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Improvements in Self-Reported Disease-Specific Quality of Life Among Peanut-Allergic Subjects Receiving AR101 for 28 or 56 Weeks Beyond the First Year of Treatment

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INTRODUCTION

- The prevalence of food allergy is increasing in the United States[1] and has been associated with a negative impact on the quality of life (QoL) of allergic individuals and their families[2]
- 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[3]
- In the international phase 3 PALISADE trial (NCT02635776), subjects treated with PTAH demonstrated increased tolerability to peanut protein[4]
- The impact of immunotherapy on food allergy-related QoL has become a central outcome when assessing the efficacy of immunotherapy[5]

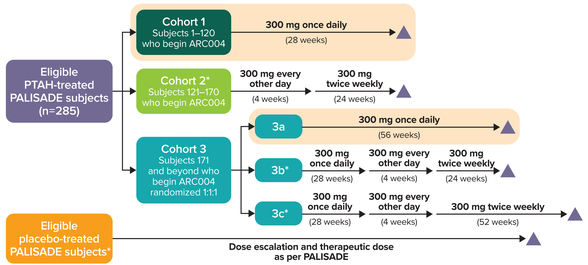
OBJECTIVE

- To assess QoL in unblinded PTAH-treated PALISADE subjects following an additional 28 or 56 weeks of therapeutic dosing (300 mg/day; ARC004, NCT02993107)

METHODS

- Subjects who completed PALISADE were eligible for enrollment into one of three dosing cohorts in the open label extension study ARC004 (**Figure 1**)
- This analysis focuses on subjects who received continued 300 mg PTAH once daily for an additional 28 weeks (~80 weeks total including PALISADE) or 56 weeks (~108 weeks total including PALISADE)

Figure 1. ARC004 Study Design



▲ Indicates the end of the study period. Subjects underwent a double-blind, placebo-controlled food challenge at this time.
*Data from these cohorts will be presented at another time.

- QoL evaluation included subjects 8–17 years old who completed an age-appropriate Food Allergy Quality of Life Questionnaire (FAQLQ) and Food Allergy Independent Measure (FAIM)
  - The FAQLQ-Teenager Form is a validated 28-item QoL questionnaire for teenagers aged 13–17; scores range from 1 ("no impairment") to 7 ("maximal impairment")[6]
  - The FAQLQ-Child Form is a validated 24-item QoL questionnaire for children; scores range from 1 ("not troubled") to 7 ("extremely troubled")[7]
  - The 6-question FAIM-Child Form (age range, 8–12 years) and 5-question FAIM-Teenager Form (age range, 13–17 years) are validated self-report instruments intended to reflect the perception of food allergy severity and related risk[8]
- Questionnaires were completed at PALISADE screening and exit and at ARC004 exit
- Changes (Δ) in Total and subdomain scores (PALISADE screening to ARC004 exit, mean [95% CI]) following 300 mg/day PTAH were calculated for:
  - Cohort 1 (28 weeks [~80 weeks total])
  - Cohort 3a (56 weeks [~108 weeks total])
- A developer-referenced minimally important difference (MID)—defined as a reduction in mean score of ≥0.5 at study exit in comparison to baseline—was considered a clinically significant indicator of change in QoL

RESULTS

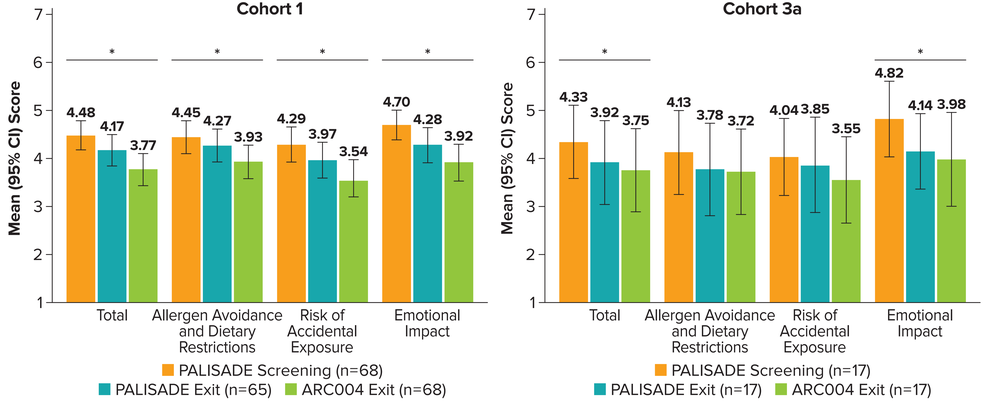
- Demographics for the extension study population are shown in **Table 1**
  - Median age of subjects was 8–10 years
  - More than half of subjects were male; most subjects were white
- Of 285 eligible PALISADE PTAH-treated subjects, 110 subjects (38.6%) and 32 subjects (11.2%) were assigned to Cohorts 1 and 3a, respectively
  - Subjects completing FAQLQ: Cohort 1, n=68; Cohort 3a, n=17
  - Subjects completing FAIM: Cohort 1, n=72; Cohort 3a, n=18

