Biologic Drugs: Innovative Treatments to Target Food Allergy

Presented by
Thomas B. Casale, MD

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Today’s Presenter

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Biologics for Food Allergy

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Objectives

• To provide an overview of the biology of allergic reactions and illustrate how biologics work

• To discuss the therapeutic potential of biologics for Food Allergy
Unmet Treatment Need in Food Allergy

**Current Standard of Care**

- **Strict Avoidance**
- **Management of Reactions** (e.g., epinephrine, antihistamines)

**Primary Prevention**
- Early introduction to prevent development of food allergy

**Investigational Treatments**
- Several immunotherapy treatments under clinical investigation
- Other approaches, such as biologics and vaccines, in early investigation
The Risk of Accidental Exposure Is Constant and Widespread

Avoidance is difficult to achieve and requires the participation of a variety of stakeholders

Patients with food allergy and their caregivers experience tremendous anxiety and stress, and report poor quality of life

- Birthday and other parties: Particularly when children are younger and will eat what is given to them
- Friends and family: Some report “well-meaning” family insisting a little bite of peanut won’t hurt
- Social activities: Young children especially can share snacks without adults knowing
- Packaged foods: Labels can be hard to comprehend; risk can be mistakenly assigned based on precautionary allergen labeling
- School: Substitute teachers, lunch rooms and other parents are all sources of stress

Patients may feel restricted in where they go and/or where they live due to fear of accidental exposure
Caregivers frequently miss work to help manage the safety of the places that their loved ones visit

Immunotherapy Strategies Aim to Balance Efficacy, Safety and Practicality\textsuperscript{1,2}

The goal of food immunotherapy is to safely protect against reactions due to accidental exposure with minimal disruption to daily life.

Biologics Defined

**Biologic** drugs (**biologics**) are products that are produced from living organisms or contain components of living organisms.

**Biologic** drugs include a wide variety of products derived from humans, animals, or microorganisms by using biotechnology.

**Biologics** are genetically engineered proteins that target specific parts of the immune system that fuel inflammation.
Food Allergy Biologics in Development: Monoclonal Antibodies
Biologics for Asthma and Non-Asthma Conditions

• Approved Indications:
  • Asthma: omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab
  • Atopic dermatitis (eczema): dupilumab
  • Chronic rhinosinusitis with nasal polyps: dupilumab
  • Chronic spontaneous urticaria / chronic idiopathic urticaria (chronic hives with unknown cause): omalizumab
  • Eosinophilic granulomatosis with polyangiitis (vasculitis): mepolizumab

• Experimental/In Development
  • Food allergy
  • Chronic obstructive pulmonary disease (COPD)
  • Allergic rhinoconjunctivitis/ allergic rhinitis
  • Allergic bronchopulmonary aspergillosis (ABPA)
  • Eosinophilic esophagitis
IgE-Dependent Release of Inflammatory Mediators
Leading to Early/Acute Allergic Symptoms

Immediate Release
Preformed Mediators:
Histamine, TNF-α,
Proteases, Hydrolases,
Proteoglycans (Heparin)

Over Minutes
Lipid mediators:
Prostaglandins
Leukotrienes
Thromboxanes

Over Hours
Cytokine production:
ILs-3, 4, 5, 6, 8, 9, 11, 13
TNF-α, MIP1, MCP

Acute Symptoms
Mucus Production
Edema
Bronchoconstriction
Abdominal Distress
Cardiovascular Effects

Chronic Inflammation
Food Allergy Targets for Biologics

Vickery et al, JACI IP, 02/2019
Biologic Clinical Trials Ongoing or Planned

• Omalizumab alone/adjunct to OIT
  • OUTMATCH: Omalizumab + Multi OIT
• Dupilumab alone/adjunct to OIT+/− Omalizumab
• Anti-IL-33 +/- OIT
• Anti-ST2+/− OIT
• Anti-IL-5
• Anti-IL-13
• Anti-TSLP
• DNA vaccines and novel allergen immunotherapy approaches
Omalizumab binds to circulating IgE\(^1\):

- ↓ amount of IgE available to interact with Fc\(\varepsilon\)RI on mast cells and basophils surfaces
- ↓ IgE/Fc\(\varepsilon\)RI interactions results in a decreased expression of Fc\(\varepsilon\)RI

As a result, mast cells and basophils exhibit reduced degranulation in response to an allergen

