
# Corporate Presentation

April 2019

# Forward-Looking Statements

This presentation contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, clinical development plans, anticipated milestones, product candidate benefits, potential market size, product adoption, market positioning, competitive strengths, product development, and other clinical, business and financial matters. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially. Risks and uncertainties include, but are not limited to, our limited operating history, our need for additional financing to achieve our goals, our dependence on our lead product AR101, the need for additional clinical testing of AR101, uncertainties relating to the regulatory process, uncertainties relating to the timing and operation of clinical trials, potential safety issues, possible lack of market acceptance of our product candidates, the intense competition in the biopharmaceutical industry, our dependence on exclusive third-party suppliers and manufacturers, and limitations on intellectual property protection. A further list and description of these risks, uncertainties and other factors can be found in our report on Form 10-K filed on February 28, 2019. Copies of this filing are available online at www.sec.gov or www.aimmune.com. Any forward-looking statements made in this presentation speak only as of the date of the presentation. We do not undertake to update any forward-looking statements as a result of new information or future events or developments.

# Aimmune: A Leader in Developing Food Allergy Treatments

1

Will address the large and growing societal need for food allergy treatments

2

Founded through innovative private/non-profit partnership

3

AR101 (lead program) could be first approved treatment for peanut allergy

- Submitted BLA in December 2018
- Planning for U.S. launch in 2H 2019

4

Comprehensive commercial strategy with probable first-mover advantage

5

Strong proprietary position including biologic data exclusivity, issued patents, and exclusive commercial supply

6

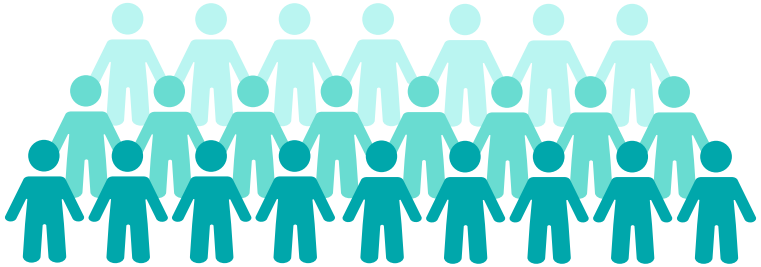
Well-funded with approximately $470M in financial resources[1]

[1] 1-4-19 cash, cash equivalents and investments of $340M and $130M potential from January 2019 KKR loan

# We Continue to Deliver

- Submitted AR101 BLA to U.S. FDA for peanut allergy
- Published Phase 3 PALISADE results in *New England Journal of Medicine*
- Announced Phase 3 RAMSES topline data
- Initiated Phase 2 AR101 + dupilumab trial (Sponsor: Regeneron/Sanofi)
- Initiated Phase 3 AR101 trial in children ages 1-3 years
- Submitted AR201 IND for egg allergy and established exclusive supply agreement
- Announced Positive Phase 3 ARTEMIS topline data

# Approved Food Allergy Treatments Are a Major Unmet Need



**Over 15 million** people in the U.S. have food allergies[1-3]

**Every 3 minutes,**
a food allergy reaction sends someone in the U.S. to the ER[4]

**~$4 billion** per year in direct medical expenses in the U.S.[5]

**50%**
increase in the prevalence of food allergy in children between 1997 and 2011[6]


1. National Institute of Allergy and Infectious Diseases, National Institutes of Health. Retrieved from www.niaid.nih.gov/topics/foodallergy/research/pages/reportfoodallergy.aspx.
2. United States Census Bureau Quick Facts (2015 estimates).
3. Gupta RS, et al. *Pediatrics* 2011;128(1):e9-17.
4. Clark S et al. *J Allergy Clin Immunol.* 2011;127(3):682-3.
5. Gupta RS, et al. *JAMA Pediatr.* 2013;167(11):1026-31.
6. CDC. Trends in Allergic Conditions Among Children: United States, 1997–2011. Retrieved from https://www.cdc.gov/nchs/data/databriefs/db121.pdf.

