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

Allergy Therapeutics provides further detail from positive top line results from G306 Phase III field trial to evaluate efficacy and safety of Grass MATA MPL

- *Statistically significant reduction in Combined Symptom Medication Score (CSMS) seen in active treatment group compared to placebo*

- *Sensitivity analyses of primary endpoint and secondary endpoints show high consistency with primary endpoint results*

- *The Group is preparing marketing authorisation application (MAA) for planned submission in Q4 2024*

7 May 2024 Allergy Therapeutics plc (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, today provided further detail from the positive top line results from its pivotal Phase III field study G306 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. The trial successfully met its primary endpoint as previously announced on 14 November 2023.

An evaluation was conducted in both the EU and US to assess the impact of a treatment regimen consisting of six pre-seasonal injections given over a span of 14 weeks. The key findings from this evaluation are as follows:

- The primary endpoint of the trial, "Combined Symptom & Medication Score (CSMS) averaged over the peak pollen season", demonstrated a statistically significant improvement of 20.3% (p=0.00024) for Grass MATA MPL compared to placebo, providing evidence of a substantial reduction in daily symptoms and use of relief medication among participants receiving Grass MATA MPL
- A highly statistically significant improvement in the rhinoconjunctivitis quality of life questionnaire (RQLQ) (p=0.0003) was observed during the peak season
- The protective biomarker immunoglobulin (IgG4), measured during the grass pollen season, showed a large increase of approximately five-fold after treatment with Grass MATA MPL compared to placebo which achieved high statistical significance (p<0.0001) consistent with data from the earlier G309 exploratory field trial
- 555 subjects with allergic conjunctivitis and/or rhinitis were randomised and 528 (95%) completed all six injections of Grass MATA MPL or placebo. Demographics, allergic history and immunoglobulins were generally well-balanced at baseline between the Grass MATA MPL and placebo groups. In total, 278 and 277 patients received Grass MATA MPL and placebo, respectively.

As previously communicated, the treatment was well tolerated with no unexpected safety signals. Further exploratory endpoint analyses (including an extensive biomarker evaluation) of the G306 trial are now underway. Full results, including secondary and exploratory endpoints, will be presented at the upcoming European Academy of Allergy & Clinical Immunology conference in June 2024 and submitted for peer-reviewed publication later this year. The Group's preparation for the marketing authorisation application (MAA) is well underway, with a planned submission in Q4 2024.

2024.

Manuel Llobet, CEO at Allergy Therapeutics, stated: "*The findings announced today further demonstrate the beneficial treatment effect of our Grass MATA MPL immunotherapy candidate. Grass pollen, a common cause of seasonal allergy, significantly impacts the lives of many people, necessitating the development of new treatment options.*

"The results of our G306 study, alongside the results of our earlier G309 exploratory field study, provide a strong and consistent data package for progression to an MAA submission. This affords us the potential to provide a unique offering to the market as the only Grass SCIT product registered through the TAV programme in Germany. I would like to express my gratitude to our team at Allergy Therapeutics and our partners at multiple trial sites and countries for their exceptional work and dedication to this trial. A special thank you goes to the patients who participated in our trial programme. Without their involvement, we would not be able to bring these urgently needed treatments to the market."

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

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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

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.

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