

Allergy Therapeutics

Imperial peanut allergy biomarker study underway

5 January 2021

- Allergy Therapeutics has initiated an *ex vivo* biomarker study with Imperial College London for its novel VLP-based peanut allergy vaccine candidate. The information generated from this study will be used to support clinical development of the peanut vaccine programme and will establish the starting dose of the first-in-human Phase I study. The IND application will be filed with the FDA in 2021, with the Phase I trial also planned to start this year.
- This study will explore an extensive array of functional and molecular biomarkers using blood samples from peanut allergy patients to evaluate and confirm the hypoallergic potential of the vaccine candidate and the potency of the immune response induced.
- Allergy's peanut allergy vaccine candidate is based on virus-like particle (VLP) technology licenced from Saiba AG and DeepVax and incorporates a single peanut allergen that appears to confer immunity against all peanut allergens. Preclinical data has provided proof of concept for sustained immunity and protection against peanut anaphylaxis through short-course vaccination. If confirmed in the clinic, this would be transformative for patients.
- Peanut allergy is a leading cause of anaphylaxis and is one of the most common food allergies, especially in children. A VLP-based vaccine could induce protective antibodies with a limited number of injections vs current treatment approaches that require daily dosing as a maintenance therapy. These typically involve allergen specific desensitisation, either orally (Nestle/Aimmune's Palforza) or via transdermal patches.
- In parallel, Allergy and Imperial College have entered into a broader research collaboration to evaluate the relationship between allergy biomarkers and clinical outcomes. Samples taken at baseline and throughout the treatment course from both the current G309 (Grass MATA MPL field study) and the preclinical and clinical peanut allergy programme will be analysed against an extensive set of predetermined biomarkers. Key aims will be to gain a better understanding of the underlying science, to develop an objective validated endpoint vs the more subjective measures commonly used, and to apply any new insights to future clinical trials to help advance Allergy's R&D pipeline.

Price	16.0p
Market Cap	£102.4m
Primary exchange	AIM
Sector	Healthcare
Company Code	AGY
Corporate client	Yes

Company description:

Allergy Therapeutics specialises in the diagnosis and treatment of allergy. The existing European business generates c £80m annual sales. Near-term R&D efforts are focussed on the Pollinex Quattro platform, whilst in the medium-term the VLP platform is highly promising.

Trinity Delta view: The start of the biomarker study of Allergy Therapeutics' peanut allergy vaccine candidate represents a step forward for this development programme and should facilitate a smooth transition into Phase I later this year. It is the first VLP-based vaccine in Allergy's portfolio and addresses a sizeable and underserved market. The collaboration with Imperial College is significant as both the peanut allergy biomarker study and the wider collaboration should generate important new insights that can be used by Allergy in the design of future allergy immunotherapy clinical trials, mitigating the risks of inconclusive results based on subjective endpoints. Our current £325m (51p/share) SOTP valuation of Allergy Therapeutics includes a DCF of the commercial operations (£87m or 14p/share), a pipeline rNPV (£204m or 32p/share), and net cash.

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