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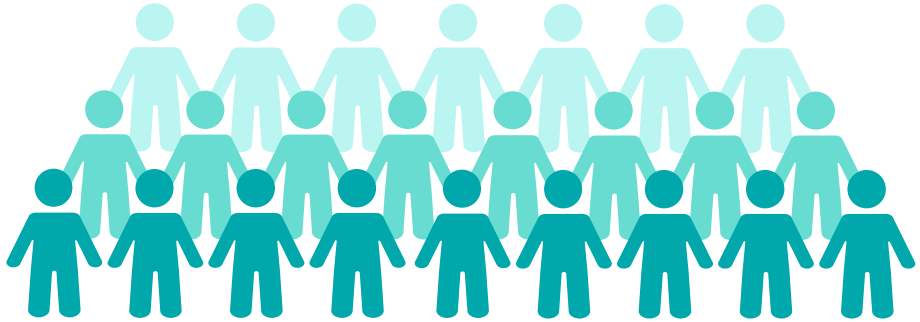
# Peanut Allergy Is One of the Most Common Food Allergies



## Over 1.6 million

kids and teens affected in the U.S.[1]

## 8 out of 10

children with peanut allergy never outgrow it[2]

## 1 out of 4

children with peanut allergy visit the ER every year[3]

[1] Aimmune market research
[2] Gupta RS, Lau CH,, Sita EE, el al. Factors associated with reported food allergy tolerance among US children. *Ann Allergy Asthma Immunol*. 2013;111(3):194–198.e4
[3] Gupta RS, Warren CM, Smith BM, et al. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. *Pediatrics.* 2018;142(6):e20181235

# Peanuts Are Everywhere: Avoidance Is a Challenging Strategy

**Peanut allergens can be hard to spot**

**1 of 4 peanut-allergic patients** visit the ER every year[1]

**Median accidental exposure that causes a reaction is ~ 1/2 a peanut**[2]

**Fear, anxiety and confusion** set in immediately after diagnosis[3]

**One accident can be fatal**

**~80% of caregivers** say peanut allergy makes attending social events difficult[4]

[1] Gupta RS, Warren CM, Smith BM, et al. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. *Pediatrics.* 2018;142(6):e20181235
[2] The median estimated eliciting dose in real life was 125 mg (N=238 peanut-allergic patients) as reported by Deschildre A, et al. *Clinical & Experimental Allergy*; 46:610-620
[3] Patient Journey Emotional Insights market research 2018
[4] MyHealthTeams social media research survey, April 2017, 129 respondents



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# Oral Pathway Provides Robust Desensitization and Patient Convenience

Goal of oral immunotherapy is to minimize the body's reaction to trigger foods

High levels of desensitization can be achieved with oral immunotherapy[1]

Convenient, once-daily, oral dose
taken with food doesn't stigmatize patients

Aimmune is developing FDA-regulated biologic products with characterized allergen profiles

[1]As reviewed in Burks, Sampson, Plaut et al. Treatment for Food Allergy. *Journal Allergy Clin Immunol* (2018)

# Our Goal is for AR101 to be the Bridge to Confidence

- Accidental exposures happen
- Constant risk and worry
- Risk of death

**Desensitization and Immunomodulation**

- Protection from life-threatening reactions
- Daily confirmation
- Peace of mind

***Regular interaction with allergist during desensitization process offers reassurance***

# We Also Are Pursuing a Large Opportunity in Egg Allergy

## Egg Allergy

- **~ 6M** egg-allergic people across U.S., EU5, China and Japan
- **Majority** of patients ages **1-4 years old**
- Most common food allergy in **China** and **Japan**

