Health Technology Briefing
May 2022

AR101 for peanut allergy in children aged 1 – 3 years

Company/Developer	Aimmune Therapeutics Inc

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 26919	NICE ID: 10510	UKPS ID: 652865

Licensing and Market Availability Plans

Currently in phase III clinical trials.

Summary

A food allergy is when the body's immune system reacts to proteins from specific foods, as if it were a threat. Common foods that cause an allergic reaction are milk, eggs, peanuts, tree nuts, fish, and shellfish. Most food allergies affect younger children under the age of 3 years old, however peanut and tree nut allergies are longer-lasting and persist into adulthood. Symptoms include itching inside the mouth, throat or ears, hives (itchy red rashes), swelling of the face, vomiting and, in serious cases, severe allergic reaction (anaphylaxis). There are currently no recommended treatments for peanut allergy in children under the age of 4 years and the main way to prevent an allergic reaction is to identify the food causing the allergy and avoid it.

AR101 is in clinical development for children, aged 1-3 years old, with peanut allergy. It is administered orally as a sachet or capsule. AR101 works by exposing the body's immune system to the peanut protein that triggers an allergic reaction, in a safe and controlled manner, in order to minimise symptom development and desensitise the body. AR101 is already approved for treatment in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy. If licenced, AR101 would be the first available treatment option for children aged 1–3 years with peanut allergy.

Proposed Indication

For the treatment of peanut-allergic children aged 1 to <4 years old.[1]

Technology

Description

AR101 (Palforzia, Arachis hypogaea) is a new peanut-derived, oral biologic drug that delivers a target daily maintenance dose of 300mg of peanut protein with a characterised protein profile. Previous studies have suggested that oral immunotherapy is a potential strategy for the treatment of peanut allergy by inducing desensitisation, which is generally understood as a transient up-ward shift in threshold reactivity to an allergen as a result of ongoing controlled exposure to that same allergen.[2] Oral immunotherapy involves exposing allergic individuals to gradually escalating doses of an allergen to render effector cells less reactive, thereby inducing desensitisation.[3] The precise mechanism of desensitisation is not fully understood.[4]

AR101 is in phase III (NCT03736447, POSEIDON) clinical development for peanut-allergic children aged 1 to <4 years. A101 powder is provided in oral capsules and sachets, and is administered in escalating doses for approximately 6 months.[1]

Key Innovation

There are currently no licenced, or National Institute for Health and Care Excellence (NICE)-recommended, treatment options for peanut allergy for children <4 years old; as such AR101 would offer the first treatment option for this population.[2,5]

In a phase III clinical trial (NCT03201003, ARTEMIS) for children aged 4-17 years old with peanut allergy, AR101 treatment led to rapid desensitisation to peanut protein, with a predictable safety profile that improved with treatment, and an associated improvement in self-reported and caregiver-reported food allergy-related quality of life.[6]

Regulatory & Development Status

In the EU/UK, AR101 is indicated for the treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy. AR101 may be continued in patients ≥18 years old.[4]

AR101 is phase II and III clinical trials for peanut allergy.[7]

Patient Group

Disease Area and Clinical Need

Peanut allergy is a type of food allergy whereby the body's immune system reacts to the proteins found in peanuts. This results in common symptoms, such as itching sensation in the mouth, throat or ears, hives (itchy raised red rashes), swelling of the face, and vomiting. In serious cases anaphylaxis (a severe allergic reaction) can occur causing breathing difficulties, trouble swallowing or speaking, and feeling dizzy or faint. Food allergies often affect younger children under the age of 3 years, and peanut allergies are usually longer-lasting allergies, which persist into adulthood.[8] Peanut allergy affects all aspects of daily life and can cause extreme anxiety for children and young people with the allergy and their carers. It can have

implications for shopping and preparing food, weaning infants, eating out, travelling, seasonal events, education, socialising and work. Parents may experience anxiety, in particular around the time their children start secondary school or leave home.[9]

In the UK, peanut allergies affects between 0.5-2.5% of children.[10] Applying these estimates to the most recent population estimates for England (mid-2020) would approximate between 9,734 and 48,668 children aged 1-3 have a peanut allergy.[11] For reasons that are unclear, rates of food allergies have risen sharply in the last 20 years, however, deaths from anaphylaxis-related food reactions are now rare.[8]

Recommended Treatment Options

There are currently no licensed (nor NICE-recommended) treatments for peanut allergy in under 4-year-old children. Currently standard of care is based around supporting the use of strict elimination diet and the timely administration of rescue medications in case of an allergic reaction on accidental exposure.[2,5]

Clinical Trial Information

Trial	**POSEIDON; NCT03736447;** Peanut Oral Immunotherapy Study of Early Intervention for Desensitisation **Phase III –** Active, not recruiting **Location(s):** 2 EU countries, UK, and United States **Primary completion date:** June 2022
Trial Design	Triple masked (participant, care provider, investigator), randomised parallel assignment.
Population	N=146 (actual); aged 1 to <4 years old; sensitivity to peanut.
Intervention(s)	AR101 powder provided in capsules and sachets, in escalating doses for approximately 6 months.
Comparator(s)	Matched placebo.
Outcome(s)	Efficacy of AR101 [Time Frame: 12 months] The proportion of subjects treated with AR101 compared with placebo who tolerate an at least 600 mg single dose (for patients in the US) or 1000 mg single dose (for patients in Europe) of peanut protein with no more than mild allergy symptoms during the exit double-blind placebo-controlled food challenge (DBPCFC).
Results (efficacy)	-
Results (safety)	-

Estimated Cost

The list price of Palforzia is £10.12 per day. A flat price is applied for each Palforzia dose (range 0.5 mg to 300 mg).[12]

Relevant Guidance

NICE Guidance

- NICE clinical guideline. Food allergy in under 19s: assessment and diagnosis (CG116). February 2011.

NHS England (Policy/Commissioning) Guidance

- NHS England. 2013/14 NHS Standard Contract for Paediatric Medicine: Specialised Allergy services. E03/S/j.

Other Guidance

- European Academy of Allergy and Clinical Immunology (EAACI). EAACI guideline: Preventing the development of food allergy in infants and young children (2020 update). March 2021.[13]
- British Society for Allergy and Clinical Immunology (BSACI). BSACI guideline for the diagnosis and management of peanut and tree nut allergy. June 2017.[10]
- EAACI. EAACI Food Allergy and Anaphylaxis Guidelines: diagnosis and management of food allergy. June 2014.[14]

Additional Information

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NB: This briefing presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.