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

Allergy Therapeutics announces successful primary outcome of VLP Peanut 001; a study evaluating biomarkers from peanut allergic patients

- *Study results confirm peanut vaccine candidate's hypoallergic potential*
- *Findings support VLP Peanut first in-human Phase I study design, on track to start Q1 2022*
- *Short-course peanut allergy vaccine candidate represents a significant opportunity in $8 billion worldwide food allergy market*
- *Results strengthen Phase I study IND application being submitted to US FDA in late 2021*

03 August 2021 Allergy Therapeutics (AIM: AGY), the fully integrated commercial biotechnology pharmaceutical company specialising in allergy vaccines, today announces positive primary results from an *ex-vivo* biomarker study evaluating the Group's novel virus-like particle (VLP) based peanut allergy vaccine candidate ("VLP Peanut").

The study, which took place at Imperial College London, evaluated the Group's short-course VLP Peanut and aimed to demonstrate the vaccine candidate's hypoallergic potential. If a vaccine is hypoallergenic, it means it does not illicit an allergic reaction in patients upon dosing. The study used blood samples from peanut allergy patients to evaluate an extensive set of functional and molecular biomarkers. This resulted in a successful primary outcome, with the trial demonstrating a significant 24-fold reduction in basophil activation and histamine release after blood samples were challenged with VLP Peanut compared to a recombinant peanut extract, signifying the hypoallergenic potential of the vaccine candidate. These positive clinical data add to the Group's strong pre-clinical research package, which has demonstrated sustained immunologic protection following peanut exposure after just one single vaccination.

The biomarker study results are encouraging and provide strong support for the human translation of the pre-clinical results and strong confidence in the data to be generated in the planned Phase I study (the PROTECT study). The data also provide important information to establish the starting dose for PROTECT, which is expected to commence in Q1 2022.

Moreover, the results from this study further strengthen the Group's Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA), which is expected to be submitted in late 2021. Further data will be released in due course once secondary endpoints of the study have been analysed.

In addition, the Group has also recently completed an extensive multiple dose toxicology study with VLP Peanut, applying the maximum subcutaneous doses expected to be administered in clinical trials, which further supports the dose escalations planned in the first in-human Phase I study. More information on VLP Peanut will be provided by the Group at a Key Opinion Leader investor event, currently planned for September 2021.

VLP Peanut is being developed as a novel VLP-based therapy for the treatment of peanut allergy. This novel immunogenic, protective, and non-reactogenic vaccine candidate is based on immunologically optimised Cucumber Mosaic Virus-derived VLPs (CuMVTT) with the major peanut allergen (*Arachis hypogaea*) (Ara h 2) displayed on its surface. Patents behind the technology to treat peanut allergy with VLP Peanut have now been granted in the US and are at the national phase in other territories.

The potential of an effective short-course peanut allergy vaccine represents a significant opportunity in the $8 billion worldwide food allergy market[1]. Peanut allergy is one of the most common types of food allergy and its symptoms can range from mild to severe and life-threatening. In the western world, the prevalence of peanut allergy doubled between 2005 and 2015 and it is becoming apparent in Africa and Asia[2]. Only about 20% of children diagnosed with peanut allergy outgrow it by the time they reach school age. In the US (as of 2014), peanut allergy was the most common cause of severe and fatal food-induced anaphylactic reactions[3].

Manuel Llobet, CEO of Allergy Therapeutics, stated: "*We are pleased to have reached this important milestone in the development of our ground-breaking and disruptive vaccine candidate, VLP Peanut. Through our collaboration with Imperial College London and the dedication of our clinical and R&D teams at Allergy Therapeutics, we are another step closer to offering a potentially transformative treatment option for one of the most dangerous allergies. I am proud of the work we do in helping to transform patients' lives and look forward to our upcoming IND submission at the end of this year and expected initiation of our Phase I PROTECT trial in 2022.*"

This announcement contains inside information for the purposes of Article 7 of Regulatory (EU) No596/2014.

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References

1. The Journal of Allergy and Clinical Immunology 2016. 1% of US population. EACCI Food Allergy and Anaphylaxis Guidelines Group 2016 0.2% of Western European Population. Management assumption of annual treatment of $2k

2. Du Toit G, Roberts G, Sayre PH, et al. Randomized trial of peanut consumption in infants at risk for peanut allergy [published correction appears in N Engl J Med. 2016 Jul 28;375(4):398]. N Engl J Med. 2015;372(9):803-813.

3. Sampson H, Shreffler W, Yang W, Sussman G, Brown-Whitehorn T, Nadeau K et al. Effect of Varying Doses of Epicutaneous Immunotherapy vs Placebo on Reaction to Peanut Protein Exposure Among Patients With Peanut Sensitivity. JAMA. 2017; 318 (18):1798.

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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 11,000m^2 of state-of-the-art MHRA-approved manufacturing facilities and laboratories. The Group, which has achieved over 9% compound annual growth since formation, employs c.600 employees and is listed on the London Stock Exchange (AIM:AGY). For more information, please see www.allergytherapeutics.com.

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