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Epicutaneous Immunotherapy (EPIT) is effective and safe to treat Peanut Allergy: a multi-national double-blind placebo-controlled randomized phase IIb trial.

Sampson H.A.[1], Agbotounou W.K.[2], Thébault C.[2], Ruban C.[2], Martin L.[2], Yang W.H. [3], Sussman G.L.[4], Brown-Whitehorn T.F.[5], Nadeau K.C.[6], Cheema A.S.[7], Leonard S.A.[8], Pongracic, J.A.[9], Sauvage-Delebarre C.[10], Assa'ad A.H.[11], De Blay F.[12], Bird, J.A.[13], Tilles S.A.[14], Boralevi F.[15], Bourrier T.[16], Shreffler, W.G.[17], Hébert J.[18], Green T.D.[19], Gerth Van Wijk R.[20], Knulst A.C.[21], Kanny G.[22], Kowalski M.L.[23], Schneider L.C.[24], Benhamou P.H.[2], and Dupont C.[25].

Rationale: To date there is no specific approved treatment for peanut allergy. EPIT is well tolerated and appears promising for the treatment of peanut allergy.
Methods: In a multicenter double-blind, placebo-controlled phase IIb trial, 221 subjects (6 – 55 years) reacting at a peanut protein (pp) eliciting-dose (ED) ≤300mg during DBPCFC were randomized to 1 year Viaskin® Peanut (VP), at different doses (50µg, 100µg, 250µg pp), or Viaskin® placebo. The primary efficacy endpoint at 1 year was the proportion of responders with a pp ED 10-fold greater than the pp ED at entry or achieving a post-treatment ED ≥1000mg. Cumulative reacting dose (CRD) of pp was also measured. Immunologic studies were performed at entry, 3, 6 and 12 months.

Results: The overall primary efficacy endpoint was met, with VP250 showing best results: 50.0% responders vs 25.0% with placebo, p=0.0108; children (6-11 years) exhibited 53.6% responders vs 19.4% for placebo, p=0.0076. In children, the mean CRD showed a VP dose-dependent response: +61mg, +471mg, +570mg and +1121mg for placebo, VP50, VP100 and VP250 respectively. Children's immunological responses were robust: with VP250 - PN-IgE exhibited a median increase ≥50 kUA/L at 3 months and decreased back to baseline at 12 months; median PN-IgG4 at 12 months increased in a dose-dependent fashion: 5.5-, 7.2- and 19.1-fold for VP50, VP100 and VP250, respectively. Compliance was >95%, dropout for adverse events <1%, and there were no serious adverse events related to treatment.

Conclusion: In peanut allergy, EPIT appears safe and effective; the CRD was dose-dependent and maximum efficacy was seen with VP250.

1 Icahn School of Medicine at Mount Sinai, New York 10029-6574, USA,
2 DBV Technologies, Bagneux, France,
3 University of Ottawa Medical School, Ottawa, ON Canada

4 University Of Toronto, Toronto, ON Canada
5 Children's Hospital of Philadelphia, Philadelphia, PA, USA
6 Stanford University School Medicine, Palo Alto, CA, USA
7 Mississauga, ON Canada
8 Rady Children's Hospital, University of California, San Diego, CA USA
9 Ann and Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, USA
10 Hôpital St Vincent de Paul, Lille, France
11 Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA
12 Nouvel Hôspital Civil, Strasbourg, France
13 University of Texas Southwestern Medical Center, Dallas, TX, USA
14 Northwest Asthma and Allergy Center, Seattle, WA, USA
15 Hôpital Pellegrin-Enfants, Bordeaux, France
16 Hôpitaux pédiatriques de NICE CHU-LENVAL, Nice, France
17 Massachusetts General Hospital for Children, Boston, MA, USA
18 CRAAQ, Québec, QC, Canada
19 Children's Hospital of Pittsburgh of UPMC, Pittsburgh, PA, USA
20 Erasmus Medical Center Rotterdam, Netherlands
21 University Medical Center, Utrecht, Netherlands
22 Hôpitaux de Brabois, Vandoeuvre-lès-Nancy, France
23 Medical University of Lodz, Lodz, Poland
24 Boston Children's Hospital, Boston, MA, USA
25 Hôpital Necker, Enfants Malades, France, 25Université Paris-Descartes, France.