Allergy Therapeutics announces top-line Phase III results from its B301 clinical trial

- Study primary endpoint not achieved -
- Highly statistically significant and relevant increase in immune response observed in active group compared to placebo -
- Clinical development programme to continue after review of the full dataset -

18 March 2019 Allergy Therapeutics plc (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, today announced top-line results from the Phase III clinical trial B301 of its new adjuvanted birch allergoid product. The trial did not show a statistically significant difference between active and placebo arms in the primary endpoint of a combined symptom medication score averaged over the peak birch pollen season. The safety and tolerability profile was positive and consistent with that observed in previous trials. Importantly, secondary endpoint analyses of immunoglobulin markers including IgG and IgG4 showed highly statistically significant differences between active and placebo, suggesting a strong and sustained immune response to treatment (p <0.0001).

Manuel Llobet, CEO at Allergy Therapeutics, stated: “We are surprised by the result, given the strong immune response suggested by the increased immunoglobulin markers in the treatment arm and the substantial symptom improvement we had observed in earlier trials. We will now undertake a comprehensive review of the full dataset to determine our path forward with the investigational product. As a science-driven company we are conscious at Allergy Therapeutics of the challenges regarding subjective measures in allergy field studies. We are committed to overcoming these challenges and bringing this new product to market.”

Allergy Therapeutics has extensive experience with other approved and commercialized birch products. Since 2010, the investigational product has undergone two successful Phase II trials where a highly statistically significant 32% reduction in allergic symptoms between the active and placebo was observed. The Group will undertake a review of the full trial dataset to understand any cause for the lack of consistency in the clinical outcomes seen between the studies.

The B301 trial was a multi-centre, double-blind, placebo-controlled study designed to test the efficacy in birch-pollen induced seasonal allergic rhinitis. The European study took place in Germany, Poland, Austria and Sweden with 582 patients over 59 centres being randomised into active and placebo arms, to evaluate the safety and efficacy measured as a reduction in allergic symptoms as determined by the combined symptom medication score.

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

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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 double digit 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](http://www.allergytherapeutics.com).

The Investigational Product

The investigational product is a 6 injection, subcutaneous allergen-specific immunotherapy designed to treat the cause of allergic rhinitis not just mask the symptoms. It contains three distinct components: A birch allergoid, micro-crystalline tyrosine (MCT) and monophosphoryl lipid A (MPL®). Allergoids are natural allergens chemically modified to exhibit reduced allergenicity that improves tolerability and allows for delivery of higher doses. These are combined with the depot adjuvant technology MCT to provide enhanced immune exposure and further improved tolerability.

Finally, the immune response is enhanced and directed by the adjuvant MPL®. MPL is a toll-like receptor 4 (TLR4) agonist which has been extensively used in the Group's other allergy vaccines available on the market and in vaccines registered in the USA.

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