## AR201 Program

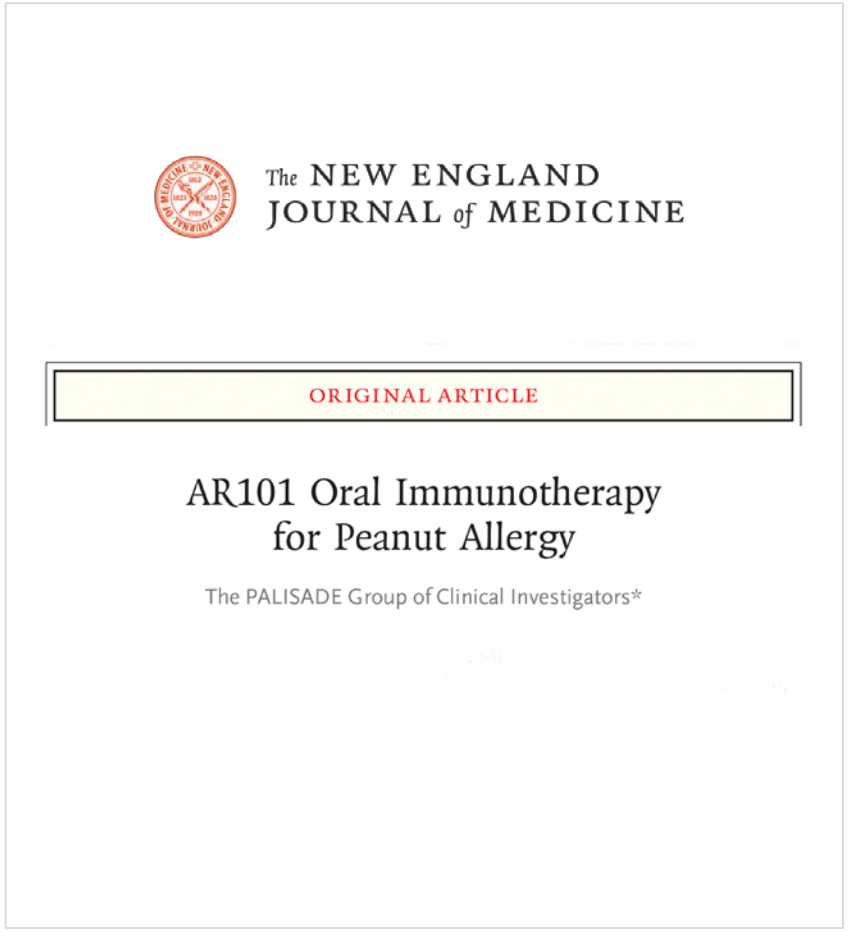
AR201

- **IND submitted** in December 2018
- **Phase 2 trial planned** for mid 2019
- **Exclusive clinical** and **commercial supply** agreement for egg protein with Michael Foods

