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

Allergy Therapeutics Submits Marketing Authorisation Application for Grass MATA MPL to the Paul Ehrlich Institut in Germany

- *Marketing Authorisation Application for Grass MATA MPL submitted to* the Paul Ehrlich Institut*, Germany under a national registration procedure*
- *Regulatory submission based on a comprehensive data package including the pivotal Phase III G306 clinical trial*
- *Marketing Authorisation Application to undergo review by* the Paul Ehrlich Institut once the submission has been validated

25 November 2024 Allergy Therapeutics (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy immunotherapy announces that it has submitted a full Marketing Authorisation Application (MAA) to the Paul Ehrlich Institut (PEI) for its Grass MATA MPL subcutaneous immunotherapy (SCIT) candidate designed to address the cause of symptoms of allergic rhinoconjunctivitis due to grass pollen.

The application has been submitted under a National procedure in Germany and following completion of standard validation checks by PEI, the Group expects the formal MAA review process to begin shortly.

Grass MATA MPL incorporates MicroCrystalline Tyrosine ("MCT®") adsorbed allergoids and the innovative adjuvant Monophosphoryl-lipid A ("MPL"). Grass MATA MPL has been developed to modify the allergic response following only six injections prior to the grass allergy season.

The full MAA comprises a comprehensive evidence package of quality, safety and clinical efficacy including the Group's pivotal Phase III G306 trial in adults. In that trial, Grass MATA MPL demonstrated a highly statistically significant reduction in the Combined Symptom & Medication Score (CSMS) compared to placebo over the peak pollen season.

Manuel Llobet, CEO of Allergy Therapeutics, commented: *"The submission of the MAA to the PEI in Germany marks a significant milestone in our regulatory pathway, and brings us closer to potentially offering an important new treatment option for patients affected by seasonal grass allergy. We look forward to continuing to work closely with the PEI during the review process of the MAA and I would like to thank the team at Allergy Therapeutics for their dedication in advancing this innovative product toward market."*

- ENDS -

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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 immunotherapies 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. For more information, please see www.allergytherapeutics.com.

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 to form allergoids that

Grass MATA MPL contains an extract of 15 grass pollens modified with glutaraldehyde to form allergoids that reduces 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 microcrystalline 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.

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