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FcgRI=high affinity IgE receptor.
Mean Threshold Dose (±95% CI) to Peanut

- Placebo
- 450 mg dose group vs. placebo, p<0.001 (log₁₀-transformed data)

~25% could ingest 8 gm
~25% were no better

Effects of TNX-901 on Peanut Allergy

## Omalizumab as Monotherapy

<table>
<thead>
<tr>
<th>Reference/Age (median)</th>
<th>Patients</th>
<th>Treatment Regimen</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampson et al 2011¹</td>
<td>14 peanut-allergic&lt;br&gt;9 treated, 5 placebo</td>
<td>q2–4 weeks for 24 weeks vs placebo</td>
<td>Increase threshold dose compared with baseline&lt;br&gt;Study terminated due to 2 severe reactions during entry DBPCFC</td>
</tr>
<tr>
<td>18–44 years (19)</td>
<td></td>
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<tr>
<td>Savage et al 2012²</td>
<td>14 peanut-allergic&lt;br&gt;All treat with OMA</td>
<td>q2–4 weeks for 24 weeks</td>
<td>Increased median tolerated dose from 80 mg to 6500 mg at week 5&lt;br&gt;4/14 tolerated full 10,000 mg at week 24</td>
</tr>
<tr>
<td>18–44 years (23)</td>
<td></td>
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<tr>
<td>Brandström et al 2017³</td>
<td>23 peanut-allergic&lt;br&gt;All treated with OMA</td>
<td>q2–4 weeks for 1–4 8-week cycles&lt;br&gt;Dose adjusted based on basophil activation test</td>
<td>15/23 (65%) were able to tolerate full dose (2800 mg) after OMA&lt;br&gt;All ingested at least 840 mg</td>
</tr>
<tr>
<td>12–19 years (17)</td>
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<tr>
<td>Fiocchi et al 2019⁴</td>
<td>15 multi-food allergic&lt;br&gt;(or single if failed OIT)&lt;br&gt;All treated with OMA for asthma</td>
<td>q2–4 weeks for 16 weeks</td>
<td>Mean increase in threshold from 1013 mg to 8727 mg (milk, egg, wheat, hazelnut)&lt;br&gt;70% tolerated complete OFC dose and able to reintroduce into diet without OIT</td>
</tr>
<tr>
<td>8–23 years (12)</td>
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</tbody>
</table>

Content courtesy of Dr. David Fleischer, University of Colorado Denver School of Medicine Aurora, CO. DBPCFC=double-blind, placebo-controlled food challenge; OFC=oral food challenge; OMA=omalizumab; q=every.

Omalizumab increased the median tolerated threshold dose of peanut protein from 80 mg at baseline to 6500 mg at week 5 ($P=0.002$) and 5080 mg at week 24 ($P=0.005$).

4 patients were able to tolerate the full 10,000 mg peanut protein challenge dose at weeks 5 and 24.

Symptoms recorded during OFCs did not appear to change during treatment, although it took a higher oral dose of allergen to elicit gastrointestinal (local) and nongastrointestinal (systemic) symptoms during OFC 2.

### Study design
- Observational, real-life, efficacy study
- In patients with severe asthma (n=15), food allergen thresholds (2+ foods) were evaluated before and after a 4-month treatment with omalizumab
- Control of asthma and patient quality of life (PedsQL) were also evaluated

### Patient population
- Median age: 12 years
- Total IgE: 208–1491 kU/L
- Median (range) ACT: 16 (9–19)
- Baseline PedsQL (median): Parent, 61; Patient, 65

### Primary endpoints
- Tolerance threshold to foods (TTF); full TTF defined as:
  - Cow’s milk: 144.4 mL (4700 mg of protein)
  - Baked milk: 80 g (6960 mg of protein)
  - Hen’s egg: two 45 g eggs (11,160 mg of protein)
  - Baked egg: 80 g (9520 mg of protein)
  - Hazelnut: 64 g (8847.5 mg of proteins)
  - Wheat: 220 g (10,060 mg of protein)
Omalizumab induced an increase in the allergen threshold for milk, egg, wheat, and hazelnut from a mean of 1012.6 ± 1464.5 mg protein to 8727 ± 6463.3 mg protein (8.6-fold increase; P<0.001)

A total of 70.4% of patients tolerated the complete challenge dose after 4 months of treatment with omalizumab

- These foods were reintroduced in the patients’ diet without the need for any oral immunotherapy procedures
- The remaining foods were partially tolerated
- The number of reactions to the unintended ingestion of allergenic foods over 4 months dropped from 47 to 2

PedsQL increased from 61±5.32 to 87±7.33 (parent; P<0.001) and from 65±7.39 to 90±4.54 (patients; P<0.001)

**Initial Threshold (mg) and Threshold After 4 Months of Omalizumab Treatment (4 foods*)**

*Hazelnut data not provided.