Estimates based on Aimmune proprietary market research

# PALISADE:
## First Successful Phase 3 Trial in Peanut Allergy (ARTEMIS is the Second)

# PALISADE Is the First Phase 3 Peanut Allergy Trial to Meet Its Primary Endpoint

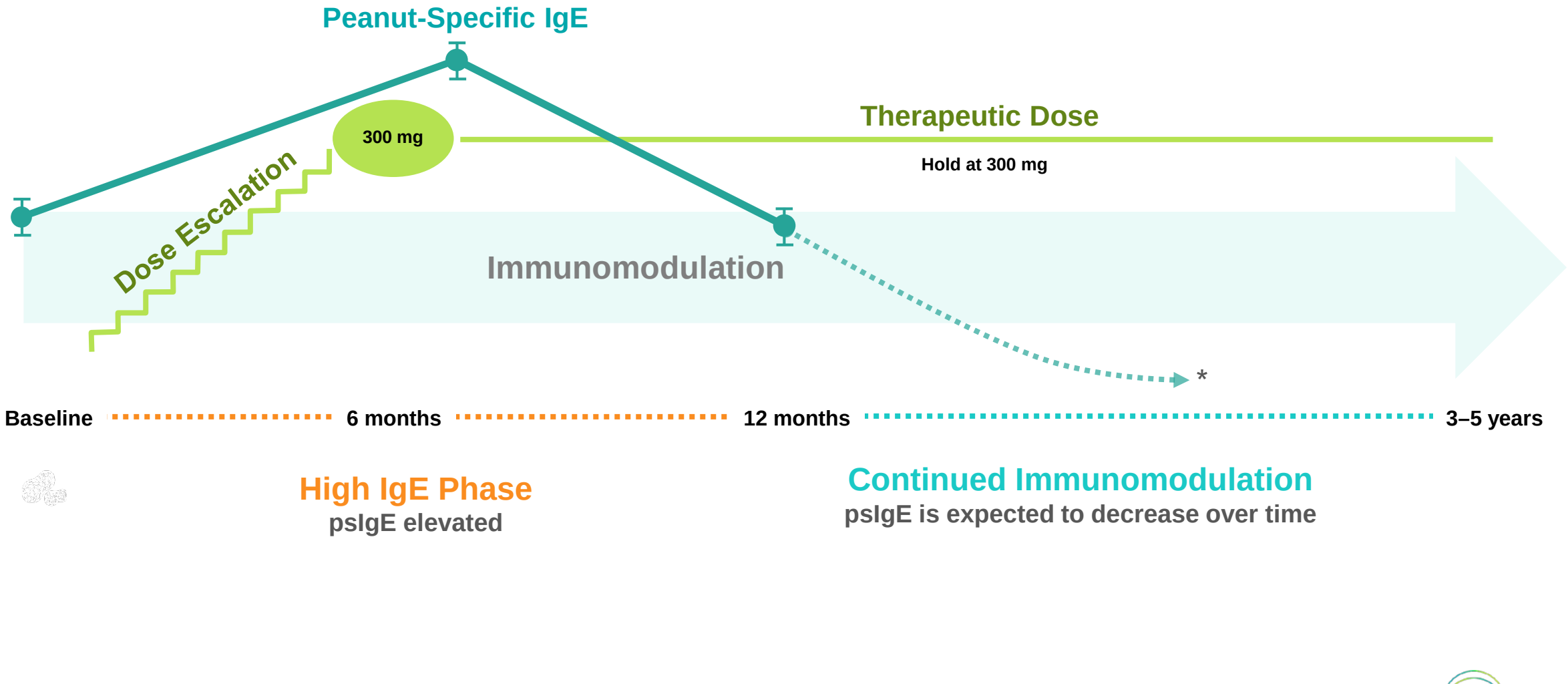



| | AR101 | Placebo |
|---|---|---|
| **Primary Endpoint** Percent who tolerated ≥600 mg in exit food challenge at 12 months (ITT Population) | 67% | 4% |
| Percent who tolerated ≥600 mg in exit food challenge at 12 months (Completer Population) | 85% | 4% |
| Highest median tolerated dose: Baseline → 12 months (cumulative) | 10 mg → 1,000 mg<br>(14 mg → 2,043 mg) | 10 mg → 30 mg<br>(14 mg → 43 mg) |
| Fold-increase in median tolerated dose | 100-fold | 3-fold |



Vickery et al., *NEJM*, November 18, 2018 (online publication)

# Biologic Mechanics of Oral Immunotherapy




## High IgE Phase

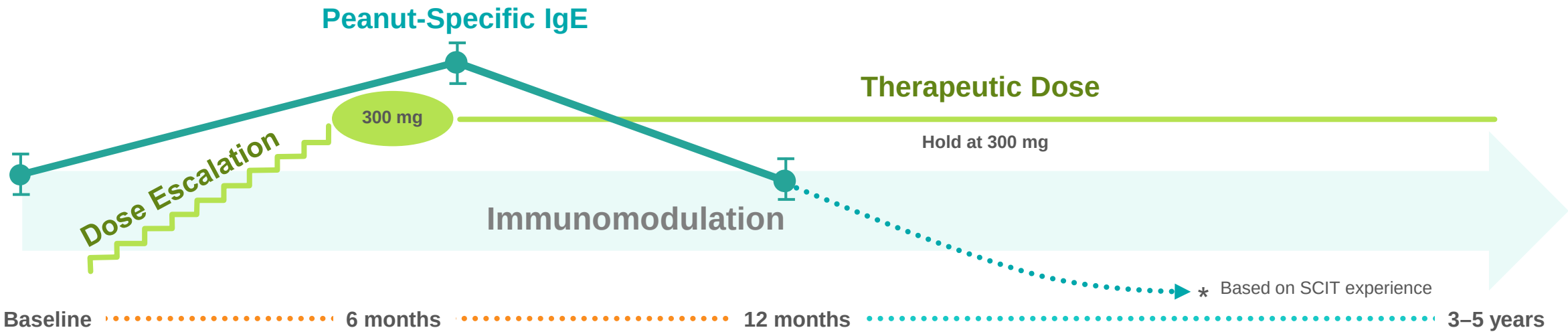
psIgE elevated

## Continued Immunomodulation

psIgE is expected to decrease over time

IgE, immunoglobulin E.
*Based on SCIT experience.

