Treatment Satisfaction With AR101 Oral Immunotherapy for Peanut Allergy in a European Paediatric Population

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A conflict of interest is any situation in which a speaker or immediate family members have interests, and those may cause a conflict with the current presentation.
Conflicts of interest do not preclude the delivery of the talk, but should be explicitly declared. These may include financial interests (eg. owning stocks of a related company, having received honoraria, consultancy fees), research interests (research support by grants or otherwise), organisational interests and gifts.

1 Introduction

- Peanut allergy is a potentially life-threatening and typically lifelong condition prevalent in children[1]

- The current standard of care for peanut allergy is strict dietary avoidance and symptomatic treatment of allergic reactions with emergency medications, including auto-injectable adrenaline, upon allergen exposure[2]
  - Burden of peanut avoidance negatively affects health-related quality of life for peanut-allergic individuals and their caregivers[3]

- OIT can induce clinically meaningful desensitisation to peanut and is associated with allergic reactions that are typically mild-to-moderate in severity and decrease in frequency and severity with ongoing treatment[4]

OIT, oral immunotherapy.

1. Nwaru BI et al. *Allergy*. 2014; 69:992-1007. 2. Muraro A et al. *Allergy*. 2014; 69:1008-1025. 3. Primeau MN et al. Clin *Exp Allergy*. 2000; 30(8):1135-1143. 4. PALISADE Group of Clinical Investigators. *N Engl J Med*. 2018;379(21):1991-2001.

2 Introduction

- AR101 is a standardised oral biologic drug for peanut OIT
  - AR101 was recently approved by the FDA and is investigational outside of the United States

- Efficacy and safety of OIT for peanut allergy with AR101 was investigated in ARTEMIS, a European phase 3, randomised, double-blind, placebo-controlled trial in peanut-allergic participants aged 4–17 years
  - Assessment of **treatment satisfaction** was an exploratory endpoint in ARTEMIS

ARTEMIS, (NCT03201003) FDA, United States Food and Drug Administration; OIT, oral immunotherapy; TSQM-9, Treatment Satisfaction Questionnaire for Medication

3 Methods: Study Design

- ARTEMIS was conducted across 18 sites in 7 European countries: France, Germany, Ireland, Italy, Spain, Sweden and UK

- Participants underwent a screening DBPCFC and were randomised 3:1 (AR101:placebo)

- Participants received daily doses of AR101 or placebo that were escalated every 2 weeks over ~6 months until a maintenance dose of 300 mg/day was reached, and underwent an exit DBPCFC after ~3 months of therapeutic maintenance dosing

- After exit DBPCFC and unblinding, AR101-treated participants were asked to complete the **9-item Treatment Satisfaction Questionnaire for Medication** (**TSQM-9**)

4 Methods: TSQM-9

- TSQM-9 is a validated instrument designed to assess patient-reported treatment satisfaction with medication across 3 domains[1]

1	2	3
Effectiveness	Convenience	Global Satisfaction

- Each domain is comprised of 3 "Items" that are scored on a 5- or 7-point scale with scores ≥3 or ≥4 indicating satisfaction, respectively
- Composite "Total" scores are calculated from each domain and normalised on a 0–100 scale with scores ≥60% indicating satisfaction[2]
- TSQM-9 is designed for participants who have received active treatment and has been used in trials investigating asthma, atopic dermatitis, arthritis, multiple sclerosis and others[2-5]

TSQM-9, Treatment Satisfaction Questionnaire for Medication.

1. Bharmal M et al. *Health Qual Life Outcomes*. 2009; 7:36. 2. Ueda K et al. *Clin Interv Aging*. 2018.; 13. 3. Chapman K et al. *Allergy*. 2019; 74:9. 4. Nakahara T et al. *Allergy*. 2018; 74:6. 5. Meyer T et al. *BMC Neurology*. 2019; 19:222.

