



DBV Technologies Announces Primary Endpoint Met in VIPES, Viaskin Peanut's Phase IIb Clinical Trial in Peanut Allergy

- **Largest clinical trial in peanut allergy desensitization ever completed, VIPES meets primary endpoint with Viaskin® Peanut at the 250 µg dose**
- **Safety profile confirmed and excellent patient compliance demonstrated**

Bagneux, France, September 22nd, 2014 - DBV Technologies, (Euronext: DBV – ISIN: FR0010417345), today announced topline results for its VIPES (Viaskin Peanut's Efficacy and Safety) phase IIb clinical trial of Viaskin Peanut in peanut allergic patients. The trial met its primary endpoint at the highest explored dose (Viaskin Peanut 250 µg), achieving statistical significance ($p=0.0108$) in desensitizing a higher proportion of patients versus placebo after 12 months of Epicutaneous Immunotherapy (EPIT). Patients treated with Viaskin Peanut 250 µg also showed statistically significant changes in measured serological markers while placebo patients did not exhibit material differences. The safety profile was confirmed across all active arms with no serious treatment-related adverse events reported, and patient compliance with daily Viaskin Peanut application was above 97%. The trial drop-out rate was 6.4%, below the 15% rate initially anticipated. The VIPES trial is the largest clinical trial in peanut allergy desensitization ever completed, and full results of efficacy and safety will be presented at future scientific meetings.

Dr. Pierre-Henri Benhamou, Chairman and Chief Executive Officer of DBV Technologies said: *"We are delighted to see that VIPES provides significant support of our belief that EPIT has the potential to improve the lives of patients suffering from life-threatening peanut allergy. This is a crucial step toward finding a safe treatment for this unmet medical need and we plan to enter into a phase III program informed by the results of the VIPES trial in all patient populations in approximately 12 to 18 months."* Dr. Benhamou concluded: *"Today is an important day for DBV. After more than 10 years of intense development, we believe that a major medical breakthrough in the field of immunotherapy is within our grasp."*

Bertrand Dupont, Chief Technical Officer and co-founder of DBV Technologies said: *"Being at the origin of the Viaskin technology, I am very pleased to see that, throughout the trial, treatment compliance was so high. We believe this demonstrates that our product candidate is patient friendly and well-suited for the treatment of allergy."*



In VIPES, a double-blind, placebo-controlled, multicenter Phase IIb clinical trial, 221 patients highly allergic to peanut were randomized to either a 50 µg, 100 µg or 250 µg peanut protein dose of Viaskin Peanut versus placebo. The trial was prospectively organized across the three dose levels with two patient strata composed of three different patient age groups; children (113 subjects, ages 6-11) for the first stratum and adolescents (73 subjects, ages 12-17) plus adults (35 subjects, ages 18-55) for the other stratum. All patients received a daily application of the Viaskin Peanut patch over a 12-month treatment period. Trial responders were defined as patients who, after 12 months of treatment with Viaskin Peanut and using a double-blind, placebo controlled food challenge, started to react at a dose of peanut protein equal to or greater than 1,000 mg, or at least a 10-fold increase in the eliciting dose of peanut protein compared to baseline. As a secondary efficacy endpoint, Cumulative Reactive Dose, or CRD, was also used to establish the total quantity of peanut protein that begun triggering patient reactions at month 12 versus placebo. Serological markers were also measured as additional secondary endpoints at baseline, 3, 6, and 12 months in order to characterize the immunological changes in subjects.

Overall, the 250 µg dose showed the highest efficacy with statistical significance for these endpoints. In terms of peanut consumption and immunological changes, a consistent dose effect was observed.

A total of 56 patients were randomized to the Viaskin Peanut 250 µg dose. In this arm, 50% of patients responded, compared to 25% in the placebo group, showing statistical significance ($p=0.0108$).

- Specifically, 53.6% of children responded to treatment compared to a 19.4% response in placebo ($p=0.008$). Children treated with Viaskin showed a strong increase in peanut consumption, with an increase in LS mean (Least Squares Mean is a statistical model adjusted for multiple factors including both categorical, such as treatment, country and continuous covariates, such as baseline peanut dose measures allowing to better isolate solely the effect of treatment) in the change of CRD from baseline of 390.4 mg ($p<0.001$). Serological responses also showed treatment effect. In treated children, peanut-specific immunoglobulin E (IgE) increased over the first 6 months before decreasing toward initial levels at 12 months, while peanut-specific immunoglobulin G4 (IgG4) increased by more than 19 times over 12 months of treatment. Both biomarkers suggest a powerful desensitization effect.
- Adolescents showed a trend toward efficacy, showing a response rate of 38.9% in the active arm versus 22.2% in the corresponding placebo group. A statistically significant improvement in the adolescents' ability to consume peanut protein was also observed, as the LS mean in change of CRD from baseline of this subgroup was 276.0 mg ($p=0.047$). The IgG4 increase observed in adolescents, a 3.3 fold increase over 12 months, suggests the beginning of a successful desensitization process. At this stage, the adult subgroup is inconclusive due to a small sample size and a high placebo effect.

