

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

**Allergy Therapeutics announces invalidation of the Birch MATA MPL Phase III primary endpoint results**

- *Technical issues with the endpoint measurements invalidated B301 trial*
- *New pivotal Phase III Study with Birch MATA MPL to be conducted within TAV time frame*

**09 July 2020** Allergy Therapeutics plc (AIM: AGY), the fully integrated commercial biotechnology company specialising in allergy vaccines, today is pleased to announce the outcome of scientific advice from the German Regulatory Authority, the Paul Ehrlich Institute (PEI), regarding invalidation of the primary endpoint data of the Birch MATA MPL pivotal Phase III clinical trial (B301).

Further to the announcement on 18 March 2019 and following extensive data investigations and discussions with PEI, the analysis of the primary endpoint of the Birch B301 clinical trial has been declared invalid. Technical issues encountered in the study made it impossible to reconstruct the primary endpoint data and the PEI agreed that B301 cannot be considered for assessment of clinical efficacy and a new pivotal Phase III study will be conducted within the therapy allergens ordinance ("Therapieallergene-Verordnung", TAV) time frame.

The Group's confidence in its short course immunotherapies remains unchanged and lessons learned from the Birch B301 field study have already been introduced for future studies including the Grass MATA MPL programme to be conducted simultaneously in the US and Europe.

**Manuel Llobet, CEO at Allergy Therapeutics, commented:** *"We are encouraged by our constructive discussions with the PEI who, based upon the clear scientific evidence, decided to invalidate the primary endpoint of the B301 study and agreed to a new pivotal Phase III clinical study for Birch MATA MPL. We remain committed to Birch MATA MPL, especially considering the results of the independent secondary endpoint data and the supportive safety profile observed in the B301 study and two successful phase II trials showing significant primary efficacy results.*

*"We look forward to progressing our portfolio of unique allergy vaccines and helping the millions of patients affected by allergy via our phase III studies with Birch MATA MPL as well as Grass MATA MPL and our upcoming first in human peanut trial."*

**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 focussed on the treatment and diagnosis of allergic disorders, including 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 and tree with a 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<sup>2</sup> of state-of-the-art MHRA-approved manufacturing facilities and laboratories. The Group, which has achieved double digit 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](http://www.allergytherapeutics.com).

**About Birch MATA MPL**

Birch MATA MPL is a subcutaneous allergen-specific immunotherapy designed to treat the cause of allergic rhinitis not just mask the symptoms. It consists of a birch pollen allergoid combined with an adjuvant system comprised of microcrystalline tyrosine (MCT) and monophosphoryl lipid A (MPL<sup>®</sup>).

Allergoids (natural allergens chemically modified to form allergoids) exhibit reduced allergenicity that improves tolerability and allows for delivery of higher doses. These allergoids are combined with an adjuvant system including depot adjuvant technology MCT to provide enhanced immune exposure and further improved tolerability and MPL<sup>®</sup> to enhance and direct the immune response. MPL is a toll-like receptor 4 (TLR4) agonist that has been extensively used in the Group's other allergy vaccines available on the market and in vaccines registered in the USA.

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