5 Results: Overview

- Baseline characteristics were well-balanced between AR101 and placebo groups and typical of a highly atopic peanut-allergic population

- 80.3% of AR101-treated participants and 93.0% of placebo-treated participants completed the trial

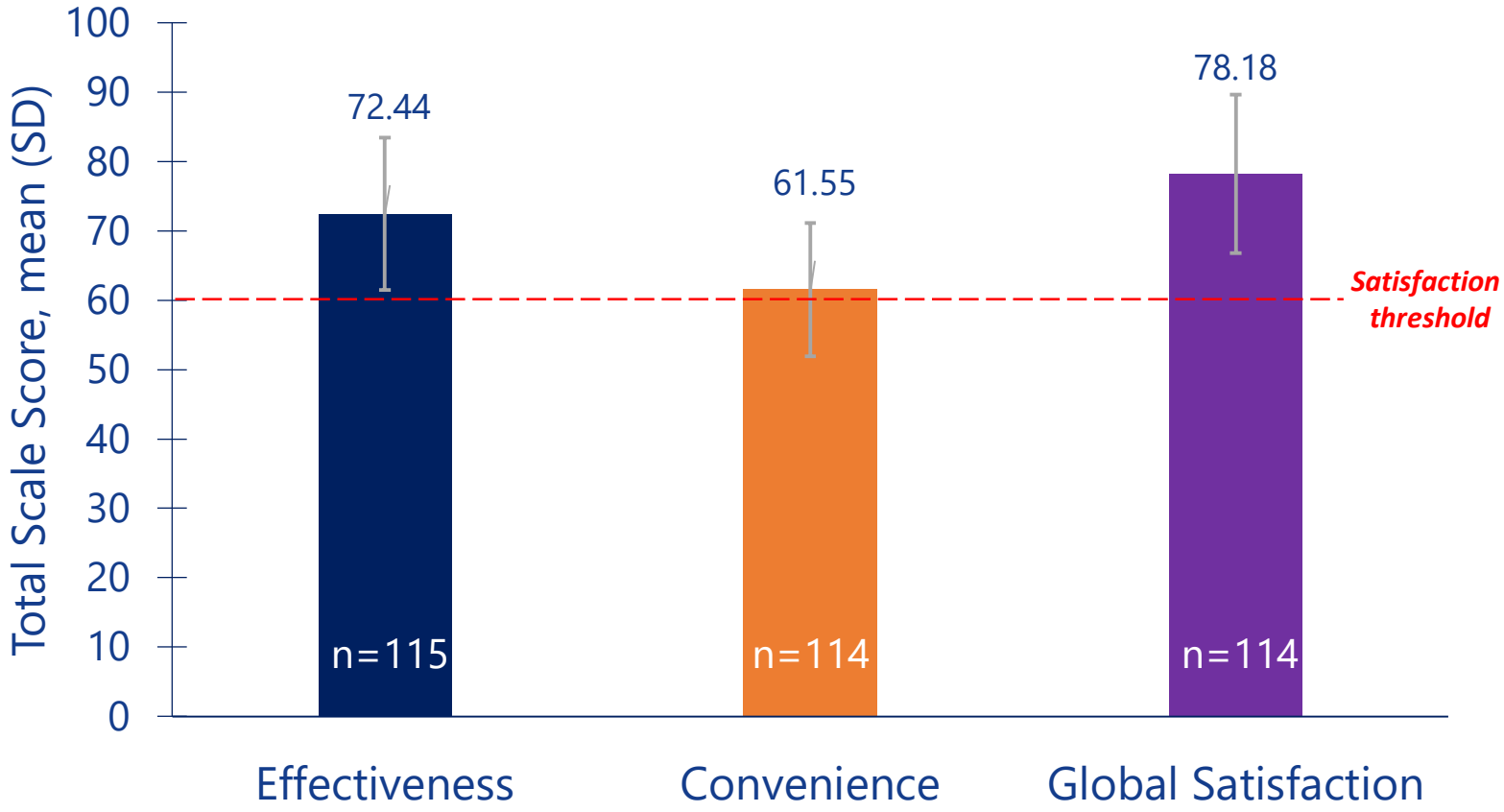
- All primary, secondary and safety endpoints were met
  - In the ITT population, 58% of participants receiving AR101 versus 2% of participants receiving placebo could tolerate 1000 mg peanut protein at exit DBPCFC ($P<0.0001$)
  - Most participants in both treatment groups experienced AEs (AR101, 98.5%; placebo, 97.7%) which were typically mild or moderate in maximum severity (AR101, 99.2%; placebo, 100%)
  - Systemic allergic reactions were reported in both treatment groups (AR101, 12.1%; placebo, 2.3%) all of which were mild or moderate – No severe systemic allergic reactions (severe anaphylaxis) were reported

