

Allergy Therapeutics^{PLC}

Allergy Therapeutics plc
("Allergy Therapeutics", "ATL" or the "Group")

Allergy Therapeutics announces further positive progress in Phase I/IIa PROTECT trial evaluating safety and tolerability of short-course peanut allergy vaccine candidate

- *Dosing in healthy volunteers completed; VLP Peanut well tolerated up to the highest planned dose*
- *Final cohort of peanut allergic patients with multiple escalating doses of VLP Peanut/placebo progressing as planned with supportive safety and tolerability profile*
- *Encouraging dose-dependent biomarker responses and consistent safety data to inform Phase IIb dose selection*

16 October 2025 Allergy Therapeutics (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy immunotherapies, today announces further positive progress in its Phase I/IIa PROTECT trial, evaluating the safety and tolerability, and exploring preliminary proof of efficacy, of its innovative, short-course peanut allergy vaccine candidate, VLP Peanut, in healthy and peanut allergic adult subjects.

No relevant safety signals were identified across each of the trial's cohorts, which supports the safety profile of VLP Peanut. This is achieved by disguising the major peanut allergen (Ara h2) on the surface of the nanoparticle used in the vaccine candidate, reducing its allergenicity and inducing a favourable pro-tolerogenic immune response.

In earlier stages of the trial, as previously announced, peanut allergic patients treated with ascending concentrations of the vaccine candidate showed a marked reduction in wheal size versus placebo using a whole peanut extract skin prick test. The study subsequently progressed to include both healthy volunteers and peanut allergic patients who were dosed subcutaneously with further ascending concentrations of VLP Peanut, aiming to determine the maximum tolerated dose.

Healthy cohorts have now completed dosing at the maximum intended levels, with no dose-limiting safety or tolerability signals observed. One final cohort of peanut allergic patients remains, with dosing expected to extend beyond the candidate's anticipated therapeutic range. This final stage of the trial is progressing as planned, with safety and tolerability data to date continuing to support the candidate's positive profile.

A total of 48 subjects have been enrolled and investigated during the trial.

Earlier [interim analysis](#) from the first two cohorts of peanut allergic patients, suggested that VLP Peanut is driving a reduction in allergic response to the major peanut allergen (Ara h2):

- A protective dose-dependent inhibition of Ara h2 IgE binding to B cells was observed after treatment with VLP Peanut compared to placebo. This inhibitory effect is indicative of how VLP Peanut induces blocking antibodies that may reduce the pro-allergic response.
- A trend towards a reduction of both basophil sensitivity and basophil reactivity to Ara h2 was seen, especially for the higher VLP Peanut dose, and an induction of protective specific IgG towards the major peanut allergen Ara h2 was observed compared to placebo.

Findings from the PROTECT trial will guide dose selection for the Group's planned Phase IIb trial which is expected to commence in H2 2026.

Manuel Llobet, Chief Executive Officer of Allergy Therapeutics, commented: *"These results signal a major advance in the allergy research community's search for what remains our holy grail - an effective short-course vaccine for people living with peanut allergy. This vaccine candidate's positive safety profile, together with encouraging early efficacy signals showing a strong immune response and reduced allergic reactivity, further strengthen our confidence in the programme and its potential to transform the lives of those affected by this most common and severe food allergy. We look forward to progressing VLP Peanut, the most advanced peanut vaccine programme in the industry, into Phase IIb development and continuing to lead the way in allergy innovation."*

More information about the PROTECT trial can be found on [ClinicalTrials.gov](https://clinicaltrials.gov) under the identifier [NCT05476497](https://clinicaltrials.gov/ct2/show/study/NCT05476497).

This announcement contains inside information for the purposes of the UK Market Abuse Regulations.

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Notes for editors:

About Allergy Therapeutics

Allergy Therapeutics is an international commercial biotechnology company, headquartered in the UK, focussed on the treatment and diagnosis of allergic disorders, including aluminium free immunotherapies that have the potential to cure disease. The Group sells proprietary and third-party products from its subsidiaries in nine major European countries and via distribution agreements in an additional ten countries. For more information, please see www.allergytherapeutics.com.

About the PROTECT Trial

The PROTECT trial, across multiple clinical trial sites in the US, is being conducted in both healthy subjects and peanut allergic patients and consists of Part A and Part B. Part A involved subcutaneous immunotherapy (SCIT) dosing in healthy subjects (Group A1) and skin-prick testing in peanut allergic patients (Group A2). Part B of the clinical trial is double-blind, placebo-controlled and in patients with peanut allergy.

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