**REDUCTION IN SEVERITY FOLLOWING 12 MONTHS OF EPICUTANEOUS IMMUNOTHERAPY FOR PEANUT ALLERGY**

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**Rationale**

- Peanut allergy, one of the most common food allergies, can result in severe, potentially life-threatening reactions. 1, 2, 3
- A major goal of food allergy immunotherapy is to reduce the likelihood of reactions to accidental peanut ingestion by desensitization, i.e., increasing the reaction threshold to the eliciting dose (ED) 3, 4, 5
- An important goal of food allergy immunotherapy is for both caregivers and patients. 6
- In the severity of reactions to accidental ingestion. 7
- The 12-month Phase 3 PERTES clinical trial demonstrated that daily epicutaneous immunotherapy (EPI) with DBV712 250 µg (approximately 1/1000 of a peanut) was statistically superior to placebo in desensitizing peanut-allergic children aged 6 to 15 years based on double-blind, placebo-controlled food challenges (DBPCFCs) at study entry and Month 12 post-treatment. 8

**Objective**

- To compare the severity of allergic reactions elicited during standard DBPCFCs to peanut at baseline and Month 12 between DBV712 250 µg and placebo groups by post hoc analysis of the PERTES trial.

**Methods**

- PERTES was a Phase 3, randomised, double-blind, placebo-controlled clinical trial to assess the efficacy and safety of DBV712 250 µg in 356 children aged 4 to 11 years with physician-diagnosed peanut allergy. 9, 10
- Subjects in PERTES were randomised 2:1 to receive DBV712 250 µg or placebo daily for 12 months.
- In PERTES, DBPCFCs were conducted according to PRACTALL guidelines at Month 0 (baseline) and at Month 12 post-treatment using a standardized, blinded food matrix. 11

**Results**

**All Organ Systems (AOS)**

- The PFA population consisted of 222 subjects in the DBV712 250 µg group and 109 in the placebo group.
- At Month 12, the proportion of subjects with mild, moderate, or severe objective signs/symptoms for AOS were similar in each treatment group (P=0.631) (Table 2).
- In contrast, there was a significant between-group difference (P=0.001) in the distribution of symptom severity at Month 12 (Table 2).
- Nearly twice as many DBV712 250 µg-treated subjects (31.1%) as placebo-treated subjects (16.5%) had a maximum symptom severity score of “none” or “mild.”
- In addition, the difference in the proportion of subjects with a maximum severity score of “severe” differed significantly between the DBV712 250 µg group (16.2%) and the placebo group (27.5%; P=0.029).
- These domains included wheezing, cardiovascular, laryngeal, vomiting, and diarrhea.

**Conclusions**

- This post hoc analysis demonstrated that, in addition to increasing reactivity threshold in 4- to 11-year-old peanut-allergic children, investigational ERT with DBV712 250 µg may also reduce the severity of allergic reactions.
- For all organ systems, as well as 5 significant symptom domains, the distribution of symptom severity scores differed significantly between the DBV712 250 µg and placebo groups at the Month 12 DBPCFC irrespective of ED.
- These results suggest that DBV712 250 µg treatment may address dual goals of immunotherapy: decreasing the likelihood of reactions to accidental ingestion of peanut allergy and reducing reaction severity outcomes of importance to caregivers and patients.

**References**