- **TSQM-9**
  - 114 (84.1%) AR101-treated participants completed ≥1 question on the TSQM-9

AE, adverse event; DBPCFC, double-blind, placebo-controlled food challenge; ITT, intention-to-treat; TSQM-9; TSQM-9, Treatment Satisfaction Questionnaire for Medication.

6 Results: TSQM-9 Total Scale Scores, ITT AR101-Treated Population

- Mean total scale scores indicate treatment satisfaction across all domains
- Participants reported high mean total scale scores for **effectiveness** and **satisfaction** and moderate scores for **convenience**

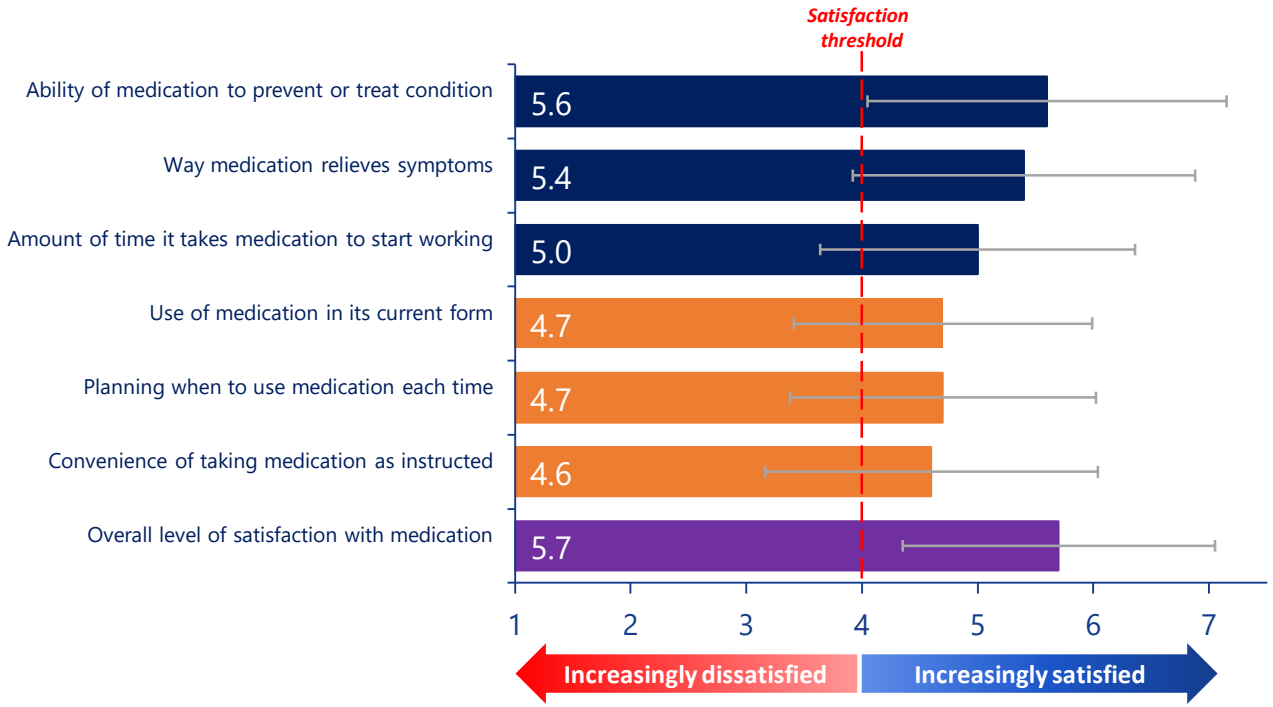


Total scale scores ranged from 0 to 100; higher scores indicate greater levels of satisfaction. Dotted line indicates minimum threshold for satisfaction.
CI, confidence interval; LS, least-squares; ITT, intention-to-treat; TSQM-9, Treatment Satisfaction Questionnaire for Medication-9.

