Allergy Therapeutics

FDA green lights VLP Peanut vaccine Phase I trial

26 January 2022

- Allergy Therapeutics has received FDA clearance to initiate the Phase I PROTECT study for its novel VLP (virus-like particle) peanut allergy vaccine candidate. The IND (Investigational New Drug) application was supported by impressive data from the P001 *ex vivo* biomarker study, performed in collaboration with Imperial College London, that met all primary and secondary endpoints. Data reported in September 2021 showed a notable shift from a T-helper type 2 (Th2)-dominated response to a Th1-dominated response in a dose-dependent manner, suggesting a lasting change from an allergic to a tolerant reaction.
- The US-based PROTECT trial is likely to start in Q122 (COVID-19 permitting) with top line data expected in H123. The format will use a stepwise protocol; the first stage involving non-allergic volunteers, proceeding to skin prick tests in adult peanut allergy patients, before embarking on the subcutaneous injection stage. Peanut allergy is one of the leading causes of severe and fatal food-induced anaphylactic reactions, hence the importance of demonstrating that the VLP Peanut vaccine candidate is hypoallergic.
- The PROTECT study results will guide the format of the Phase II proof-of-concept trials, which could start as early as 2024. If these clinical trials confirm the profile seen in the highly promising preclinical studies, which were replicated in the Imperial biomarker study, then the VLP Peanut allergy vaccine could transform the lives of peanut allergy sufferers. The clear medical need for such a potentially life-saving treatment could see an expedited approval pathway agreed, with potential for first availability as soon as late-2026.
- The VLP Peanut vaccine is the leading programme employing the VLP technology platform. If successful, the suggested potency and flexibility mean it could be developed for other conditions such as cat, mould, and house dust mite allergies as well as venom and stings. It is worth noting that management has secured broad licenses for uses as diverse as solid tumours (notably melanoma), asthma, atopic dermatitis, and psoriasis.

Price	23.75p
Market Cap	£153m
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: Our investment case for Allergy Therapeutics centres on the R&D pipeline, where two novel programmes, Grass MATA MPL and VLP Peanut allergy vaccines, are progressing through clinical trials. Success with either of these would propel the company into new geographies, notably the commercially important US market. However, were VLP Peanut to confirm the highly promising preclinical results seen to date in future pivotal human trials, then the outcome would be transformational for Allergy Therapeutics. Our current valuation is £350.7m (54.7p/share), including cash and opex. We value the existing commercial business at £91.1m (14.2p/share) with the pipeline contributing £222.8m (34.7p/share). Allergy Therapeutics reports H122 results on March 3.

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