Vincent Buono; Gregory Tsodikov; Carl Kraus, MD

Introduction:
During an emergency allergic reaction, access to and prompt administration of epinephrine correlates with improved patient outcomes. In support, the drug product and packaging must withstand extreme temperatures and real-world conditions resulting from varied lifestyles in which the emergency use medication needs to be available. Anaphylm is a sublingual film that contains a novel prodrug of epinephrine packaged with the intent to support each potential patient use situation.

Methods:
Packaging and drug product were subjected to temperatures outside of acceptable storage conditions (excursions) followed by long-term storage. Additional testing involved exposure to water submersion and fold endurance. Package integrity and retained drug product potency were evaluated, as were dissolution profiles when either at elevated or freezing temperatures.

Results:
Potency prior to temperature exposures was 102.2% LC. After exposure to 50°C for 28 days, potency was 97.7% LC and 96.9% LC after 12 months at 25°C/60% RH post-excursion. After exposure to 60°C for 21 days, potency was 97.3% LC and 95.2% LC after 12 months at 25°C/60% RH post-excursion. After exposure to 70°C for 7 days, the potency was 96.6% LC and 91.7% LC after 12 months at 25°C/60% RH post-excursion. When frozen and thawed to 25°C, 40°C, and 60°C, the potency after 12 months at 25°C/60% RH post-excursion was 98.0%, 100.7%, and 99.0%, respectively. When submerged in 25°C water for 7 days or 60°C water for 30 or 60 minutes, no significant change in water content was observed. Fold tests did not reduce packaging integrity or film usability. Dissolution tests immediately after freezing to -80ºC or heating to 70ºC demonstrated consistent drug release.

Conclusion:
Anaphylm demonstrated desirable physicochemical properties regarding both packaging and film stability. Performance attributes suggest that Anaphylm has the potential to be a unique epinephrine rescue medication with stability and usability properties not possible with liquid-based epinephrine products.

Funded by: Aquestive Therapeutics, Inc.

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Process Optimization to Improve Total Protein Yield of Peanut Extract for Skin Prick Testing

Authors: Jerry Huang, PharmD; Mark Anton, MS; Inna Borinskikh, MBA; William Drewes, BS

Introduction:
Peanut allergy is a common condition that can cause severe systemic allergic reactions. Production of peanut extract for use in skin prick testing for peanut allergy diagnosis necessitates a reliable and consistent process. The historical methodology for producing peanut extract has several limitations, including variability in protein yield. The primary objective of this investigation was to identify a process that improves the total protein yield of peanut extract for use in skin prick testing for peanut allergy diagnosis.

Methods:
Four separate batches of peanut extract for skin prick testing were produced using the same defatted raw material (Arachis hypogaea [Ara h]). Each batch followed a unique process:

- Process I (historical method): Dialysis, utilizing a 1:5 weight-to-volume (w/v) ratio of peanut kernel to aqueous extraction solution.
- Process II: No dialysis, utilizing a 1:5 w/v ratio of peanut kernel to aqueous extraction solution.
- Process III: No dialysis, utilizing a 1:10 w/v ratio of peanut kernel to glycerin extraction solution.
- Process IV: No dialysis exchange, utilizing a 1:5 w/v ratio of peanut kernel to aqueous extraction solution.

Final compounding was performed for all processes into a 1:10 w/v glycerinated solution. Total protein was quantified by Bradford assay, and protein visualization was by SDS-Page.

Results:
Compared with process I, processes II, III, and IV changed the total protein content by −8%, +214%, and +61%, respectively. All 4 processes produced extracts with similar protein profiles and contained the proteins Ara h1, Ara h2, and Ara h3, indicating similarity across the different methodologies.

Conclusions:
Process III yielded the extract with the highest concentration compared with the historical process and contained diagnostically-relevant peanut allergens. Further investigations are necessary to assess the scalability of this process.

Funded by: ALK Abello, Inc.

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Health-related quality of life in patients with food allergy – analysis of associated factors

Authors: Anna Nowak-Wegrzyn, MD, PhD; Priya Bansal, MD; Jonathan M. Spergel, MD; Margie Stelwagon; Sarina Tanimoto, MD, PhD

Introduction:
Food allergies place a substantial burden on patients/caregivers, often impacting health-related quality of life (HRQOL). We evaluated HRQOL in food-allergic patients and families, and explored associated factors.

Methods:
We conducted a web-based survey of adults with severe allergies to food/venom/drug and adult caregivers of allergic children seen by healthcare providers (HCPs) within the past 3 years. HRQOL was assessed using the FAQLQ-12 (adult patients) and SOFAA-P-brief (caregivers) and analyzed by epinephrine status: "Current" (prescribed/refilling); "Lapsed" (previously prescribed, not refilling), and "Naïve" (never prescribed/filled), and by needle fear (7-scale: "not at all" to "extremely") and time since the most recent severe allergic reaction (SAR).