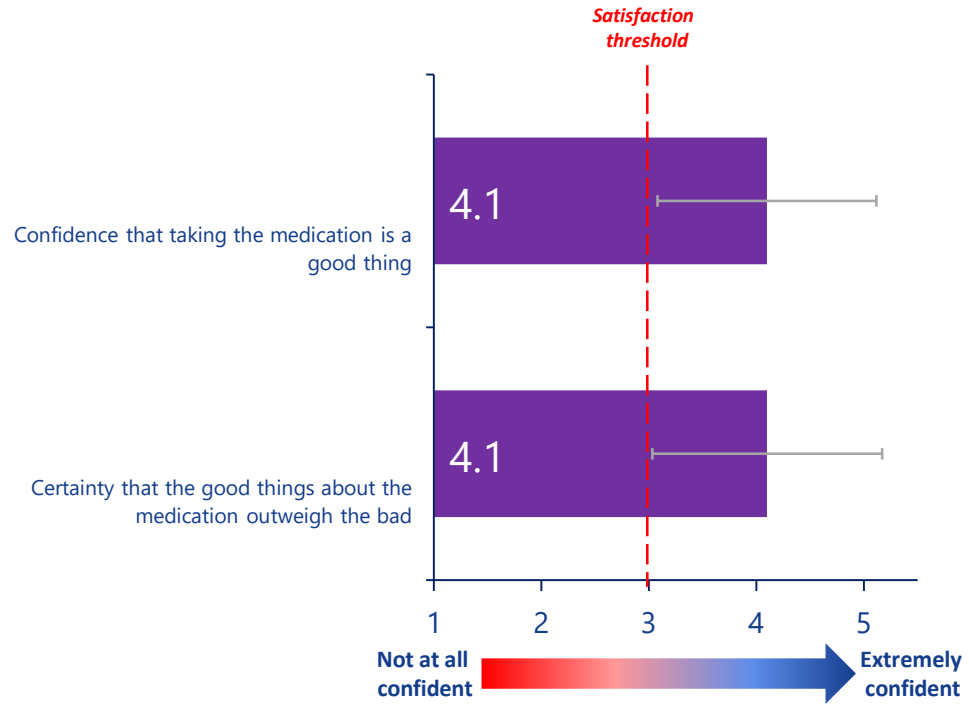
7 Results: Mean (±SD) Individual TSQM-9 Item Scores, ITT AR101-Treated Population

- Participants reported moderate-to-high individual scores across all items

Mean (±SD) TSQM-9 Individual Item Scores (7-Point Scale)



Mean (±SD) TSQM-9 Individual Item Scores (5-Point Scale)



Effectiveness Convenience Global Satisfaction

Dotted line indicates minimum threshold for satisfaction.
ITT, intention-to-treat; SD, standard deviation; TSQM-9, Treatment Satisfaction Questionnaire for Medication-9.

8 Discussion

- Collecting treatment satisfaction data provides meaningful insight into the perception of the **convenience of** and **confidence in** a medication that isn't captured in other clinical outcomes

- Treatment satisfaction is shown to affect **treatment-related behaviours**[1] such as:
  - Correct use of the medication
  - Continued use of the medication
  - Adhering to medication regimens

- As such, a patient's perspective on how satisfactory a medication is can have direct implications on the medication's safety, effectiveness and adherence

1. Atkinson M et al. *Health Qual Life Outcomes*. 2004; 2:12.

9 Conclusions

After ~9 months of treatment with daily AR101, the majority of participants reported:

- High **global satisfaction** with treatment
- High confidence in the **effectiveness** of treatment
- Moderate-to-high satisfaction with the **convenience** of treatment

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