At-Home Dosing Adherence During Characterized Oral Desensitization Immunotherapy for Peanut Allergy

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ABSTRACT #803

• Rationale: AR101, a pharmaceutical-grade peanut protein formulation, was studied in a Phase 2, double-blind, placebo-controlled trial in subjects aged 4 to 21 years. We now report results of adherence and tolerability derived from this trial.

• Methods: Subjects took their daily dose at home by mixing the capsule/consumer content in non-allergenic, food, and consuming the home-served capsule/consumer. Subjects documented capsules consumed at home using diary kits and returned unused capsules to the dose. Full adherence, defined as all, partial (at least half the dose was taken), and missed doses, were expressed as a percentage of planned home doses.

• Results: Subjects (AR101, n=29; PBO, n=26) received at least 1 dose of randomized study treatment. The number of days planned at home doses was 138.3 (standard deviation [SD]: 33.6) for the overall group. The percentage of days [% (SD)] with any adherence at home (either a full or partial dose) was similar for AR101 and PBO groups (94.7 (8.0) vs 93.3 (7.3), respectively), as was the percentage of days [% (SD)] with a partial dose (% (SD): 10.6 (9.3) vs 10.4 (8.9), respectively). The percentage of days [% (SD)] with partial dose was higher for AR101 than PBO (13 (9.7) vs 10 (8.7), respectively) and the percentage of days [% (SD)] with missed doses (% (SD) for AR101 and 4.7 (6.84) for PBO) was 93.6 (6.9) for AR101 and 96.7 (3.4) for PBO. The number of days of home adherence, was expressed as a percentage of planned home doses that were fully consumed. Overall adherence, or full doses consumed at home, of days (% (SD)) with missed doses (4.7 (6.84) for AR101 and 93.6 (6.86) for AR101 and 96.7 (3.4) for PBO) was 93.6 (6.9) for AR101 and 96.7 (3.4) for PBO. The number of days of home adherence, was expressed as a percentage of planned home doses that were fully consumed. Overall adherence, or full doses consumed at home, of days (% (SD)) with missed doses (4.7 (6.84) for AR101 and 93.6 (6.86) for AR101 and 96.7 (3.4) for PBO) was 93.6 (6.9) for AR101 and 96.7 (3.4) for PBO.

• Conclusions: Overall adherence in the combined analysis of AR101 and PBO was 93.6 (6.9) and 96.7 (3.4), respectively. Overall adherence was >90% were mild reactions and the rest were moderate to severe. Considering missed doses to be a safety issue that could warrant study discontinuation, subjects were called 1 week after each dose escalation visit to assess adherence and tolerability.

**Background

Currently, there is no FDA-approved therapy for peanut allergy – a prevalent disorder affecting >5 million individuals in the United States and Europe today. Reactions to the allergen can be severe and include potential fatal anaphylaxis.

Peanut allergy tends to be lifelong, with only approximately 20% of those afflicted outgrowing the allergy. AR101 is a novel investigational, characterized, oral peanut protein product, in phase 3 clinical studies for peanut allergy desensitization. A previously reported double-blind, placebo-controlled Phase 2 study (AR0252)1, AR101 or PBO was administered daily using the Characterized Oral Desensitization Immunotherapy (CODIT2) approach. 99% of active-treated patients exhibited a hyperimmunogenic reaction: 96% were mild reactions and the rest were moderate. After 2 weeks of maintenance doses, 95% of subjects were desensitized to 432 mg peanut protein on an intention-to-treat basis and 100% of subjects on a complete basis. In any oral immunotherapy (OTC) protocol, most subjects are home treated, and without direct physician supervision. Adherence to therapy is important, not only for efficacy, but also for patient safety.

METHODS

• At-Home Dosing Adherence: The oral dosing of AR101 or PBO was given daily (Figure 1) – Subjects were up-down dosed based on clinical dosing, and the rest of the doses were taken at home (at home dosing) – Subjects were called 1 week after each dose escalation visit to assess home dosing adherence and dose reactions – Dose escalations were used by subjects to document doses taken, reasons for missed doses, and any dose related symptoms during the dose escalation visit – Subjects were given home dosing instructions to take their daily dose by mixing the capsule content in non-allergenic food and consuming the home-served capsule.

• Subjects were educated on potential reactions (eg, skin, respiratory, and gastrointestinal [GI]) and symptoms were recorded per subject assessment – If adverse events (AEs) occurred, investigations could withdraw placebo, dose escalation, dose withdrawal, dose withdrawal if no doses were taken at home, or dose escalation at the same dose, or to the same study group. The percentage of days [% (SD)] with any adherence at home was similar for AR101 and PBO groups (94.7 (8.0) vs 93.3 (7.3), respectively), as was the percentage of days [% (SD)] with a partial dose (% (SD): 10.6 (9.3) vs 10.4 (8.9), respectively). The percentage of days [% (SD)] with missed doses (% (SD): 4.7 (6.84) for AR101 and 93.6 (6.86) for AR101 and 96.7 (3.4) for PBO) was 93.6 (6.9) for AR101 and 96.7 (3.4) for PBO. The number of days of home adherence, was expressed as a percentage of planned home doses that were fully consumed. Overall adherence, or full doses consumed at home, of days (% (SD)) with missed doses (4.7 (6.84) for AR101 and 93.6 (6.86) for AR101 and 96.7 (3.4) for PBO) was 93.6 (6.9) for AR101 and 96.7 (3.4) for PBO.

• Conclusions: Overall adherence in the combined analysis of AR101 and PBO was 93.6 (6.9) and 96.7 (3.4), respectively. Overall adherence was >90% were mild reactions and the rest were moderate to severe. Considering missed doses to be a safety issue that could warrant study discontinuation, subjects were called 1 week after each dose escalation visit to assess adherence and tolerability.

ACKNOWLEDGEMENTS

We are grateful to the subjects and their families for their participation in this study, which was funded by Aimmune Therapeutics.