Background

Peanuts (Arachis hypogaea) are one of the most common allergens. Although peanut allergy is a significant health concern, it is associated with limited treatment options and high levels of burden and cost. Oral immunotherapy (OIT) is a potential treatment for peanut allergy, and the efficacy and safety of a novel OIT product, PALFORZIA™ (ARTEMIS), have been demonstrated in clinical trials for children aged 4-17 years old. The aim of this analysis was to summarize the overall safety profile of PALFORZIA™ up to ~3.5 years of exposure.

Methods

Participants were included in the study if they had peanut-specific IgE (kUA/L) ≥0.35 and were aged 4-17 years old. The safety analysis included both treatment-related (TRAEs) and non-treatment-related AEs (NTRAEs). The 5-point Consortium of Food Allergy Research (CFAR) grading scale was used to assess severity of non-systemic AEs, and the 3-point Muraro grading scale was used for systemic reactions.

Results

Most frequent AEs were abdominal pain and oral paraesthesia. Updosing was necessary for 40.1% of participants. A total of 13.3% (n=150) of PALFORZIA™-treated participants discontinued trial participation due to AE(s).

Conclusions

The most frequently reported TRAEs were throat irritation, abdominal pain, and oral paraesthesia. The data may be used to facilitate shared decision-making discussions between peanut-allergic individuals, their caregivers, and clinicians.

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References


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