KURZPROTOKOLL
EPITOPE

Öffentlicher Titel	Phase III Studie zur Immuntherapie bei Erdnussallergie bei Kindern von 1-3 Jahren
Wissenschaftl. Titel	A double-blind, Placebo-controlled, randomized Phase III Trial to assess the safety and efficacy of viaskin peanut in peanut-allergic young children 1-3 years of age
Kurztitel	EPITOPE
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Kinder: Allergien: Nahrungsmittelallergien
Einschlusskriterien	- Male or female from 1-3 years of age at Visit 1 - Physician-diagnosed peanut allergy or high suspicion of peanut allergy as assessed by the physician: child presenting signs, symptoms and a medical and/or a family history putting him/her at high risk of having a peanut allergy and/or history of presence of peanut-specific IgE and/or positive SPT - Subject currently following a strict peanut-free diet - Signed informed consent of parent(s)/guardian(s) of the children aged 1-3 years - Peanut-specific immunoglobulin E (IgE) level (ImmunoCAP system) > 0.7 kU/L - Positive peanut SPT with a largest wheal diameter >= 6 mm - Positive DBPCFC to peanut, with symptoms meeting the challenge stopping criteria at an Eliciting Dose (ED) <=300 mg peanut protein - Parents/guardians and subjects willing to comply with all study requirements during their participation in the study
Ausschlusskriterien	- Peanut allergic subjects presenting a medical history of severe anaphylaxis to peanut will be excluded for this study. Severe anaphylaxis is defined by the Grade 3 of the Anaphylaxis Staging System(Appendix 4), including: • Severe hypoxia, persistent hypotension or more than 20% drop in blood pressure, neurological compromise, or • Cyanosis or SpO2 92% at any stage, confusion, cardiovascular collapse, loss of consciousness, bradychardia, cardiac arrest - Severe reaction during the entry/screening DBPCFC, defined as any of the following: •Need for intubation •Hypotension persisting after epinephrine administration •Need for three doses or more of systemic epinephrine - Subject with reactions to the placebo formula during the screening DBPCFC(with reactions deemed to stopping the challenge) - Subjects who fail to complete the entry food challenge due to any reason including clear aversion to the food formula matrix - Subject with any clinically significant abnormality identified at the time of screening such as major infantile infectious diseases (pox, measles) which in the judgment of the Investigator can preclude safe participation or strict compliance to the protocol procedures. Subjects can be considered for the study after recovery from these diseases - Viral upper respiratory infection or gastroenteritis or any severe disease within 7 days of food challenge (challenge must be rescheduled at least after 7 days upon recovery) - Hypersensitivity to any of the Viaskin® patch components (except to peanut protein), including the adhesive film - Hypersensitivity to any component of the food challenge formula (except to peanut protein) or a known history of apple allergy - Inability to discontinue short-acting antihistamines or long-acting antihistamines for the minimum wash-out periods required (depending on half-lives and specified in APPENDIX 3) prior to the skin prick testing or the food challenges

- Diagnosis of asthma that fulfills any of the following criteria: • Uncontrolled asthma (as per Global Initiative for Asthma [GINA] latest guidelines; see APPENDIX 8) • Asthma requiring controller treatment step 3 or higher (as per GINA latest guidelines: either moderate [double low dose] of inhaled corticosteroid, or association of inhaled corticosteroid with leukotriene receptor antagonist [see APPENDIX 8]. Long acting beta agonists are not recommended below 5 years) • History of 2 or more systemic corticoid courses within the 3 previous months prior to Visit 1 or 1 systemic corticoid course within the 4 weeks prior to Visit 1 for treating a diagnosed asthma. • Prior intubation/mechanical ventilation for asthma within one year prior to Visit 1. Asthmatic subjects with the following treatment options are eligible: No controller treatment (GINA Step 1), Controller treatment monotherapy (GINA Step 2): o with daily or short -term course (intermittent) low dose inhaled corticosteroid, o or with leukotriene receptor antagonist
- Presence of more than 3 episodes of wheezing in the past year (each lasting more than 10 consecutive days, apart from colds) or presence of respiratory symptoms (wheezing, cough, heavy breathing) between these episodes, and/or other respiratory symptoms suggesting either undiagnosed asthma or asthma not controlled by asthma treatment (as per GINA latest guidelines, see APPENDIX 8)
- Generalized dermatologic disease (e.g. severe atopic dermatitis, uncontrolled generalized eczema, ichthyosis vulgaris) extending widely on the skin and especially on the back with no intact zones to apply the Viaskin® patches
- Diagnosis of mast cell disorders including mastocytosis or urticaria pigmentosa as well as hereditary or idiopathic angioedema
- Prior history of any immunotherapy to any food (e.g. oral immunotherapy, sublingual immunotherapy, specific oral tolerance induction). Subjects who received a prior oral immunotherapy of less than 1 month-duration which ended at least 3 months before Visit 1 are eligible for inclusion
- Subject receiving or planning to receive any immunotherapy (aeroallergens, venoms, anti-infective) during their participation in the study. These immunotherapies must be discontinued at the time of Visit 1
- Symptomatic seasonal allergies that may interfere with the conduct of a DBPCFC. These subjects could be screened at a time when such allergies are asymptomatic (for example outside of the culprit season)
- Subject receiving -blocking agents, angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers, calcium channel blockers or tricyclic antidepressant therapy
- Subject who received anti-tumor necrosis factor drugs or anti-IgE drugs (such as omalizumab), any biologic immunomodulatory therapy, cyclosporine or other immunosuppressive drugs within one year prior to Visit 1 or during screening period. Topical calcineurin inhibitors are permitted
- Any disorder in which epinephrine is contraindicated such as congenital cardiac malformation, uncontrolled hypertension, or serious ventricular arrhythmias
- Current participation in another clinical trial or participation in another clinical trial in the last 3 months prior to Visit 1
- Subjects having any sibling already randomized in any study involving DBV712, including in this EPITOPE study
- Subjects or parent(s)/guardian(s) of subjects with obvious excessive anxiety and unlikely to cope with the conditions of a food challenge or unable to follow the protocol requirements

	- Past or current disease(s) which, in the opinion of the Investigator or the Sponsor may affect the subject's participation in this study or place the subject at increased risk during participation in the study, including but not limited to past or active eosinophilic gastrointestinal disorders, autoimmune disorders, immunodeficiency, malignancy, uncontrolled diseases (e.g. hypertension, psychiatric, neurologic, cardiovascular), or other disorders (e.g. liver, gastrointestinal, kidney, pulmonary disease or blood disorders) - Subjects being in any relationship or dependency with the sponsor and/or the investigator or the study staff
Alter	1 - 3 Jahre
Sponsor	DBV Technologies S.A.
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03211247 (primäres Register) EudraCT 2016-003679-23