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

Allergy Therapeutics announces completion of treatment phase in innovative G309 exploratory field study to evaluate efficacy and safety of Grass MATA MPL

- *Important milestone in planning of the pivotal Phase III Grass trial in the USA and Europe*
- *Breakthrough study design to establish cutting edge scientific study design methodology to optimise the Group's pivotal Phase III SCIT trial designs.*
- *Read out for G309 study remains on course for H2 2021*

6 May 2021 Allergy Therapeutics plc (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, today announces the completion of treatment period of all patients in its exploratory field study (G309) to evaluate the efficacy and safety of Grass MATA MPL in subjects with seasonal allergic rhinitis and/or rhinoconjunctivitis induced by grass pollen. Grass MATA MPL is a short course, aluminium-free allergen-specific subcutaneous immunotherapy (SCIT) that aims to address the cause of symptoms of allergic rhinoconjunctivitis due to grass pollen.

Completion of the treatment phase of the study has been achieved despite the challenges caused by the continuing COVID-19 pandemic. The Group has executed the dosing phase of the study in such a way that high patient retention has been achieved (97%) without any delay to the scheduled read-out of the data. The G309 double-blind, placebo controlled, randomised study, performed simultaneously in the USA and EU, remains on track to read out in H2 2021.

Grass pollen is one of the most common causes of seasonal allergic rhinitis in the Western world[1]. The symptoms caused by allergic rhinitis reduce patients' quality of life as well as performance at work or school. The World Allergy Organization estimates that the prevalence of allergic rhinitis in the whole population ranges between 10 - 30%[2].

The primary objective of the study is to evaluate the safety and efficacy of a dose of 27,600 SU Grass MATA MPL, previously proven as the optimal efficacious dose in the successful Phase II dose-finding study (G205). The study is being conducted in patients with grass pollen induced rhinoconjunctivitis and the primary endpoint is the combined symptom medication score (CSMS) averaged over the peak grass pollen season.

Results from the G309 study will provide valuable information to optimise the study design of the pivotal Phase III study (G306). The G309 study will inform the sample size of the G306 study which is expected to involve approximately 900-1200 patients over more than 100 trial sites in the EU and USA. Successful completion of the trial is expected to enable the Group to register the Grass MATA MPL product under the TAV (Therapy Allergy Ordinance) process in Germany and should also pave the way forward for registration via a Biological License Application (BLA) in the USA.

Manuel Llobet, CEO at Allergy Therapeutics, stated: "*This ground-breaking exploratory trial design has the potential to greatly increase our understanding of allergic rhinitis and how to effectively generate data for product registration via field trials. Challenges brought about by COVID-19 were alleviated by the excellent clinical team here at Allergy Therapeutics and we are very much looking forward to the results later this year. The results of the G309 trial will enable us to optimise the design of the pivotal trial G306, which we expect to begin in H2 2022.*"

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 11,000m^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 (AR) and/or rhinoconjunctivitis is a type I allergic disease to common aeroallergens such as pollen, mould spores and house dust mite residue. SAR/rhinoconjunctivitis is most commonly caused by allergy to pollen from tree, grasses or weeds, while perennial allergic rhinitis (PAR) and/or rhinoconjunctivitis is most commonly associated with allergy to dust mite residue, mould spores or animal dander[3]

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

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