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*Presented at*

**The 2018 AAAAI/WAO Joint Congress**

March 2–5, 2018 • Orlando, FL

# Exploration of Non-Daily Maintenance Dosing Regimens in Peanut Oral Immunotherapy

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## INTRODUCTION

- Oral immunotherapy (OIT) in small academic trials has demonstrated promising safety and desensitization efficacy, although further study data are needed to support its routine clinical use[1,2]
- AR101 is an investigational oral biologic drug product with a characterized peanut-protein profile for use in OIT in subjects with peanut allergy
- PALISADE (**P**eanut **AL**lergy Oral **I**mmunotherapy **S**tudy of **A**R101 for **DE**sensitization in Children and Adults) was an international, randomized, placebo-controlled, phase 3 safety and efficacy study of AR101 intended to support routine use of OIT in clinical practice. PALISADE enrolled more than 550 participants.
- ARC004, presented here, is an open-label follow-on trial to PALISADE to explore various non-daily dosing intervals of AR101 for safety purposes

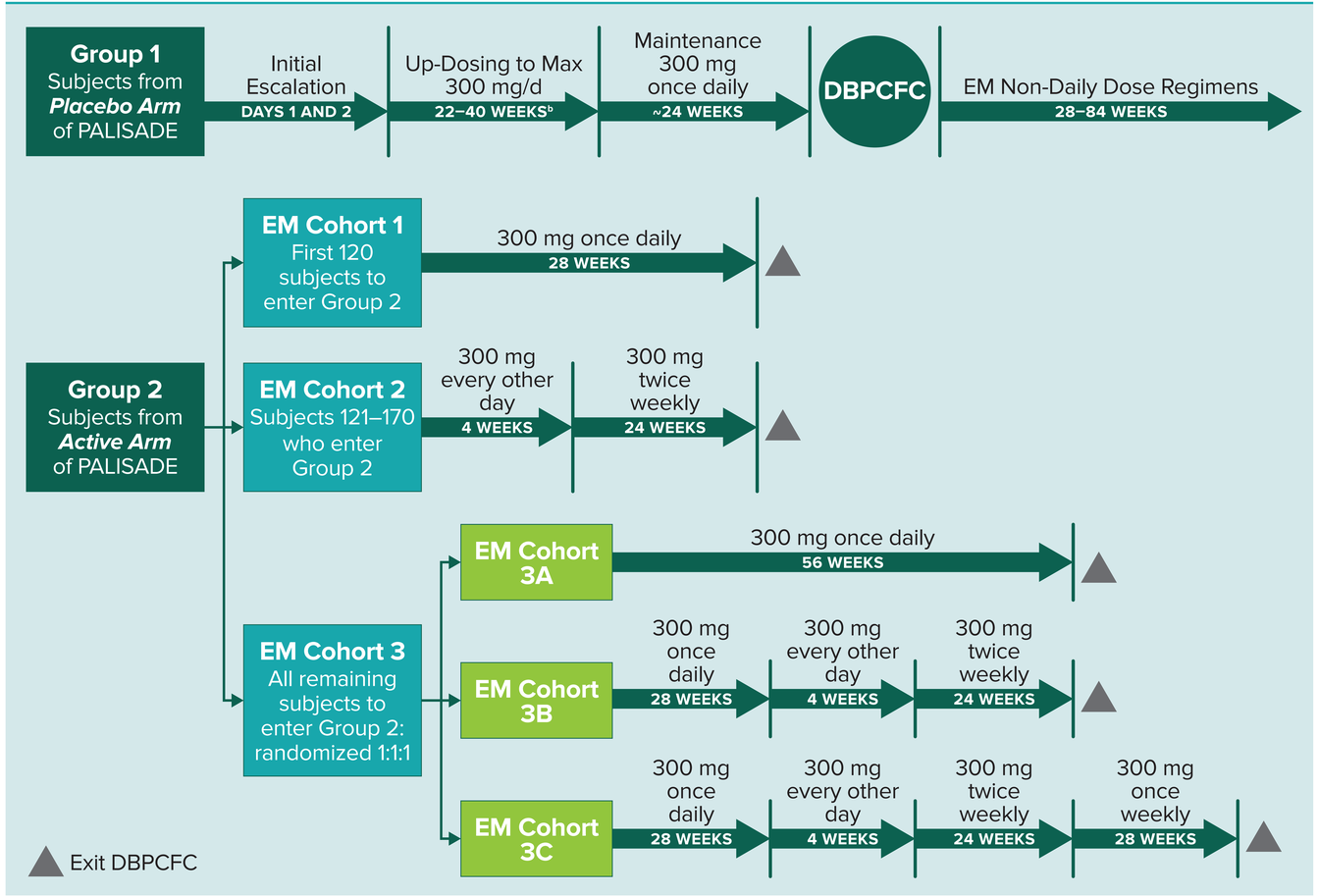
## KEY ENDPOINTS

- Frequency of treatment-related AEs, including serious AEs, from enrollment to end of the extended maintenance (EM) period
- Long-term immunologic effects of AR101 treatment

**Acknowledgements** We are grateful to the subjects and their families for their participation in this study. We appreciate the contributions of the investigators, coordinators, and other staff at each of the PALISADE/ARC004 study sites. This study (ClinicalTrials.gov ID: NCT02993107) was sponsored by Aimmune Therapeutics. Editorial assistance and medical writing support was provided by Larry Deblinger and was funded by Aimmune Therapeutics.

**References** **1.** Anagnostou K, Islam S, King Y, et al. Assessing the efficacy of oral immunotherapy for the desensitisation of peanut allergy in children (STOP II): a phase 2 randomised controlled trial. *Lancet.* 2014;383(9925):1297–1304.
**2.** Deol S, Bird JA. Current opinion and review on peanut oral immunotherapy. *Hum Vaccin Immunother.* 2014;10(10):3017–3021.

**Figure 1. ARC004 Open-Label AR101 Treatment Groups and Regimens[a]**




[a]All treatments administered as tolerated; [b]Each interval for dose escalation is a minimum of two weeks.
DBPCFC, double-blind, placebo-controlled food challenge; EM, extended maintenance.

## METHODS

### Study Design

- Designed to explore extended non-daily maintenance dosing, including every other day (QOD), twice weekly (BIW), and once weekly (QW)
- Stringent individual and cohort stopping criteria are in place to ensure safety

### Treatment Groups/Regimens

- Subjects are divided into 2 groups (**Figure 1**):
  - **Group 1** includes subjects who completed the placebo arm of PALISADE and receive AR101 once daily (QD)
  - **Group 2** includes subjects who completed the active arm of PALISADE and tolerated a single highest dose of ≥300 mg peanut protein at Exit DBPCFC
  - At the end of each treatment period, qualifying subjects will be given a maximum challenge dose of 2000 mg at Exit DBPCFC (**Table 1**)

**Table 1. Double-Blind, Placebo-Controlled Food Challenge (DBPCFC) Schedule**

| Challenge Dose, mg |
|---|
| 3 |
| 10 |
| 30 |
| 100 |
| 300 |
| 600 |
| 1000 |
| 2000 |

## CONCLUSION

- The novel study design of ARC004 is a critical step in determining the dosing regimen requirements for long-term immunotherapy to provide protection against accidental peanut exposure in peanut-allergic patients.