

Allergy Therapeutics^{PLC}

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

Allergy Therapeutics advances to the final phase of treatment in Phase I/IIa VLP Peanut PROTECT trial and announces publication of mechanism of action data

- *Healthy volunteers now receiving highest doses with no safety signals observed*
- *Third cohort of peanut allergic patients progressing through therapeutic dose range*
- *New peer-reviewed publication in Journal of Allergy and Clinical Immunology validates mechanism of action*

27 March 2025 Allergy Therapeutics (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy immunotherapies, today announces that its VLP Peanut Phase I/IIa PROTECT trial has entered the final phase of treatment, with healthy volunteers progressing to the highest dose levels and no safety signals observed to date.

As part of this phase, the final cohort of healthy volunteers is now receiving subcutaneous doses of VLP Peanut, the Group's innovative, short-course peanut allergy vaccine candidate, beyond the expected therapeutic dose level to establish a strong safety margin. Meanwhile, the third of four planned cohorts of peanut-allergic patients is progressing through dose escalation, also including levels beyond the anticipated therapeutic range. These data will supplement previously [reported](#) biomarker efficacy findings observed at lower cumulative doses, strengthening the understanding of treatment response at higher doses.

Results from the current patient cohort will also be key in defining the optimal dose range for the upcoming Phase IIb study while reinforcing confidence in the treatment's safety profile. Both healthy volunteers and peanut-allergic patients have progressed through their initial dose escalation, and, following a safety review, the committee has recommended advancing to the second of three planned dose increases for each cohort.

In addition, Allergy Therapeutics announces the publication of a [new paper](#) in the *Journal of Allergy and Clinical Immunology* (JACI), which evaluates the beneficial tolerogenic properties and immunological reactivity of VLP Peanut.

Peanut allergy remains a growing public health concern, particularly in the US and Europe, with limited effective treatment options. Results detailed in the paper, from earlier research conducted by Allergy Therapeutics, demonstrate that VLP Peanut can reduce allergic responses while promoting protective immune mechanisms in cells from peanut-allergic individuals. Preliminary skin testing in six peanut-allergic adults further confirmed the vaccine candidate was safe and well tolerated.

The PROTECT trial continues to progress to plan and the Company expects to announce the initial topline data later this summer.

Professor Mohamed Shamji, Professor of Immunology and Allergy at Imperial College London and senior author of the paper, commented: *"There remains an urgent and compelling need for a therapy that not only ensures sustained protection during extended treatment-free periods but also holds the promise of curing peanut allergies. Our dedicated efforts are aimed at fulfilling this significant unmet need, and the data we have collected thus far are exceptionally promising. We have established that the vaccine not only circumvents triggering allergic reactions but also skilfully modulates the immune system, potentially leading to long-term protection. This marks a significant advancement in food allergy therapeutics, and the findings from the clinical trial phase set the stage for new therapies for peanut allergy."*

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).

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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 is being conducted in both healthy subjects and peanut allergic patients and consists of Part A and Part B. Part A involves subcutaneous immunotherapy (SCIT) dosing in healthy subjects (Group A1) and skin-prick testing in peanut allergic patients (Group A2), the latter of which was completed in April 2023.

Part B of the clinical trial is double-blind, placebo-controlled and has commenced in patients with peanut allergy at multiple clinical trial sites in the US. Up to 36 peanut-allergic patients will be enrolled in Part B of the clinical trial, should the dosing advance to the highest dose as currently planned.

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