RNS Number : 3057T
Allergy Therapeutics PLC
14 November 2023

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

G306 pivotal Phase III trial to evaluate efficacy and safety of Grass MATA MPL meets primary endpoint

- *Study demonstrated a highly statistically significant reduction in Combined Symptom & Medication Score (CSMS) ($p \leq 0.0024$) achieved in active treatment group compared to placebo*

- *Analysis of primary outcome and secondary endpoints including quality of life and biomarkers to be announced once full analysis of the data has been completed*

14 November 2023 Allergy Therapeutics plc (AIM: AGY), the integrated commercial biotechnology company specialising in allergy vaccines, today announces interim top line results from its pivotal G306 Phase III trial of Grass MATA MPL, the Group's short-course subcutaneous allergen-specific immunotherapy (SCIT) candidate that aims to address the cause of symptoms of allergic rhinoconjunctivitis due to grass pollen.

The adaptive G306 study design, endorsed by regulators, allowed an interim analysis to determine whether a 2nd cohort would be required. The trial met its primary endpoint demonstrating statistically significant superiority of Grass MATA MPL compared to placebo ($p \leq 0.0024$, one-sided) in the CSMS during the peak pollen season, and the study was stopped for success. Top line analysis is expected to be available in mid-December. This will include treatment effect data and secondary endpoint analysis.

The G306 trial was a multi-centre, randomised, parallel group, double-blind, placebo-controlled clinical trial to evaluate the efficacy of Grass MATA MPL 27600 SU in subjects with grass pollen induced seasonal allergic rhinitis and/or rhinoconjunctivitis based on symptoms and medications. The trial was conducted in the US and Europe at 89 sites.

Manuel Llobet, CEO at Allergy Therapeutics, stated: *"The completion of the G306 study is an important milestone in our efforts to register this innovative treatment for the benefit of the millions of patients affected by grass allergies. I would like to thank our trial investigators, the team at Allergy Therapeutics and, most importantly, the patients, for their contributions. This result builds upon the statistical significance also seen in the earlier G309[1] field study and, subject to full top line analysis, we look forward to commencing discussions with relevant regulatory authorities to continue our journey to bring this important product to market."*

Preparation for a clinical trial application for the Group's G308 paediatric study is currently underway to meet the previously communicated requirements of the German regulatory framework (Therapy Allergen Ordinance) as well as the approved Paediatric Investigation Plan (PIP).

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

- ENDS -

For further information, please contact:

Allergy Therapeutics
Manuel Llobet, Chief Executive Officer

Shaun Furlong, Chief Financial Officer
+44 (0)1903 845 820

Panmure Gordon
Emma Earl, Mark Rogers, Freddy Crossley, Corporate Finance
Rupert Dearden, Corporate Broking
+44 (0) 20 7886 2500

ICR Consilium
Mary-Jane Elliott / David Daley / Davide Salvi
+44 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. Its broad pipeline of products in clinical development includes vaccines for grass, tree, house dust mite and peanut. For more information, please see www.allergytherapeutics.com.

About Allergic Rhinitis
Allergic rhinitis and/or rhinoconjunctivitis is a type I allergic disease to common aeroallergens such as pollen, mould spores and house dust mite residue. Seasonal allergic rhinitis is most commonly caused by allergy to pollen from tree, grasses or weeds, while perennial allergic rhinitis is most commonly associated with allergy to dust mite residue, mould spores or animal dander[2]

About Grass MATA MPL
Grass MATA MPL is being developed as a pre-seasonal subcutaneous immunotherapy product for the treatment of allergic rhinitis and/or rhinoconjunctivitis.

Grass MATA MPL contains an extract of 13 grass pollens modified with glutaraldehyde (allergoid) to reduce the reactivity with immunoglobulin E (IgE) antibodies without a reduction in other important immunological properties, such as T-cell reactivity. The allergoid is adsorbed to L-tyrosine as a depot adjuvant system formulation. Monophosphoryl lipid-A (MPL), is included as an adjuvant to increase the immunogenic effect of the immunotherapy and to enhance the switch from an allergen specific helper T-cell Type 2 (Th2) to helper T-cell Type 1 (Th1) like immune response.

More information about the Phase III G306 Grass MATA MPL trial can be found on ClinicalTrials.gov under the identifier NCT05540717.

References

1. Short-course subcutaneous treatment with PQ Grass strongly improves symptom and medication scores in grass allergy. de Kam PJ, Zielen S, Bernstein JA, Berger U, Berger M, Cuevas M, Cypcar D, Fuhr-Horst A, Greisner WA, Jandl M, Laßmann S, Worm M, Matz J, Sher E, Smith C, Steven GC, Mösges R, Shamji MH, DuBuske L, Borghese F, Oluwayi K, Zwingers T, Seybold M, Armfield O, Heath MD, Hewings SJ, Kramer MF, Skinner MA. Allergy. 2023 Oct;78(10):2756-2766.
2. van Cauwenberge P, Bachert C, Passalacqua G, Bousquet J, Canonica GW, Durham SR, et al. Consensus statement on the treatment of allergic rhinitis. European Academy of Allergology and Clinical Immunology. Allergy. 2000; 55(2):116-34.

END

MSCEAFFDFLEDFAA