



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

Allergy Therapeutics reports progress of Phase I VLP Peanut PROTECT Trial

- Approval granted to commence escalating subcutaneous dosing in peanut allergic patients
- 25-fold dose escalation successfully completed in healthy subjects using VLP Peanut vaccine candidate
- Safety review committee approves further dose escalation in subsequent cohorts

26 September 2023 Allergy Therapeutics (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, today announces the completion of dosing of healthy volunteers in the first two cohorts in the Phase I PROTECT trial ("PROTECT trial") of its novel virus-like particle (VLP)-based peanut allergy vaccine candidate ("VLP Peanut"). Dosing of the subsequent cohorts will begin now that the approval from the external safety review committee (SRC) has been received.

Additionally, after the successful skin-prick testing phase completed in [April 2023](#), the SRC approved the commencement of subcutaneous dose escalation in peanut allergic subjects, marking the start of the early proof of concept phase of the PROTECT trial. This pivotal stage of the PROTECT trial is expected to begin imminently. The full results from the trial are expected in 2024.

Manuel Llobet, Chief Executive Officer of Allergy Therapeutics, commented: "We welcome the positive progress in our PROTECT trial and are pleased with the safety review committee's approval to begin multiple subcutaneous dosing of peanut allergic patients in the final phase of the trial."

"Peanut allergy is one of the most common types of food allergies. For some people, even the smallest amounts of peanuts can cause a potentially life-threatening reaction. A safe and effective short-course vaccine that provides long-term protection and a long-lasting protective immune response can bring a paradigm shift in treating peanut allergy, changing the lives of those living with the allergy."

The PROTECT trial is being conducted in both healthy volunteers and peanut allergic patients and consists of two parts:

- **Part A:** Open-label study of four cohorts of healthy subjects (Group A1) who undergo subcutaneous dosing with ascending concentrations of VLP Peanut. Peanut allergic subjects (Group A2) underwent skin prick tests performed with ascending concentrations of the vaccine candidate (completed April 2023).
- **Part B:** Double-blind, placebo-controlled Part B enrolling peanut allergic patients who receive ascending doses of the vaccine candidate administered subcutaneously.

The PROTECT trial builds on the findings from the VLP001 study, which took place at Imperial College London. The *in-vivo* biomarker study revealed that VLP Peanut significantly reduced certain allergic responses compared to the major allergen Ara h2, indicating a promising safety profile with reduced potential to induce allergic reactions.

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 Article 7 of the UK Market Abuse Regulations.

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Notes for editors:

About Allergy Therapeutics

Allergy Therapeutics is an international commercial biotechnology company focussed on the treatment and diagnosis of allergic disorders, including aluminium free immunotherapy vaccines 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. Its broad pipeline of products in clinical development includes vaccines for grass, tree and house dust mite, and peanut allergy vaccine in pre-clinical development. Adjuvant systems to boost performance of vaccines outside allergy are also in development.

Formed in 1999 out of Smith Kline Beecham, Allergy Therapeutics is headquartered in Worthing, UK with more than 11,000m² of state-of-the-art MHRA-approved manufacturing facilities and laboratories. The Group, which employs c.600 employees, is listed on the London Stock Exchange (AIM:AGY). For more information, please see www.allergytherapeutics.com.

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