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.

AR101 is an investigational oral biologic drug product with a characterized peanut protein profile for use in OIT in subjects with peanut allergy.

PALISADE (Peanut Allergy Oral Immunotherapy Study of AR101 for Desensitization 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

**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

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

**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.