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

Allergy Therapeutics announces positive interim analysis data from the Phase I/IIa VLP Peanut PROTECT Trial

- *Interim efficacy biomarker analysis of the first two of four peanut allergic patient cohorts demonstrates a positive and consistent immunological response to VLP Peanut*
- *Dose-dependent reduction in wheal size after skin-prick testing indicates the skin is becoming significantly less reactive to peanut extract in patients receiving VLP Peanut compared to placebo*
- *Observed biomarker profile, including induction of protective antibodies and reduced basophil reactivity at relatively low doses, suggests that VLP Peanut has the potential to simultaneously elicit a strong boost of the immune system while suppressing an allergic response*

04 December 2024 Allergy Therapeutics (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy immunotherapies, today announces positive interim biomarker efficacy data from its Phase I/IIa VLP Peanut PROTECT trial, demonstrating the first evidence of treatment effect in peanut allergic patients.

Interim analysis of the first two cohorts of peanut allergic patients showed that treatment with VLP Peanut resulted in a meaningful dose-dependent reduction in skin sensitivity to peanut allergen, with treated patients in cohort 2 showing a 48% reduction in wheal size after skin-prick test compared to an 8% reduction in those treated with placebo.

Additionally, a comparison of the biomarker profile between treatment and placebo points to VLP Peanut 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.

This interim analysis stage involved 12 peanut allergic patients across three treatment groups. The data represents the first demonstration of an immunologic response using a nanoparticle-based approach in peanut allergic patients. Following administration of initial escalating doses, patients underwent comprehensive assessment including skin-prick testing with whole peanut extract and blood sampling to identify key biomarkers of efficacy. As previously communicated, no relevant safety signals have been observed to date.

Prof. Mohamed Shamji, Imperial College London, commented: *"Peanut allergy affects around 3% of the worldwide population and there remain gaps in current therapeutic options. Novel therapeutics are needed and the interim findings from the PROTECT study demonstrate a desirable clinical immunologic response. This includes a reduction in skin reactivity and basophil responsiveness in peanut allergic patients and a dose-dependent induction of IgG antibodies with inhibitory activity of IgE binding to B-Cells. Taken together, these findings support the modulation of the peanut induced allergic response and supports VLP Peanut being potentially effective and safe as a novel therapeutic for peanut allergy."*

Manuel Llobet, Chief Executive Officer of Allergy Therapeutics, commented: *"These initial efficacy results mark an important milestone for our peanut allergy programme. The consistency in immunological response seen at these early doses is particularly encouraging. Combined with the positive safety profile, this data supports our plans to progress to higher doses in the remaining cohorts as we work towards identifying an optimal therapeutic dose for phase II development."*

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