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

Allergy Therapeutics announces start of innovative exploratory field study to evaluate efficacy and safety of Grass MATA MPL

- *Start of key exploratory field study in advance of pivotal Phase III Grass trial*

- *Breakthrough study design to deliver for the first time cutting edge scientific concepts in the Allergy field to optimize SCIT trial results.*

26 October 2020 Allergy Therapeutics plc (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, today announces the screening of the first patient 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 exposure. Grass MATA MPL is a short course, aluminium-free allergen-specific immunotherapy that aims to address the cause of symptoms of allergic rhinoconjunctivitis due to grass pollen.

This double-blind, placebo controlled, randomised study will run for one year and involve approximately 150 patients over 12 sites across Germany and the USA. The primary objective of this exploratory field study is to evaluate the safety and efficacy of its optimized Phase III dose of 27,600 SU Grass MATA MPL on grass pollen-induced rhinoconjunctivitis. The primary endpoint is the combined symptom medication score (CSMS) averaged over the peak grass pollen season. Results from the study will provide valuable information in preparation of the pivotal Phase III study (G306).

The breakthrough study design brings state of the art learnings in field trial methodology to the allergy immunotherapy research field. It is not only designed to evaluate safety and efficacy but is the first subcutaneous immunotherapy (SCIT) study to evaluate different placebo options, including normal saline. Moreover, the study combines several Phase II and Phase III endpoints to support the validation of the regulatory mandated primary endpoint and includes extensive biomarker analysis. These data aim to drive forward and underpin success in subsequent phase III trials for the Group's whole MATA MPL programme including grass, birch and ragweed.

The Group, which has mitigation strategies in place to ensure the Grass MATA MPL clinical development programme continues despite the COVID-19 situation, expects results from the field study in H2 2021.

Manuel Llobet, CEO at Allergy Therapeutics, stated: "*This exploratory grass trial will drive study design innovation in the allergy field and is an important intermediate step for the optimisation of our upcoming pivotal Phase III grass field trial, which will maximise the chances of success and entry into the US market. Parts of this protocol are ground-breaking and have the potential to significantly enhance science in this area.*"

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.500 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[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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