

## The Karl Landsteiner University of Health Sciences Announces New England Journal of Medicine Shares Phase 3 Trial Data Evaluating Viaskin™ for Peanut-Allergic Toddlers

- The New England Journal of Medicine (NEJM) recently published the results of DBV Technologies' Phase 3 EPITOPE trial assessing efficacy and safety of epicutaneous immunotherapy (EPIT) with Viaskin Peanut among peanut-allergic toddlers (1 - 3 years of age).
- Dr. Thomas Eiwegger from Karl Landsteiner University of Health Sciences (Krems, Austria) a co-author on this publication, having participated as a Principal Investigator in this global study.
- The study met the pre-specified criteria for success for the primary endpoint and safety results were generally consistent with safety profile of Viaskin Peanut 250 µg observed in children with peanut allergy ages 4 years and older in prior clinical trials.
- More than one-third (37%) of Viaskin Peanut-treated participants in the EPITOPE trial reached a cumulative reactive dose  $\geq 3444$  mg.
- After 12 months of treatment in peanut-allergic children aged 1-3 years, Viaskin Peanut was found to be statistically superior to placebo in desensitizing participants to peanuts, increasing the peanut dose triggering allergic symptoms.

The results of the Phase 3 EPITOPE trial of epicutaneous immunotherapy with Viaskin Peanut, sponsored by DBV Technologies, a clinical-stage biopharmaceutical company, were recently published in the *New England Journal of Medicine*. Dr. Thomas Eiwegger from Karl Landsteiner University of Health Sciences is a co-author on this publication, having participated as a Principal Investigator in this global study.

Viaskin is a novel form of EPIT, a potential new class of treatment that harnesses the immune properties of the skin. Viaskin Peanut has the potential to help modify individuals' underlying food allergy by desensitizing the immune system to an allergen. Viaskin Peanut is currently under clinical investigation and is not yet approved by the U.S. Food and Drug Administration or any other regulatory agencies.

Dr. Eiwegger comments: "The results of the phase 3 trial are very encouraging and offer the potential for a new treatment for peanut allergy." The new approach will address very low dose epicutaneous immunotherapy in young children. If approved, Viaskin Peanut would provide an additional treatment option to offer patients and families for whom the standard of care alone—allergen avoidance and use of rescue medication—may not be enough. There are currently no FDA approved treatment options for peanut-allergic children under the age of 4 years.

EPITOPE was a Phase 3, randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of Viaskin Peanut in children aged 1 through 3 years of age with a diagnosed peanut allergy. The EPITOPE trial was designed to allow participants to go about their normal daily activities without restrictions.

After one year of treatment, Viaskin Peanut resulted in statistically superior desensitization compared with placebo, with treatment responder rates of 67.0% and 33.5%, respectively. Additionally, a shift towards less severe food challenge reactions was seen following 12 months of treatment with Viaskin Peanut. Similar to previous studies of Viaskin Peanut in children, the most common adverse events (AEs) were

local application site reactions, which decreased in frequency and severity over time. Low rates of treatment-related anaphylaxis and epinephrine use were observed. This study demonstrated that 12 months of daily EPIT with a patch containing 250 µg peanut protein (1/1000th of one peanut) resulted in greater desensitization compared with placebo, sufficient to decrease the likelihood of experiencing an allergic reaction following accidental peanut exposure.

Viaskin Peanut was well-tolerated by a majority of participants and had low discontinuations due to AEs and high compliance rates. Subjects were able to wear the patch daily without restrictions around activities, for a sufficient duration over the course of the treatment period to induce desensitization.

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### **About Karl Landsteiner University of Health Sciences (2023)**

At Karl Landsteiner University of Health Sciences (KL) in Krems, the comprehensive approach to health and disease is a fundamental objective for research and teaching. With its Europe-wide recognized bachelor-master system, KL is a flexible educational institution that is tailored to the needs of students, the requirements of the labor market as well as the scientific challenges. Currently KL hosts about 600 students in the fields of medicine and psychology. The three university hospitals in Krems, St. Poelten and Tulln ensure clinical teaching and research at the highest quality level. In research, KL focuses on interdisciplinary fields with high relevance to health policy - including medical technology, molecular oncology, mental health and neuroscience, as well as water quality and related health aspects. KL was founded in 2013 and accredited by the Austrian Agency for Quality Assurance and Accreditation (AQ Austria). [www.kl.ac.at/en](http://www.kl.ac.at/en)

### **About DBV Technologies**

DBV Technologies is developing Viaskin, an investigational proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT™, and is DBV Technologies' method of delivering biologically active compounds to the immune system through intact skin. With this new class of non-invasive product candidates, the Company is dedicated to safely transforming the care of food allergic patients. DBV Technologies' food allergies programs include ongoing clinical trials of Viaskin Peanut. DBV Technologies has global headquarters in Montrouge, France, and North American operations in Basking Ridge, NJ. The Company's ordinary shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345) and the Company's ADSs (each representing one-half of one ordinary share) are traded on the Nasdaq Global Select Market (Ticker: DBVT).

Viaskin and EPIT are trademarks of DBV Technologies.

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