# AR101 Therapeutic Profile Consistent with Immunomodulation




## High IgE Phase

**psIgE elevated**

### After dose escalation in PALISADE

70% reductions in AR101-related adverse events[1], and in allergic reactions due to accidental exposures that required treatment compared to placebo[2]

## Continued Immunomodulation

**psIgE decreases over time**

### After 28 weeks of additional therapy at 300 mg/day

~2/3 of patients who tolerated less than the highest dose at the PALISADE exit challenge (1,000 mg single dose) were able to tolerate more peanut protein in at another challenge 28 weeks later[3]


1.Vickery BP et al. *N Engl J Med*. 2018;379:1991-2001
2.Hourihane J O'B et al. AAAAI 2019
3.Carr T et al. AAAAI 2019

# AR101 Adverse Events Consistent with Immunotherapy

| Context | Phase 3 Experience[2] |
|---|---|
| **Anaphylaxis**<br>Highly allergic patients were clinically exposed to peanut protein | ~1% anaphylaxis<br>No events reported after 52 weeks at 300 mg/day[3] |
| **Epinephrine Use**<br>Allergists consider epinephrine a useful tool during desensitization; its use was pre-specified in protocol | 98% of epinephrine use was for mild or moderate events |
| **Eosinophilic Esophagitis (EoE)**<br>Gastrointestinal eosinophilia is common in peanut-allergic adults (48%), even without associated symptoms[1] | 0.6% EoE is reassuringly low; symptoms resolved when AR101 was stopped<br>< 5% GI discontinuations |

**Key Takeaways**

- **~80% completed treatment in PALISADE and RAMSES Phase 3 trials**
- **No anaphylaxis beyond one year**
- **Very low EoE rates**
- **Tolerability profile improves with immuno-modulation**

[1] Wright BL, et al. *Journal Allergy Clinical Immunology* (Feb. 2018) (Abstract L16)
[2] Integrated Safety Summary: includes 812 subjects dosed with AR101 in Phase 3 clinical trials as of July 15, 2018
[3] Based on total of n=178 subjects on 300 mg for >52 weeks