Omalizumab as Adjunct to Food OIT: General Study Design

- **Pre-treatment with OMA**: 8–16 weeks
- **Concomitant administration**: 7–20 weeks
- **OIT dosing**: 7–36 weeks
- **Dietary food maintenance**
- **DBPCFC Primary endpoint**
## Randomized DBPC Studies: Omalizumab + OIT

<table>
<thead>
<tr>
<th>Reference/Age (median)</th>
<th>Patients</th>
<th>Treatment Regimen</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wood (2016)¹ 7–32 years</td>
<td>▪ 57 milk-allergic ▪ 28 OMA, 29 placebo</td>
<td>▪ q2–4 weeks for 16 weeks vs placebo; OMA group continued until month 28</td>
<td>▪ 88.9% (OMA) vs 71.4% (P) passed 10 g desensitization OFC at month 28 (P=0.18)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Open-label OIT started at 18 weeks to goal of 3.8 g</td>
<td>▪ At month 32 (16 weeks off OMA and 8 weeks of OIT), 48.1% (OMA) vs 35.7% (P) had SU (P=0.42)</td>
</tr>
<tr>
<td></td>
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<td>▪ Safety: 2.1% (OMA) vs 16.1% (P) doses/subject provoked symptoms in escalation (P&lt;0.001); dose-related reactions requiring treatment (0.0% vs 3.8%, P&lt;0.001)</td>
</tr>
<tr>
<td>MacGinnitie (2017)² 7–19 years</td>
<td>▪ 37 peanut-allergic ▪ 29 OMA, 8 placebo</td>
<td>▪ q2–4 weeks for 12 weeks; OMA group continued through 18 weeks</td>
<td>▪ 23 patients (79.3%, OMA) vs 1 (12.5%; P&lt;0.01) were able to tolerate 2000 mg 6 weeks off OMA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Peanut OIT started week 12 to goal of 2 g</td>
<td>▪ 22 patients (75.9%, OMA) vs 1 (12.5%; P=0.002) were able to tolerate 4000 mg peanut protein 12 weeks off OMA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Safety: reactions rates to OIT were not significantly different, but OMA-treated patients were exposed to higher peanut protein doses</td>
</tr>
<tr>
<td>Andorf (2018)³ 4–15 years</td>
<td>▪ 48 multi-food allergic ▪ 36 OMA, 12 placebo</td>
<td>▪ q2–4 weeks for 16 weeks</td>
<td>▪ At 36 weeks, 30 patients (83%, OMA) vs 4 (33%; P=0.0044) tolerated 2 g of ≥2 foods</td>
</tr>
<tr>
<td></td>
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<td>▪ Multi-food OIT started at week 8 for 2–4 foods with goal maintenance of 2 g per food</td>
<td>▪ Patients in OMA group had significantly lower median per-subject percentage of OIT doses associated with adverse events: 27% (OMA) vs 68% (P); P=0.0082</td>
</tr>
</tbody>
</table>

DBPC=double-blind, placebo-controlled; P=placebo; SU=sustained unresponsiveness.
Content courtesy of Dr. David Fleischer. University of Colorado Denver School of Medicine Aurora, CO.
If tolerated > 1g ea food

1000 mg per allergen
300 mg per allergen
0 mg per allergen
(discontinuation)

Baseline food challenges

Week 30 food challenges

Week 36 food challenges

2 to 5 foods

OIT dosing (weeks 8-30)

Omalizumab (weeks 0-16)

Open-label phase (weeks 0-30)

Randomized phase (weeks 30-36)
% intent-to-treat in pooled treatment arm (1 g + 300 mg) and discontinued arm (0 mg) who passed food challenge to 2 g to at least 2 foods (primary endpoint), and to at least 3, 4, or 5 foods or at least 2 food challenges to 4 g (secondary endpoint) at week 36.

