RNS Number : 3864E
Allergy Therapeutics PLC
17 September 2024

Porto

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

Allergy Therapeutics announces further advancement through patient cohorts in Phase I/IIa VLP Peanut PROTECT Trial

- Second cohort of peanut allergic patients have completed dosing with up to 50-fold dose increase from initial dose
- No relevant safety or tolerability findings observed in either peanut allergic patients or healthy subjects at higher doses
- Dose escalation to proceed in next cohorts
- Preliminary biomarker analysis of efficacy expected by end of 2024

17 September 2024 Allergy Therapeutics (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, today announces further progress in its Phase I/IIa VLP Peanut PROTECT trial, building on the positive developments reported in June 2024.

The second cohort of peanut allergic patients has now completed dosing, with patients receiving up to a 50-fold dose increase from the initial dose. No relevant safety or tolerability issues were observed at these higher doses.

As announced in June 2024, healthy subjects in the PROTECT trial have now received a 400-fold dose increase of VLP Peanut, providing strong confidence that the VLP technology within the vaccine candidate is safe and well tolerated at high cumulative doses.

As a result of these positive safety outcomes, the trial's external safety review committee has agreed that the doses administered so far have been safe and well tolerated. Based on this assessment, the committee has approved the progression to higher doses in cohort 3 for peanut allergic patients and cohort 4 for healthy volunteers. Final cohorts 3 and 4 are on schedule to complete dosing in H1 2025.

The ongoing Phase I/IIa VLP Peanut PROTECT trial is evaluating the maximum safe and tolerated dose of the Group's peanut allergy vaccine candidate and includes assessment of biomarker efficacy in peanut allergic patients. Blood samples taken from peanut allergic study volunteers before and after dosing in the first two cohorts are being analysed to identify key biomarker changes indicative of efficacy.

The preliminary results from the first two cohorts of peanut allergic patients assessing safety and efficacy are expected in Q4 2024.

Blood samples taken from peanut allergic study volunteers before and after dosing in cohorts 1 and 2 are being analysed to identify key biomarker changes indicative of efficacy. Basophil activation testing (BAT) mimics an allergic reaction by stimulating basophils with peanut allergens and then observing the expression of activation markers on the surface of the basophils. A reduction in the expression of those markers in the volunteers' samples would be indicative of efficacy in the VLP Peanut vaccine candidate. The preliminary results from the first two cohorts of peanut allergic patients are expected in Q4 2024.

Manuel Llobet, Chief Executive Officer of Allergy Therapeutics, commented: *"We are very grateful to both the trial participants and our partner clinicians for helping Allergy Therapeutics progress VLP Peanut through the clinic. Peanut allergy remains a disease of high unmet need and patients and their families are eager to see progress towards solutions. The data gathered through the PROTECT trial continues to be encouraging, as is the safety review committee's decision to proceed with higher doses in subsequent cohorts. We are keen to present preliminary efficacy data based upon biomarkers by the end of this year."*

More information about the PROTECT trial can be found on ClinicalTrials.gov under the identifier NCT05476497.

- ENDS -

For further information, please contact:

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

Cavendish Capital Markets Limited (Nominated Adviser and Broker)
Geoff Nash /Giles Balleny/ Seamus Fricker / Rory Sale
Nigel Birks - Life Science Specialist Sales
Tamar Cranford Smith - Sales
+44 (0)20 7220 0500

ICR Consilium
Mary-Jane Elliott / David Daley / Davide Salvi
+44 (0)20 3709 5700

+44 (0)20 3709 5700
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. 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.

END

MSCGZGMLKVMGDZM