438

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Effect of Demographics and Baseline Clinical Characteristics on the Treatment Response to AR101: Results From PALISADE

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INTRODUCTION

- Food allergy affects 7.6% of children in the United States[1] and prevalence is believed to be on the rise[2]
- Peanut allergy is the most common food allergy among children[1]
- Peanut allergy is often associated with allergic comorbidities that can affect symptoms and treatment response[3]
- Peanut (*Arachis hypogaea*) Allergen Powder-dnfp (PTAH)—formerly known as AR101—is a first-in-class standardized oral biologic drug recently approved to mitigate allergic reactions that may occur with accidental exposure to peanuts in individuals 4–17 years of age with a confirmed diagnosis of peanut allergy[4]
- In the international phase 3 PALISADE trial (NCT02635776), subjects aged 4–17 years treated with PTAH demonstrated an increase in the threshold of reactivity to peanut protein[5]

OBJECTIVE

- To evaluate the impact of selected baseline characteristics on the response to PTAH in children and adolescents participating in PALISADE

METHODS

- The primary endpoint of PALISADE was the proportion of participants aged 4–17 years who were able to tolerate a single dose of ≥600 mg of peanut protein at the exit double-blind, placebo-controlled food challenge (DBPCFC) without dose-limiting symptoms
- To examine the effects of baseline characteristics on the primary endpoint, proportions of PALISADE subjects aged 4 to 17 years achieving the primary endpoint were calculated along with the treatment difference from placebo (and corresponding 95% CI) based on the following characteristics:
  - Age subgroup (4–11 years, 12–17 years)
  - Sex
  - Asthma
  - History of peanut-related anaphylactic reaction
  - Allergic rhinitis
  - Multiple food allergies
  - Atopic dermatitis
- Treatment differences within subgroups were compared to the overall study population
- Subgroup comparisons were not corrected for multiple testing

RESULTS

- Overall, 496 children and adolescents were enrolled and randomized to treatment (372 PTAH and 124 placebo)
  - 412 children and adolescents completed approximately 1 year of treatment and the exit DBPCFC: 296 subjects in the PTAH group, 116 in the placebo group
- Selected baseline demographic and clinical characteristics are summarized in **Table 1**
  - Most subjects were <12 years of age; most subjects were male

Table 1. Baseline Demographic and Disease Characteristics of the Children and Adolescents Enrolled in PALISADE

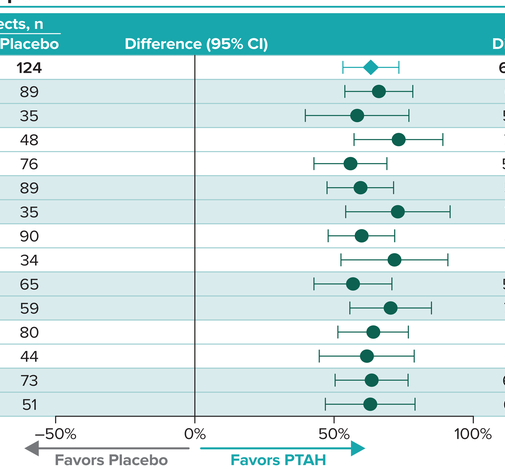
Characteristic	PTAH (n=372)	Placebo (n=124)	Total (N=496)
Age category, n (%)			
4–11 years	238 (64)	89 (72)	327 (66)
12–17 years	134 (36)	35 (28)	169 (34)
Female sex, n (%)	164 (44)	48 (39)	212 (43)
History of peanut-related anaphylactic reaction, n (%)	269 (72)	89 (72)	358 (72)
Previous or current asthma, n (%)	198 (53)	65 (52)	263 (53)
History of allergic rhinitis, n (%)	266 (72)	90 (73)	356 (72)
History of atopic dermatitis, n (%)	236 (63)	72 (58)	308 (62)
Multiple food allergies, n (%)	245 (66)	80 (65)	325 (66)

PTAH, Peanut (*Arachis hypogaea*) Allergen Powder-dnfp.

- Of the randomized subjects, 67.2% in the PTAH group versus 4.0% in the placebo group tolerated ≥600 mg of peanut protein at PALISADE exit (difference, 63.2%, 95% CI: 53.0, 73.3, p<0.0001; intention-to-treat population)
- With respect to consistency in achieving the primary endpoint, all subgroups demonstrated significant differences from placebo (**Figure 1**)
  - Age subgroup (4–11 versus 12–17 years), female sex, absence of previous peanut-related anaphylactic reaction, absence of allergic rhinitis, and absence of asthma had numerically, but not significantly, greater differences compared with placebo
- There were no discernible treatment-effect differences between children with multiple food allergies versus peanut allergy alone, or those with and without atopic dermatitis (**Figure 1**)

Figure 1. Proportion of Subjects Aged 4–17 Years in Demographic Subgroups Achieving the Primary Endpoint

600 mg Peanut Protein Highest Tolerated Dose	Subjects, n PTAH	Subjects, n Placebo	Difference (95% CI)
Overall	**372**	**124**	**63.2% (53.0, 73.3)**
Age, 4–11 years	238	89	66.1% (53.9, 78.3)
12–17 years	134	35	58.3% (39.7, 76.9)
Female	164	48	73.2% (57.2, 89.1)
Male	208	76	55.9% (42.8, 69.0)
Anaphylaxis, yes	269	89	59.5% (47.5, 71.4)
Anaphylaxis, no	103	35	72.9% (54.2, 91.7)
Allergic rhinitis, yes	266	90	59.9% (47.9, 71.8)
Allergic rhinitis, no	106	34	71.7% (52.5, 90.9)
Asthma, yes	197	65	56.8% (42.8, 70.8)
Asthma, no	175	59	70.3% (55.7, 85.0)
Multiple food allergy, yes	245	80	64.1% (51.4, 76.7)
Multiple food allergy, no	127	44	61.8% (44.7, 78.8)
Atopic dermatitis, yes	237	73	63.5% (50.4, 76.6)
Atopic dermatitis, no	135	51	63.0% (46.9, 79.1)



PTAH, Peanut (*Arachis hypogaea*) Allergen Powder-dnfp.

CONCLUSIONS

- All subgroups observed clinically meaningful treatment benefits
- Trends towards higher differences in desensitization rates relative to placebo were observed for some variables including age subgroup (4–11 versus 12–17 years), female sex, and absence of previous peanut-related anaphylactic reaction, allergic rhinitis, and asthma
- Patient characteristics alone should not be used to select those eligible for PTAH, but could be considered when counseling patients with peanut allergy

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