<table>
<thead>
<tr>
<th>Primary Endpoint</th>
<th>Secondary Endpoint (passing ≥ 3, 4, 5 OFCs [2g])</th>
<th>Secondary Endpoint (4 g OFCs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of ITT</td>
<td>% of ITT</td>
<td>% of ITT</td>
</tr>
<tr>
<td>34/40</td>
<td>25/26</td>
<td>28/40</td>
</tr>
<tr>
<td>11/20</td>
<td>8/16</td>
<td>9/20</td>
</tr>
<tr>
<td>10/11</td>
<td>3/9</td>
<td>0/3</td>
</tr>
<tr>
<td></td>
<td>P = 0.03</td>
<td>P = 0.00008</td>
</tr>
<tr>
<td></td>
<td>OR: 4.5</td>
<td>OR: 22.8</td>
</tr>
<tr>
<td></td>
<td>95% CI: 1.1 – 19.3</td>
<td>95% CI: 2.5 – 1143.5</td>
</tr>
<tr>
<td></td>
<td>P = 0.03</td>
<td>OR: 8.9</td>
</tr>
<tr>
<td></td>
<td>OR: 0.01</td>
<td>95% CI: 1.2 – 95.0</td>
</tr>
<tr>
<td></td>
<td>OR: ∞</td>
<td>95% CI: 1.5 – ∞</td>
</tr>
<tr>
<td></td>
<td>95% CI: 0.8 – 10.0</td>
<td></td>
</tr>
</tbody>
</table>

S Andorf et al., EClinMED, 2019
Multiple clinical studies have evaluated the efficacy of omalizumab as monotherapy and in combination with OIT for decreasing sensitivity to food allergens.

The results from these studies suggest:

- Omalizumab is potentially effective in treating multi-food allergies in patients allergic to ≥1 food.
- As a monotherapy, omalizumab may increase the threshold dose for inducing allergic symptoms following food exposure.
- In conjunction with OIT, omalizumab may increase OIT efficacy and enable safe and rapid desensitization.

However, differing endpoints and OIT treatment regimens make cross-study comparisons challenging.
This study is designed to evaluate omalizumab efficacy in 3 stages

**Stage 1**
Omalizumab monotherapy vs placebo

**Primary objective** is to compare the ability to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab.

**Stage 2**
Omalizumab-facilitated OIT vs Omalizumab + placebo OIT

**Secondary objective** is to compare the ability to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated OIT or omalizumab + placebo OIT.

**Stage 3**
Long-term follow-up

**Secondary objective** is to compare dietary consumption of foods after the conclusion of treatment with either omalizumab-facilitated OIT or omalizumab + placebo OIT during a follow-up period in which participants either received guided dietary instructions and/or rescue OIT for up to three foods.

*Primary objective for stage 2.
General Study Overview

- Multi-center, randomized, double-blind, placebo-controlled trial

Screening and DBPCFC

Stage 1: Omalizumab Monotherapy vs Placebo 2:1 randomization N=225

16–20 weeks

Stage 1: OMA open-label extension N=60

24–28 weeks

Stage 2: OMA + Multi-food OIT vs OMA + Placebo OIT 1:1 randomization N = 165

60–64 weeks

Stage 3: Long-term follow-up and rescue OIT

All patients followed until December 2023

Maximum individual study participation: up to 84 weeks of treatment and follow-up until December 2023
Food Allergy Targets For Biologics

Vickery et al, JACI IP, 02/2019
Phase 2a randomized, placebo-controlled study of anti–IL-33 in peanut allergy

Sharon Chinthrajah, ..., Marco Londei, Kari C. Nadeau

Study Design

Screening (baseline) visit (7-14 days prior to Day 1) (n=36)
OFC, peanut and histamine skin prick test, ex vivo whole blood for peanut antigen challenge, biomarker analysis, and WBC.

Day 1: Etokimab or placebo administration (n=20)

Day 2 and Day 5 (n=20)
Ex vivo whole blood for peanut antigen challenge, biomarker analysis, and WBC.

Day 15 (n=20)
OFC, PK, peanut and histamine skin prick test, ex vivo whole blood for peanut antigen challenge, biomarker analysis, and WBC.

