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Allergy Therapeutics PLC
25 October 2021

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

**Allergy Therapeutics announces positive top line results from G309 exploratory field trial to evaluate efficacy and safety of Grass MATA MPL**

- *Primary endpoint Combined Symptom Medication Score (CSMS) achieved with clinically relevant improvement across both active treatment groups compared to placebo*

- *Statistically significant reduction in CSMS seen in both active treatment groups of 29.1% and 36.8% compared to placebo*

- *Analysis of secondary endpoints including quality of life and biomarkers, consistent with primary endpoint results*

- *G306 Phase III pivotal trial on track for commencement in H2 2022 in US and Europe*

**25 October 2021** Allergy Therapeutics plc (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, today announces positive top line results from its exploratory field study (G309) to evaluate the efficacy and safety 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. Two short courses of six injections with treatment durations of six and 14 weeks were tested.

**Key results announced today:**

- The primary endpoint of the trial, "CSMS averaged over the peak pollen season", demonstrated a statistically significant difference between active and placebo in both active treatment groups of 29.1% (p=0.0367) and 36.8% (p=0.0088) for the 6 and 14 weeks respectively, indicating a significant reduction in daily symptoms and use of relief medication among participants receiving Grass MATA MPL
- Both dosing regimens were safe and well tolerated
- Changes in allergen specific IgE and allergen specific IgG4 were consistent with the immunological changes expected following allergen specific immunotherapy
- Improvement in rhinoconjunctivitis quality of life questionnaire (RQLQ) was observed in both active treatment groups
- Improvements in the clinical benefits seen in both US and European populations were comparable

The G309 trial was a double-blind, placebo controlled, randomised study over one year and involved 119 patients over 14 sites across Germany and the US. Results from the trial will be used to optimise the study design of the upcoming pivotal Phase III study (G306), due to begin in H2 2022 in the EU and US.

Further analyses of the G309 trial are now underway by the Group and full results, including all secondary and other exploratory endpoints, will be submitted for peer-reviewed publication and presentation at upcoming key conferences.

**Manuel Llobet, CEO at Allergy Therapeutics, stated:** "*We are delighted to announce these results demonstrating a clear treatment effect from our novel, short-course immunotherapy targeting grass pollen allergies. Grass pollen is one of the most common causes of seasonal allergic rhinitis in the Western world. Debilitating symptoms can affect so many aspects of life and new treatment options are needed.*

"*The Group used a groundbreaking study design that brought state-of-the-art learnings in allergy field trial methodology to examine multiple endpoints and will enable the potential for extensive biomarker analysis. Significantly, the results will enable us to optimally design the upcoming pivotal G306 Phase III field trial, maximising the chances of success and supporting our regulatory plans for entry into the US. I am grateful for the hard work and effort put into this trial by our team at Allergy Therapeutics and everyone across the multiple trial sites, who kept the trial on course despite the challenges faced by the continuing COVID-19 pandemic. I would also like to thank the trial participants, who are vital to our research developing novel, innovative allergy immunotherapies with the potential to transform patients' lives.*"

**This announcement contains inside information for the purposes of Article 7 of Regulatory**

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**Notes for editors:**

**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.

**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[1]

**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.

**References**


1. 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.




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