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

**Allergy Therapeutics announces positive top-line results from the PQBirch204 Phase II study for birch-induced seasonal allergic rhinitis**

- Primary endpoint met
- Statistically significant dose-response relationship ( $p < 0.01$ )
- All dosing regimens were safe and well tolerated
- Adherence was greater than 90%

Allergy Therapeutics, (AIM:AGY), the fully integrated specialty pharmaceutical company specialising in allergy vaccines, today announces positive top-line results from the Company's PQBirch204 Phase II study, a multi-centre, double-blind, placebo-controlled study designed to explore the safety and response of different cumulative doses of Birch Modified Allergen Tyrosine adsorbed and MPL<sup>®</sup> (POLLINEX<sup>®</sup> Quattro Birch) for birch pollen induced seasonal allergic rhinitis.

The study randomised 371 patients into six cumulative dosing regimens plus a placebo, evaluating the change in Total Symptom Score (TSS) following a conjunctival provocation test (CPT) with the objective to achieve a dose recommended for Phase III development.

**Results summary of the PQBirch 204 Phase II study programme**

- The primary endpoint, to demonstrate a statistically significant ( $p < 0.01$ ) dose-response for the 5000 standardised units (SU) to 27300 SU, was met. This enables prediction of the dose to enter Phase III development
- The study demonstrated a statistically significant ( $p < 0.01$ ) dose-response for the 5000 standardised units (SU) to 27300SU dose range studied
- The dose-response closely followed and extended the findings of the previous dose-response study (PQBirch203), which studied doses from 600SU to 13600SU
- PQBirch continues to be well-tolerated and no safety concerns were reported in any treatment arm. There was no significant relationship between any adverse drug reaction exhibited and the respective dosage of allergoid
- Overall adherence to the dosing regimens was approximately 94% with no relevant differences between treatment arms.

**Manuel Llobet, Chief Executive Officer of Allergy Therapeutics, said:** "The results of the PQBirch204 trial are very encouraging and they reaffirm the potential of our Pollinex platform to treat the underlying cause of allergic rhinitis. Approximately 6% of the population in Europe alone is allergic to birch pollen and there continues to be a need for a safe and well tolerated effective treatment for this significant health issue. Pollinex is the only ultra-short course aluminium-free treatment in the market and its convenience for patients is driving our market penetration in all our European markets.

"This study is a significant milestone in our route to Marketing Authorisation and keeps us on track to commence the Phase III study in early 2017."

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**Note for editors:**

**About Allergy Therapeutics**

Allergy Therapeutics is an international specialty pharmaceutical company focussed on the treatment and diagnosis of allergic disorders including immunotherapy vaccines that cure disease. The Company sells proprietary products and third party products from its subsidiaries in nine major European countries and via distribution agreements in an additional ten countries.

Formed in 1999 out of Smith Kline Beecham, Allergy Therapeutics is headquartered in Worthing, UK with MHRA-approved manufacturing facilities. The Company employs c.420 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 Modified Allergen Tyrosine adsorbed + MPL**

Birch Modified Allergen Tyrosine adsorbed + MPL is a unique allergen-specific immunotherapy that comprises three key technologies tailored to reduce irritation and systemic reactions; modified allergens, microcrystalline tyrosine (MCT) and Monophosphoryl lipid A (MPL).

The ultra-short duration of Birch Modified Allergen Tyrosine adsorbed + MPL is achieved via allergen modification that transforms the structure of allergens to allow increased doses to be delivered compared to traditional unmodified preparations. The potent depot adjuvant, MCT, has a Th1 immunomodulating action that acts in synergy with the TLR4 receptor agonist MPL to augment a shift in the immune reactions responsible for the symptoms of allergic rhinitis.

**About Allergic Rhinitis**

Allergic rhinitis and conjunctivitis affects between 10% and 30% of the population worldwide<sup>1</sup>. Symptoms can be intrusive and debilitating and can include watery eyes, runny nose and inflammation. Current first line treatments such as antihistamines and corticosteroids lead to insufficient symptom control and add to the economic and patient burden. Currently, specific immunotherapy is the only known treatment that addresses the underlying cause of symptoms.

**References**

<sup>1</sup>World Health Organization. White Book on Allergy 2011-2012 Executive Summary. By Prof. Ruby Pawankar, MD, PhD, Prof. Giorgio Walker Canonica, MD, Prof. Stephen T. Holgate, BSc, MD, DSc, FMed Sci and Prof. Richard F. Lockey, MD