Day 45 (n=9)
OFC, peanut and histamine skin prick test, ex vivo whole blood for peanut antigen challenge, biomarker analysis, and WBC, and end of study visit.
CCTD 275 mg
### Dupilumab Monotherapy for Peanut Allergy Study Information

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Interventional (Clinical Trial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated Enrollment</td>
<td>48 participants</td>
</tr>
<tr>
<td>Allocation</td>
<td>Randomized</td>
</tr>
<tr>
<td>Intervention Model</td>
<td>Parallel Assignment</td>
</tr>
<tr>
<td>Masking</td>
<td>Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)</td>
</tr>
<tr>
<td>Primary Purpose</td>
<td>Treatment</td>
</tr>
<tr>
<td>Official Title</td>
<td>A Study to Evaluate the Efficacy and Safety of Dupilumab Monotherapy in Pediatric Patients with Peanut Allergy</td>
</tr>
<tr>
<td>Actual Study Start Date</td>
<td>March 12, 2019</td>
</tr>
<tr>
<td>Estimated Primary Completion Date</td>
<td>August 13, 2020</td>
</tr>
<tr>
<td>Estimated Study Completion Date</td>
<td>November 10, 2020</td>
</tr>
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</table>

# Dupilumab as Adjunct to AR101 Study Information

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Interventional (Clinical Trial)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated Enrollment</td>
<td>156 participants</td>
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<td>Primary Purpose</td>
<td>Treatment</td>
</tr>
<tr>
<td>Official Title</td>
<td>A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Study in Pediatric patients with Peanut Allergy to Evaluate the Efficacy and Safety of Dupilumab as Adjunct to AR101 (Peanut Oral Immunotherapy)</td>
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<tr>
<td>Actual Study Start Date</td>
<td>October 3, 2018</td>
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<tr>
<td>Estimated Primary Completion Date</td>
<td>June 1, 2020</td>
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<tr>
<td>Estimated Study Completion Date</td>
<td>March 10, 2021</td>
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</table>

<table>
<thead>
<tr>
<th>Treatment Modality</th>
<th>Efficacy</th>
<th>Safety</th>
<th>Practicality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omalizumab</td>
<td>✓✓✓✓</td>
<td>✓✓✓✓</td>
<td>✓✓✓✓</td>
</tr>
<tr>
<td>Palforzia (OIT)</td>
<td>✓✓✓</td>
<td>✓✓</td>
<td>✓</td>
</tr>
<tr>
<td>Viaskin (EPIT)</td>
<td>✓✓</td>
<td>✓✓✓</td>
<td>✓✓</td>
</tr>
<tr>
<td>SLIT</td>
<td>✓✓✓</td>
<td>✓✓✓</td>
<td>✓✓</td>
</tr>
<tr>
<td>Dupilumab</td>
<td>✓</td>
<td>✓✓✓</td>
<td>✓✓✓</td>
</tr>
<tr>
<td>Office-based OIT</td>
<td>✓✓</td>
<td>✓✓</td>
<td>✓✓</td>
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</tbody>
</table>
### Biologics and Novel Modalities Presently Active in Clinical Trials

<table>
<thead>
<tr>
<th>Subcutaneous immunotherapy (SCIT)&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Cytokine antibodies&lt;sup&gt;2,3&lt;/sup&gt;</th>
<th>Vaccine&lt;sup&gt;4,5&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>(eg, HAL-MPE1)</td>
<td>(eg, Anti-TSLP, Anti-IL-33)</td>
<td>(eg, SPP0892*, BCG immunization)</td>
</tr>
<tr>
<td>Intralymphatic immunotherapy&lt;sup&gt;6&lt;/sup&gt;</td>
<td>Bacteria&lt;sup&gt;7&lt;/sup&gt;</td>
<td>Microbiota Transplant&lt;sup&gt;8,9&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>(eg, VE416*)</td>
<td>(eg, fecal matter capsule, vaginal seeding)</td>
</tr>
<tr>
<td>Skin Barrier Protection&lt;sup&gt;10&lt;/sup&gt;</td>
<td>Vitamin D&lt;sup&gt;11&lt;/sup&gt;</td>
<td>Traditional Chinese Medicine&lt;sup&gt;12&lt;/sup&gt;</td>
</tr>
<tr>
<td>(eg, EpiCeram)</td>
<td></td>
<td>(eg, Chinese Herbal Formula-X [CHFX])</td>
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</table>

*<sup>A</sup> single multivalent peanut (Ara h1, h2, h3) lysosomal associated membrane protein DNA plasmid vaccine; †dormant [inactive] bacteria that is reactivated once reaching the intestines.

BCG=Bacille Calmette Guérin; IL=interleukin; TSLP=thymic stromal lymphopoietin.