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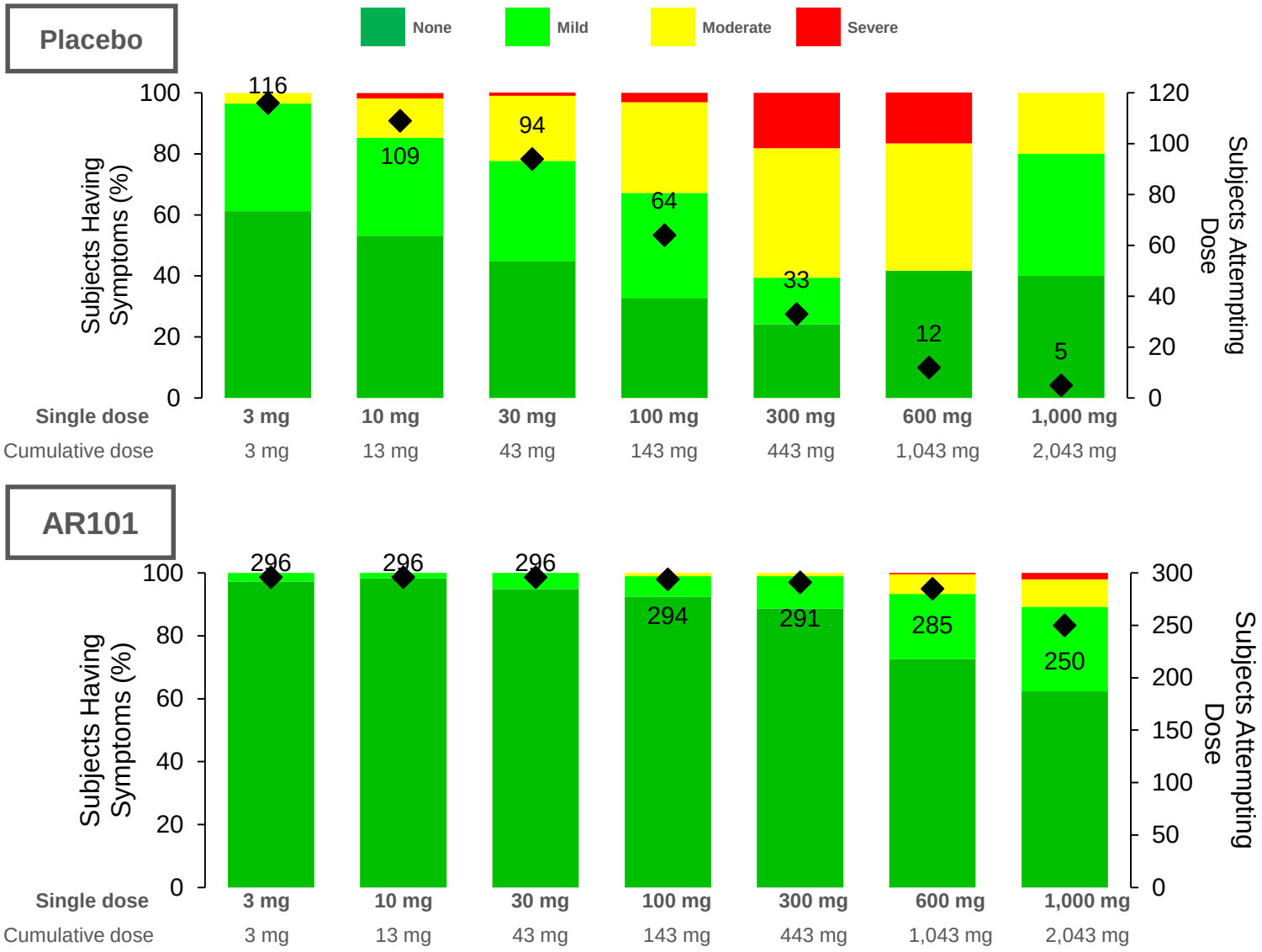
# AR101 Reduced the Frequency and Severity of Allergic Reactions




## % Reduction in Epinephrine Use During PALISADE Exit DBPCFC (AR101 vs Placebo)

| | |
|---|---|
| 3 mg | 100% |
| 10 mg | 100% |
| 30 mg | 100% |
| 100 mg | 99% |
| 300 mg | 99% |
| 600 mg | 94% |
| 1,000 mg | 81% |

