

## **Allergy Therapeutics**<sup>PLC</sup>

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

### **Allergy Therapeutics commences subcutaneous dosing in peanut allergic patients in Phase I/IIa VLP Peanut PROTECT Trial**

- *First patient receives subcutaneous dosing with no safety signals observed*
- *Subjects will receive a total of three escalating doses over three separate dosing days*
- *This marks the start of the clinical proof of concept phase using biomarkers to assess preliminary efficacy*
- *No safety signals observed in the cohorts treated to date*
- *In addition, having already demonstrated tolerability of a 25-fold dose increase in 2 cohorts of healthy subjects, dose escalation in healthy subjects has progressed to a third cohort to pave the way for dose escalation to similar strengths in peanut allergic patients*

**12 March 2024** Allergy Therapeutics (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, today announces the commencement of subcutaneous dosing of peanut allergic patients in the Phase I/IIa PROTECT trial evaluating its novel virus-like particle (VLP)-based peanut allergy vaccine candidate ("VLP Peanut").

Patients allergic to peanuts have previously undergone skin-prick testing in part A of the PROTECT trial. Following an external safety review committee (SRC), it was determined that no safety signals had been observed and it was safe to proceed with incremental subcutaneous dosing in healthy subjects in the Phase I stage and in peanut allergic patients in the Phase IIa part of the trial.

**Manuel Llobet, Chief Executive Officer of Allergy Therapeutics, commented:** *"This is a key milestone in our journey to offer transformative outcomes to patients living with peanut allergies. We are excited to begin gathering data supportive of efficacy using biomarker technology which is aligned with recent FDA workshop thinking on demonstrating efficacy in clinical trials. We look forward to the complete results of this trial and continue to work towards the required planning for the phase II."*

The PROTECT trial is being conducted in both healthy volunteers and peanut allergic patients and consists of Part A and Part B. Part A involves subcutaneous immunotherapy (SCIT) dosing in healthy volunteers (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 subjects with peanut allergy at multiple clinical trial sites in the US. Up to 36 peanut-allergic subjects will be enrolled in Part B of the clinical trial, should the dosing advance to the highest dose as currently planned.

The Group will announce trial updates as is appropriate.

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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**For further information, please contact:**

**Allergy Therapeutics**

Manuel Llobet, Chief Executive Officer  
Shaun Furlong, Chief Financial Officer  
+44 (0)1903 845 820

**Panmure Gordon (Nominated Adviser and Broker)**

Emma Earl, Freddy Crossley, Mark Rogers, Corporate Finance  
Rupert Dearden, Corporate Broking  
+44 (0)20 7886 2500

**ICR Consilium**

Mary-Jane Elliott / David Daley / Davide Salvi  
+44 (0)20 3709 5700  
[allergytherapeutics@consilium-comms.com](mailto:allergytherapeutics@consilium-comms.com)

**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 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, house dust mite and peanut. For more information, please see [www.allergytherapeutics.com](http://www.allergytherapeutics.com).

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