Potential Biologics for Food Allergy

Adapted from: P Kolkhir, et al Annals Allergy
**Novel Future Approaches to Food Allergy**

<table>
<thead>
<tr>
<th><strong>Allergen Immunotherapy (AIT)</strong></th>
<th>Administering antigen which helps desensitize mast cells and basophils and to stimulate production of regulatory cells and cytokines as well as upregulating blocking antibodies such as IgG4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaccines and immune regulation</strong></td>
<td>Vaccines, adjuvants and other emerging modalities (e.g., nanoparticle formulations) that promote regulatory mechanisms and re-balance patients’ immune phenotype (e.g., Th2 to Th1)</td>
</tr>
<tr>
<td><strong>Pro-Th2 / pro-inflammatory cytokine inhibition</strong></td>
<td>Inhibiting key pro-Th2 alarmins (IL-33, IL-24, TSLP) and downstream cytokines (IL-4, IL-5, IL-9, IL13). May also consider inhibiting related ILC2 cells upstream</td>
</tr>
<tr>
<td><strong>IgE inhibition</strong></td>
<td>Removing IgE and stopping its production including inhibition of IgE-producing B cells</td>
</tr>
<tr>
<td><strong>Mast cells and basophil stabilization</strong></td>
<td>Anergizing key effector cells. Many pathways are being explored (e.g., blocking / removing mast cell surface receptors, activating inhibitory receptors, disrupting signaling)</td>
</tr>
<tr>
<td><strong>T and B cell targeting</strong></td>
<td>Targeting pathogenic T and B cell populations to inhibit, deviate and/or exhaust function including depleting long-term memory</td>
</tr>
<tr>
<td><strong>Restoring microbiome and barrier protection</strong></td>
<td>Numerous intersecting pathways involved in protecting gut / skin barrier, restoring a healthy microbiome and achieving immunometabolic homeostasis</td>
</tr>
</tbody>
</table>

**Antigen-dependent treatments**

**Not Antigen-dependent treatments**
**FOOD ALLERGY DRUG PIPELINE**

<table>
<thead>
<tr>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>FDA Approved</th>
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</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td>AR101 (Peanut OIT) &amp; Viaskin peanut</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td>Viaskin milk &amp; Xolair (omalizumab) &amp; Multi-allergen</td>
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<tr>
<td></td>
<td>AnaptysBio</td>
<td>ABN-020 (anti-IL-33 mAb) &amp; AR101 + Dupixent (anti-IL-4Ra mAb)</td>
<td>PPOIT-103 (probiotic oral immunotherapy)</td>
<td></td>
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<tr>
<td></td>
<td>REGENERON</td>
<td>Peanut immunotherapy + TLR4 agonist (on hold) &amp; ASP0892 (DNA vaccint)</td>
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<td></td>
<td>Sanofi</td>
<td>PVX-108 (peptide therapy)</td>
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<tr>
<td></td>
<td>Astellas</td>
<td>HAL-MPE1 (modified peanut immunotherapy) &amp; AK002 (anti-siglec 8)</td>
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<tr>
<td></td>
<td>ARAVAAX</td>
<td>Nanoparticle immunotherapy &amp; Egg OIT</td>
<td>Undisclosed</td>
<td></td>
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</tbody>
</table>

- A food allergy pipeline has begun to take shape with growing interest from biopharma.
- Current efforts are still mostly targeted towards peanut, milk and egg allergy using allergen-specific immunotherapy.
- Novel non-antigen-based therapies are also emerging, however, are still limited in total number.

Source: Company websites and press releases, AAAI abstracts and presentations, N Ventures and Advisory research and analysis.
Points for Consideration

• Will a biologic prevent accidental exposure-induced allergic reactions (e.g., tolerate 300 to 600 mg peanut protein)?
• Will a biologic allow you to eat the food you are allergic to (e.g., a peanut butter sandwich)?
• Will a biologic drug change the immune system so you can achieve tolerance off therapy?
• With a projected 32 million food allergy patients in the U.S. and an average annual cost of $20,000 to 50,000 to treat each patient, how can the health care system afford this?
  – If everyone was treated: ~$1 Trillion/year!
Concluding Comments
Questions?
The FARE Patient Registry connects people living with food allergies to researchers seeking answers.

YOUR Food Allergy Story Drives Research Forward

FoodAllergyPatientRegistry.org
Thank you!