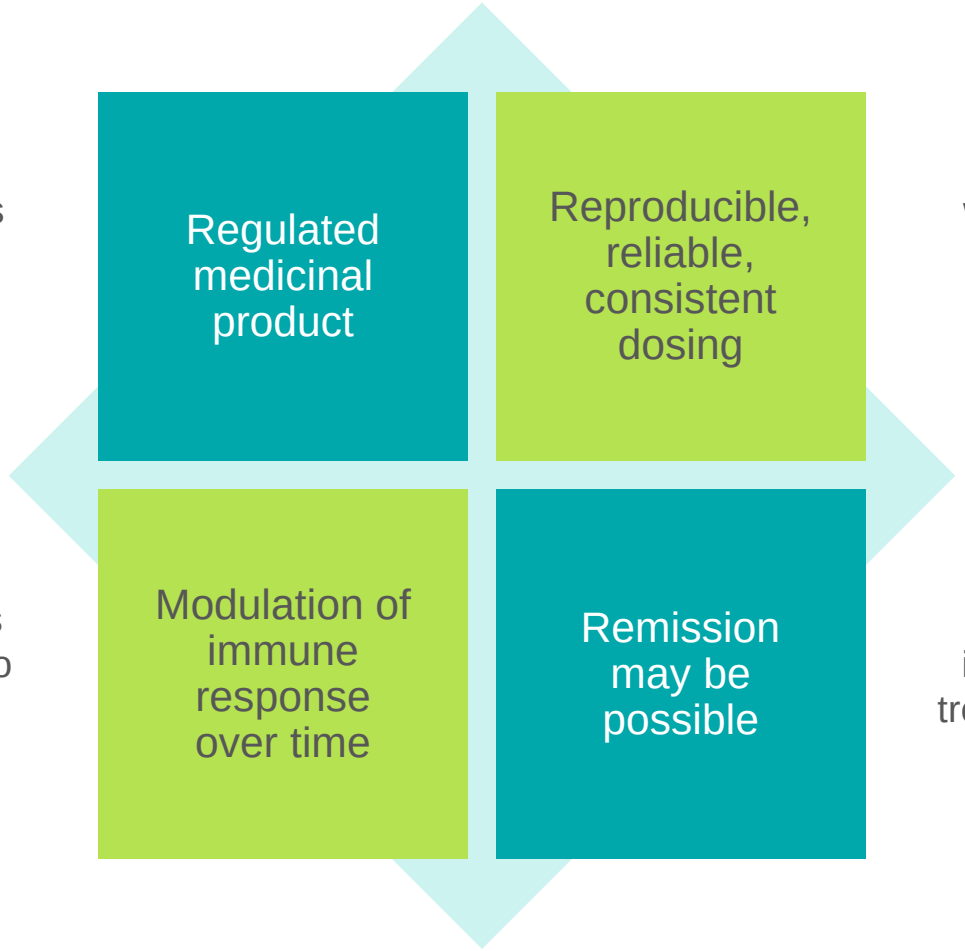


Vickery BP et al. *N Engl J Med*. 2018;379:1991-2001

# It Is Important to Stay on AR101 Treatment

In agreement with FDA, AR101 will be a regulated medicinal product to be used in peanut allergic patients

Over time on AR101, adverse events generally decreased, and the ability to tolerate the 600 mg challenge dose increased[1]




Patients can be certain that they are receiving a biologic drug with a consistent fingerprint for critical allergens

If food allergies treated with oral immunotherapy are like aero-allergies treated with allergy shots, remission may be possible after 3-5 years of consistent therapy

[1]Based on exit double-blind, placebo-controlled food challenges in ARC001, ARC002, PALISADE, and ARC004

# Preparing for Commercialization

# The Estimated U.S. Market Opportunity Exceeds $1 Billion

**1.6M**
**Prevalent Population (Ages 4-17)**

**1.25M Diagnosed and Managed**

**83%**
**peanut-allergic patients already diagnosed**

| | |
|---|---|
| PA Only | 18% |
| PA +eczema | 21% |
| PA +eczema +asthma | 42% |
| PA +asthma | 19% |

**80%**
**have asthma and/or eczema**

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**80-120 Field Team**

**5K Allergists**



Source: Symphony Health Patient Claims (Jan 2011-Dec 2017)

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# Our Focus Is to Ensure that Patients and Allergists Will Have a Frictionless Experience with AR101, Once Approved

## Patients

- A **product clinically proven to work** to protect against reactions to accidental exposure
- Convenient, **oral, once-daily dosing** that **doesn't stigmatize them** as peanut allergic
- **Daily confirmation** of protection
- Close **collaboration and oversight** from their allergist

## Allergists

- **FDA approved** product clinically proven to work
- **Support to integrate OIT** into their practice
- **Minimal time and effort** to obtain, portion, and package materials
- **Clear understanding of coding** and **medical billing** procedures

# What We Will Do To Enable Allergists To Be Leaders in Peanut Allergy Treatment and Care

**4** Customer Phenotypes


**75% of U.S. allergists would prescribe an FDA-approved oral immunotherapy[1]**

## AR101 and Patient Success Team

- FDA approved product would reduce liability
- Implementation would be analogous to allergy shots
- Standardized product would provide daily confirmation
- Provide protocol training and product education
- Support them every step of the way