The following table summarizes VIPES' key results for the Viaskin 250 µg arm versus placebo.



Summary of key data in VIPES with Viaskin 250 µg

	Viaskin 250 µg	Placebo	p value
All patients			
Number of patients	56	56	
Response rate (%)	50.0	25.0	0.0108
LS mean CRD (mg)	548.5	162.5	<0.001
Mean CRD increase from baseline (mg)	979.2	269.5	
Median CRD increase from baseline (mg)	385.0	0.0	
Fold-increase in IgG4* (x)	12.0	1.3	
Children			
Number of patients	28	31	
Response rate (%)	53.6	19.4	0.008
LS mean CRD (mg)	476.6	86.2	<0.001
Mean CRD increase from baseline (mg)	1,121.0	60.8	
Median CRD increase from baseline (mg)	400.0	0.0	
Fold-increase in IgG4* (x)	19.1	1.1	
Adolescents			
Number of patients	18	18	
Response rate (%)	38.9	22.2	n.s.
LS mean CRD (mg)	456.9	180.9	0.047
Mean CRD increase from baseline (mg)	825.4	298.1	
Median CRD increase from baseline (mg)	300.0	0.0	
Fold-increase in IgG4* (x)	3.3	1.7	

Following the blind review meeting decision, for patients able to consume the highest dose of 2,000 mg peanut protein during the M12 double blind placebo controlled food challenge without experiencing any objective reactions, the convention was to ascribe a putative eliciting dose of 3,000 mg peanut protein. Consequently, for the calculation of the cumulative reactive dose, or CRD, the maximum dose used for these subjects was fixed at 3,000 mg.

* Mean of fold increase at 12 months

"The results of the VIPES trial are promising. The Viaskin technology is convenient for patients and induces significant desensitization and favorable immunologic changes compared to placebo, especially in children." stated **Professor Hugh Sampson**, Chief of the Division of Allergy & Immunology in the Department of Pediatrics, Director of the Jaffe Food Allergy Institute, and Dean of Translational Biomedical Science at The Mount Sinai Medical Center in New York, USA. Pr. Sampson is also a member of DBV's Scientific Advisory Board as well as International Coordinating Investigator for VIPES and Principal Investigator of the National Institutes of Health-sponsored Consortium of Food Allergy Research clinical study with Viaskin Peanut (CoFAR6).

Professor Christophe Dupont, Head of the Pediatric-Gastroenterology Ambulatory Department at the Necker Hospital (AP-HP) said: "With some children getting rid of any clinical reactivity after 12 months in



this largest ever randomized placebo controlled clinical trial in peanut allergy, results go beyond expectations. In adolescents, the results also show the occurrence of immunomodulation and good clinical perspectives.” Professor Dupont is co-founder of DBV Technologies, chairman of its Scientific Advisory Board, as well as International Coordinator for VIPES.

About DBV Technologies

DBV Technologies is developing Viaskin[®], an innovative new approach to the treatment of allergies – a major public health issue that has been increasing in prevalence. DBV Technologies, incorporated in France in 2002, has developed a proprietary, worldwide-patented technology for administering an allergen to intact skin while avoiding transfer to the blood, and thus considerably lowering the risk of a systemic, allergic reaction in the event of accidental exposure. DBV Technologies is focusing on food allergies, including milk and peanut, for which there are currently no effective treatments. DBV Technologies has designed two products candidates: Viaskin[®] Peanut and Viaskin[®] Milk. The clinical development program for Viaskin[®] Peanut has received Fast Track designation from the US Food and Drug Administration.

DBV Technologies shares are traded on segment C of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345).

For more information on DBV Technologies, please visit our website: www.dbv-technologies.com

Forward Looking Statements

This press release contains forward-looking statements, including statements about the safety and efficacy of DBV Technologies' product candidates and statements concerning expected regulatory review and the timing of future clinical trials. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, and the risk that historical clinical trial results may not be predictive of future trial results. A further list and description of these risks, uncertainties and other risks can be found in the Company's regulatory filings with the French Autorité des Marchés Financiers. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release, whether as a result of new information, future events or circumstances or otherwise.

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