

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

Allergy Therapeutics initiates peanut allergy biomarker study with Imperial College London to confirm potential of novel peanut vaccine candidate

- *Ex-vivo biomarker study to evaluate VLP-based peanut allergy vaccine candidate's hypoallergic potential and potent immune response*
- *Findings to support peanut clinical programme with first-in-human trial on track for 2021*
- *Short-course vaccine candidate represents significant differentiated opportunity in \$8bn worldwide food allergy market*
- *IND application to United States Food and Drug Administration expected in 2021*

5 January 2021 Allergy Therapeutics (AIM: AGY), the fully integrated specialty pharmaceutical company specialising in allergy vaccines, today announces that an *ex-vivo* biomarker study of blood samples from peanut allergy patients has begun at Imperial College London. The study aims to evaluate the Group's novel virus like particle (VLP) based peanut allergy vaccine candidate, to confirm its hypoallergic potential and its potent immune response.

The study at Imperial College London, using human samples and an extensive set of functional and molecular biomarkers, will provide Allergy Therapeutics with important information to establish the starting dose for its first-in-human Phase I study. The data will also act as an early clinical predictor of efficacy of the VLP platform and support the acceptance of the Investigational New Drug (IND) application and a successful Phase I trial outcome. The submission of an IND application to the United States Food and Drug Administration (FDA) for that study is expected in 2021.

Allergy Therapeutic's peanut allergy vaccine programme is supported by a strong preclinical research package, providing pre-clinical proof of concept for sustained immunity and protection against peanut anaphylaxis after a single vaccination.

Importantly, in contrast to current treatment approaches such as desensitisation via oral administration or transdermal patches, which require daily dosing over several years, it is anticipated that the Group's next-generation VLP-based peanut vaccine candidate will use only 3 injections to induce sustained protection.

The potential of an effective short-course peanut allergy vaccine represents a significant opportunity in the \$8 billion worldwide food allergy market¹. Prevalence of peanut allergy in Western countries is on the rise and currently ranges from 1.4-3% of children² and, in the US, peanut allergy affects an estimated 1.2% of the overall US population³ with 1 in 4 children with a peanut allergy requiring a hospital visit each year⁴.

In parallel with the peanut allergy human biomarker study, a broader research project with Imperial College London has also commenced, focussing on the selection, measurement and analysis of pre-clinical and clinical biomarkers for allergen immunotherapy products across Allergy Therapeutics' portfolio. Clinical trials in the allergy immunotherapy area often pose challenges with interpretation as they rely on subjective non-validated endpoints. There is therefore an opportunity to explore alternative, more objective measures of success and develop a greater understanding of the underlying science in this important area.

Under this collaboration agreement, researchers will examine samples from the Group's ongoing Grass MATA MPL exploratory field study (G309), and the pre-clinical and clinical development programme for the Group's VLP-based peanut allergy vaccine candidate. Changes in an extensive set of established and innovative biomarkers will be analysed at baseline and throughout treatment with each of the allergen immunotherapies.

Manuel Lobet, CEO of Allergy Therapeutics, stated: *"A safe and effective short-course peanut allergy vaccine would be a significant breakthrough product, offering life-changing benefits to sufferers affected by this condition. The data we have generated so far for our peanut vaccine candidate give us confidence in its potential and through this study we have an opportunity to build on that confidence and provide our upcoming Phase I study with the greatest chances of success."*

"At Allergy Therapeutics we are passionate about progressing the science around allergy immunotherapies. Our collaboration with Imperial College London, who are one of the foremost experts in this field, will equip us with a greater depth of knowledge of allergy biomarkers and their relationship to clinical outcomes, which will be applied to future clinical trials and aid in the development of our allergy immunotherapy pipeline."

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

References

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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 include 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 has achieved over 9% compound annual growth since formation, employs c.500 employees and is listed on the London Stock Exchange (AIM:AGY). For more information, please see www.allergytherapeutics.com.

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