1. Aimmune internal physician market research

# Partnering with Specialty Pharmacies will Help Us Provide Flexible Product Distribution for Patients and their Caregivers

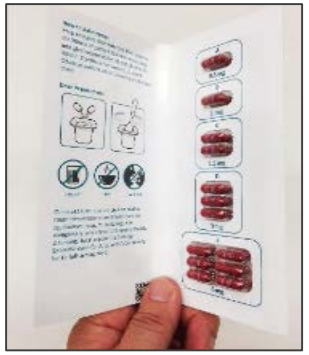
**Allergist Office**

**Diagnosis & Treatment Determination**

**1**

**Allergist Office**

**Initial Dose Escalation**



**2**

**Allergist Office and Home Use**

**Dose Escalation Phase**
~6 months

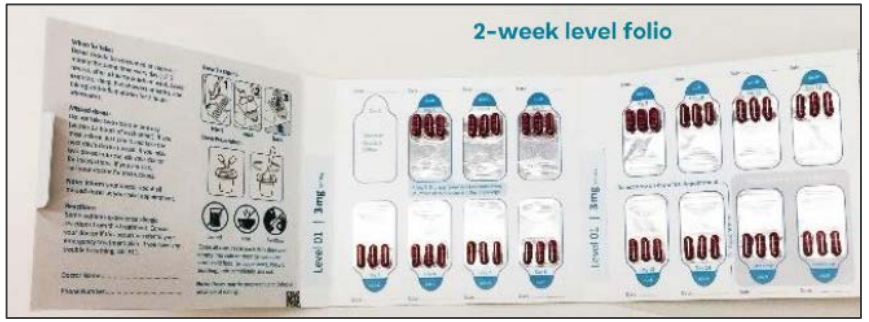
**3**

**Home Use**

**Ongoing 300 mg Therapeutic Dosing**

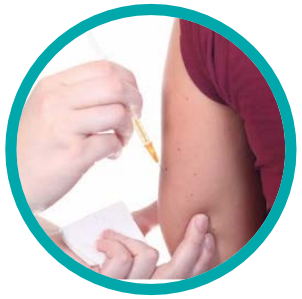
**Fixed Therapeutic Dose**
15- or 30-day option for dose escalation and then ongoing daily use at home

**Patient Prescription Folio**
Holds 2 weeks of treatment for patient use at home



# Most Allergists Doing Allergy Shots Would Have the Resources and Capacity to Implement AR101

## Allergy Shots Today[1]



## Intake Per Day

**10-30**
**Patients**

## Resource Requirements

**1**
**Doctor**

**1**
**Nursing Staff**

**1**
**Waiting or Exam Room**

## AR101

**AR101 Would Have Comparable Staff Requirements and Process[2]**



Source(s): 1) Community allergist qual market research 2018; 2) Allergist and practice manager quant market research 2018

# 2019 Is a Catalyst-Rich Year

- ✓ Complete financing
- ✓ Onboard Chief Commercial Officer
- ✓ BLA acceptance (Q1)
- ✓ ARTEMIS Phase 3 data (Q1)
  - MAA Submission for AR101 (mid-19)
  - Initiate AR201 Phase 2 for egg allergy (mid-19)
  - Potential FDA Advisory Committee for AR101 (2H)
  - Potential U.S. approval of AR101 (2H)
  - Potential U.S. commercial launch of AR101 (2H)

**Cash Resources[1] Fully Fund Commercialization of AR101 & Advance Pipeline Development**

[1] 1-4-19 cash, cash equivalents and investments of $340M and $130M potential from January 2019 KKR loan



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# Aimmune:
# Poised to Take Off in 2019!

| | |
|---|---|
| AR101 | Potential approval of first medicine for any food allergy |
| | Very large commercial opportunity |
| | Excitement from allergists, patients and families |
| | Seasoned leadership with deep development, manufacturing and commercial experience |
| | Significant pipeline progress |
| | Well-funded and resourced to execute on plans |

# Thank You