Results:
Of 400 respondents, 374 reported food allergies (n=190/184, adult patients/caregivers); 317 were Current epinephrine users (n=147/170, adult/caregiver), 39 Lapsed (29/10, adult/caregiver), and 18 Naïve (14/4, adult/caregiver). Mean Total FAQLQ-12 scores (SD) (higher = worse QoL), were higher for Current users (4.3±1.2) compared with Lapsed (3.7±1.3, $p<0.05$) or Naïve (3.4±1.7, $p<0.01$). Participants reporting quite-to-severe needle fear had worse HRQOL (4.6±1.1/2.5±0.9, FAQLQ-12/SOFAA-P-brief) compared with those reporting somewhat-to-no fear (4.0±1.3/2.2±0.8, $p<0.01$/$p<0.05$). More recent SAR (<1 year) was associated with worse HRQOL (4.3±1.3/2.3±0.8) compared with SAR ≥1 year (3.9±1.3/2.5±1.0, n.s./n.s.). The proportion of Current users declined with increasing time since last SAR.

Conclusion:
HRQOL was worse among respondents with current epinephrine prescription, those reporting needle fear and recent SAR, highlighting the importance of addressing patient anxiety alongside ensuring epinephrine access.

Funded by: ARS Pharmaceuticals Operations, Inc.

Abstracts

Not for CME credit.

9

Ease of use demonstrated in real world use of epinephrine nasal spray

Authors: Thomas B. Casale, MD; Jonathan M. Spergel, MD; David I. Bernstein, MD; Sarina Tanimoto, MD

Introduction:
An epinephrine nasal spray is the first FDA-approved needle-free epinephrine product for treatment of severe allergic reactions/anaphylaxis. A series of randomized clinical trials demonstrated that epinephrine nasal spray is pharmacokinetically and pharmacodynamically comparable to or better than intramuscular epinephrine. Although large-scale efficacy studies during anaphylaxis are limited by ethical and practical considerations, efficacy has been demonstrated in a Phase 3 oral food challenge and supported by case reports and clinician feedback.

Methods:
As part of the "***neffyExperience***" survey conducted by ARS, health care providers (HCPs) received six doses of epinephrine nasal spray (1 and/or 2 mg) to treat allergic reactions requiring epinephrine. The survey captured the number of patients treated, the number of patients requiring a second dose, and ease of use and patient comfort relative to injection. Ease of use and patient comfort were rated on a 7-point scale (1 = "much harder/worse" and 7 = "much easier/better").

Results:
Among 2,947 participating HCPs, 375 completed the survey. As of September 2025, 680 patients were treated with epinephrine nasal spray (14 with 1 mg and 666 with 2 mg), typically following allergen immunotherapy or oral food challenges. Approximately 10% of patients required a second dose, all of whom demonstrated complete therapeutic response. Ease of use versus injection was rated as "much easier" by 86.7% of HCPs and patient comfort was rated "much better" by 77.8% of HCPs. Adverse events reported during the period included headache, nasal discomfort/pain, and epistaxis.

Conclusion:
Real-world use of epinephrine nasal spray demonstrated effectiveness consistent with epinephrine injections, with high ease-of-use and patient comfort ratings.

Funded by: ARS Pharmaceuticals Operations, Inc.

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Stability of epinephrine nasal spray under freeze, thaw and extreme temperatures

Authors: David B. K. Golden MDCM; Stacy K. Silvers MD; Priya Bansal MD; Richard Lowenthal, PhD MBA; Brian T. Dorsey, MSc; Blake Burrell, MS; Sarina Tanimoto MD, PhD

Introduction:
Severe allergic reactions typically occur outside healthcare settings and require patients/caregivers to respond quickly to avoid serious complications. To be rapidly accessible in any location, it is vital that epinephrine delivery devices be able to withstand a wide range of environmental conditions, including extreme temperatures. The stability of an epinephrine nasal spray was evaluated during freeze/thaw cycles and following extended exposure to extreme heat.

Methods:
Intranasal epinephrine samples were subjected to five consecutive 24- to 72-hour freeze/thaw cycles ranging from freezing (-20°C/-4°F) to extreme heat (40°C/104°F). Heat stability was also assessed relative to other epinephrine products. Products were kept at 50°C/122°F for 3 months or 40°C/104°F for 6 months, with a reference condition of 25°C/77°F.

Results:
Following the five freeze/thaw cycles, intranasal epinephrine potency ranged from 103.6% (Day 2) to 103.3% (Day 14) of labeled potency. After 3 months at 50°C/122°F, potency decreased by 56.6% for pre-filled syringes, 41.6% for autoinjectors, and 8.6% for intranasal epinephrine. After 6 months at 40°C/104°F, potency decreased by 27.5% for autoinjectors, 17.2% for pre-filled syringes, and 13.9% for intranasal.

Conclusions
Intranasal epinephrine potency was not affected by extreme temperature fluctuations (-20/-4 to 40°C/104°F) or by multiple freeze/thaw cycles and remained within specifications for potency under extreme temperature conditions after 3-months at 50°C/122°F or 6-months at 40°C/104°F. While intranasal epinephrine is unlikely to have reduced efficacy following exposure to extreme high or low temperatures that mimic real world exposures and boosting confidence in use throughout its 24 to 30 month shelf-life, patients/caregivers should always carry devices with them.

Funded by: ARS Pharmaceuticals Operations, Inc.

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