Table 1. Baseline Demographics for ARC004 PALISADE Extension Study (Safety Population)

Characteristics	Cohort 1 (n=110)	Cohort 3a (n=32)
Age, median (Q1, Q3), years[a]	10.0 (7.0, 12.0)	8.0 (6.0, 13.0)
Male, n (%)	58 (52.7)	18 (56.3)
Ethnicity, n (%)		
Hispanic or Latino	9 (8.2)	4 (12.5)
Not Hispanic or Latino	101 (91.8)	28 (87.5)
Race, n (%)		
White	87 (79.1)	25 (78.1)
Other	23 (20.9)	7 (21.9)
Maximum tolerated dose		
None	5 (4.5)	4 (12.5)
1 mg	8 (7.3)	1 (3.1)
3 mg	23 (20.9)	6 (18.8)
10 mg	28 (25.5)	8 (25.0)
30 mg	46 (41.8)	13 (40.6)
History of asthma		
Yes	47 (42.7)	15 (46.9)
No	63 (57.3)	17 (53.1)
Peanut SPT, median wheal diameter (Q1, Q3), mm[b]	11.5 (9.0, 15.0)	10.3 (8.0, 15.5)

[a]Age is calculated relative to the date of informed consent. [b]Mean wheal diameter is calculated as the average of the long and short axes from the peanut wheal minus the average of the long and short axes from the saline wheal at the 15-minute time point.
Q1, first quartile; Q3, third quartile; SPT, skin prick test.

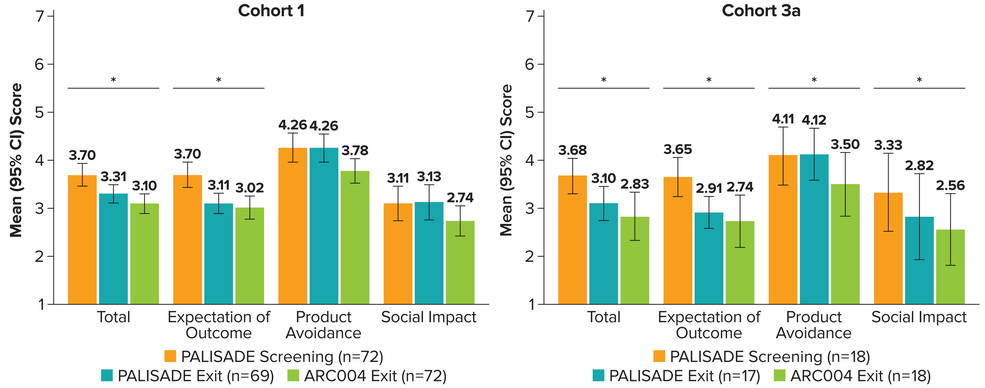
Figure 2. Subjects Aged 8–17 Years Self-Report: FAQLQ Results



*Differences in FAQLQ score improvements (PALISADE screening vs ARC004 exit) exceeded the developer-referenced MID of 0.5.
FAQLQ, Food Allergy Quality of Life Questionnaire; MID, minimally important difference.

- For FAQLQ, the MID exceeded 0.5 for Total scores (**Figure 2**)
  - Cohort 1: n=68, Δ=–0.71 (–1.01, –0.41); Cohort 3a: n=17, Δ=–0.58 (–1.27, 0.12)
  - All subdomains exceeded the MID for Cohort 1 subjects
  - The Emotional Impact subdomain showed the greatest improvement beyond the MID among Cohort 3a subjects

Figure 3. Subjects Aged 8–17 Years Self-Report: FAIM Results



*Differences in FAIM score improvements (PALISADE screening vs ARC004 exit) exceeded the developer-referenced MID of 0.5.
FAIM, Food Allergy Independent Measure; MID, minimally important difference.

- FAIM Total scores also exceeded the MID of 0.5 for both cohorts (**Figure 3**)
  - Cohort 1: n=72, Δ=–0.60 (–0.83, –0.36); Cohort 3a: n=18, Δ=–0.84 (–1.33, –0.36)
  - The Expectation of Outcome subdomain score exceeded the MID for Cohort 1 subjects
  - All subdomain scores improved beyond the MID for Cohort 3a subjects

CONCLUSIONS

- Self-reported QoL total score measurements consistently exceeded the MID following the transition to open-label ARC004 at both 28 and 56 weeks of additional PTAH therapeutic dosing
- These results suggest improvements in emotional and social QoL impacts of peanut allergy after long-term (~80 weeks and 108 weeks [~1.5 and 2 years]) treatment with PTAH
- This report of longer-term data may also be reflective of the patient experience with PTAH when administered in real-world settings, where patients will be unblinded to treatment

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