Enhanced Efficacy and Confirmed Safety of a Two-Year Epicutaneous Immunotherapy (EPIT®) Treatment of Peanut Allergy with Viaskin® Peanut: The Continuation of the Vipes Phase IIb Randomized Controlled Trial (RCT)


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Rationale: The 12-month VIPES RCT of EPIT using Viaskin® Peanut (VP) was continued as an open-label trial for an additional 24 months. We report results of the 12-month interim analysis.

Method: From 207 subjects completing the VIPES RCT (6–55 years), 171 (82.6%) entered the open-label extension. For this second year, 64.9% subjects initially treated with 50μg, 100μg, 250μg peanut protein (pp) i.e. VP50, VP100, VP250, or placebo were treated for 12 months with VP250. The remainder received VP50 or VP100 for 6 months before switching to VP250. Endpoint response was based on the proportion of successes, i.e. eliciting dose ≥10-fold above baseline or ≥1,000mg pp, at the 24-month DBPCFC.

Results: The response rates after 24 months EPIT with VP250 were 69.7% (23/33) overall and 80.0% (16/20) in children 6-11 years, compared to 50% overall and 53.6% in children after 12 months VP250 EPIT. Adolescents/adults remained stable. In children, the peanut cumulative reactive dose after 24-months increased significantly compared to VIPES entry [mean(±SD)]: +1817.0 (1853.9) mg pp; +983.3(1279.9) mg pp after 12- months. Children’s median peanut-IgE decrease from baseline was -9% and -38% after 18 and 24 months; median peanut-IgG4 increase was +793.5% at 24 months. Mean(±SD) compliance was 94.8(±11.0)%; there were no serious AEs related to VP. Interestingly, the 12-month VP250 treatment of the ex-placebo group exactly reproduced the significant response rate in VIPES study with 50.0% (23/46) overall, 53.6% (15/28) in children.

Conclusion: The 24-month EPIT with VP250 is well accepted, safe and clearly enhances the 12-month therapeutic benefit overall and in children.