**Geometric Mean (SD), mgA/L**

**ALISADE PALISADE PALISADE ARC004 ARC004**

and were funded by Aimmune Therapeutics.


To assess the tolerability and immunomodulation of continued PTAH therapeutic

• The baseline prevalence of allergic comorbidities, serum levels of peanut-specific antigens, and major peanut allergens was consistent with the initial 6 months of therapeutic dosing in PALISADE.

**RESULTS**

**Study Population**

• 110 PALISADE completors were assigned to ARC004 Cohort 1 and 32 to Cohort 3a, of which 94.5% and 91.3% completed the ARC004 exit DBPCFC, respectively.

• Most subjects were between the ages of 4 and 11 years (64.1%), male (53.5%), and white (78.9%); 62 (43.7%) subjects reported asthma at baseline.

• Baseline characteristics were overall balanced between the cohorts; more subjects in Cohort 1 (64.5%) were in North America compared to Cohort 3a (35.5%).

**Safety**

• Similar percentages of subjects experienced AEs of similar maximum severity during ARC004 compared with PALISADE; however, the total number of AEs was lower (Table 1).

• No deaths or life-threatening AEs occurred.

• Of note, tolerability of doses >300 mg peanut protein were also high among subjects who continued up to 2000 mg.

**Immunologic Changes**

Changes in immune markers continued from PALISADE exit to ARC004 exit (Figure 3).

- Reduction in SPT wheal size from baseline to PALISADE exit was maintained through ARC004 exit.
- psIgE/psIgG4 continued to increase from PALISADE exit to ARC004 exit.
- psIgE continued to decrease from PALISADE exit to ARC004 exit.

**Figure 1. ARC004 Study Design**

**Figure 2. Changes in Immune Markers Between Baseline, End of Updosing, and Exit During PALISADE and ARC004 (Completer Population)**

**CONCLUSIONS**

- An additional 28 to 56 weeks of 300 mg daily AR101 therapeutic dosing resulted in:
  - An increase in the proportion of subjects tolerating highest doses of peanut protein during DBPCFC.
  - An increase in the number and rate of AEs experienced, despite incomplete desensitization during the first year of therapeutic dosing.
  - Continued reduction in immunologic reactivity consistent with ongoing immunomodulation.

**Figure 3. Efficacy of Continued PTAH Therapeutic Dosing: Tolerated Doses at Exit DBPCFC in (A) Cohort 1 and (B) Cohort 3a**

**Table 1. Summary of Treatment-Emergent AEs During PALISADE and ARC004 Therapeutic Dosing (Safety Population)**

<table>
<thead>
<tr>
<th>AEs</th>
<th>PALISADE (n=116)</th>
<th>ARC004 (n=110)</th>
<th>Significant Difference&lt;sup&gt;†&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>All AEs</td>
<td>97 (83.2)</td>
<td>91 (82.7)</td>
<td>29 (90.6)</td>
</tr>
<tr>
<td>Moderate AE</td>
<td>5 (4.3)</td>
<td>4 (3.6)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Severe AE</td>
<td>2 (1.8)</td>
<td>2 (1.8)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

<sup>†</sup> Indicates statistically significant difference between PALISADE and ARC004 (P < 0.05).