Follow-Up Study of Viaskin® Peanut Shows Significant Increase in Peanut Consumption and Treatment Benefit in Peanut Allergic Children

Findings support Viaskin® Peanut’s efficacy, compliance and safety profile

After 24 months, 80% of treated children respond to Viaskin Peanut 250 μg

12-month response rate in treatment-naïve patients consistent with previously-reported results

On track to start Phase III trial in 4Q 2015

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced that topline findings from the first 12 months of the OLFUS-VIPES study, or OLFUS, support the long-term safety and efficacy of Viaskin Peanut for the treatment of peanut allergy. The Viaskin Peanut patch is the company’s lead product candidate, which is based on epicutaneous immunotherapy (EPIT®), a proprietary technology platform that can deliver biologically active compounds to the immune system through intact skin without allowing compound passage into the blood. OLFUS is an ongoing, open-label, follow-up study to VIPES, the company’s Phase IIb clinical trial with Viaskin Peanut. DBV previously reported positive results from VIPES in September 2014, and is on track to begin a Phase III clinical trial, ‘PEPITES’, with Viaskin Peanut 250 μg in children (ages 4-11) in the fourth quarter of 2015.

Dr. Pierre-Henri Benhamou, Chairman & Chief Executive Officer of DBV Technologies, said: “We are committed to improving the life of food allergy patients without disrupting their already burdened daily lives. With these initial results from OLFUS, we believe that we have generated sufficient scientific and clinical data to evidence that, if approved, Viaskin Peanut could be an answer to patients, caretakers, and clinicians’ need for a safe, patient-friendly and potent treatment for peanut allergy.”

During the first 12 months of OLFUS, no drug-related epinephrine use or serious adverse events (SAEs) due to Viaskin Peanut were reported. The study’s median compliance rate, which was maintained at 96%, was also consistent with previously reported results. A preliminary analysis of the OLFUS data showed that 12 additional months of therapy with Viaskin Peanut 250 μg increased the number of patients benefiting from treatment to 70% in OLFUS from 50% in VIPES, with 80% of children (ages 6-11 at entry in VIPES) responding to therapy after 24 months. Patients who received placebo for one year in VIPES and received Viaskin Peanut for 12 months in OLFUS showed a 50% response rate, which was consistent with findings from VIPES. DBV plans to present the full study results at upcoming scientific congresses.
Children treated for 24 months with Viaskin Peanut 250 µg

- Both treatment benefit and consumption of peanut protein significantly increased with an additional 12 months of therapy.
- Out of the 28 children treated for 12 months with Viaskin Peanut 250 µg in VIPES, 21 enrolled in OLFUS. One patient was lost to follow-up, but no other discontinuations were reported.
- In this subgroup, 80.0% of patients responded to treatment compared to 57.1% at the OLFUS baseline, consuming a 1,884 mg mean cumulative reactive dose (CRD) of peanut protein compared to a mean of 1,068 mg at the OLFUS trial initiation.
- Serological markers in OLFUS showed the strengthening of the immunological changes initially observed in VIPES. After 24 months, a median 40% decrease from the VIPES baseline value in peanut-specific immunoglobulin E (IgE) was observed, while the high median levels in immunoglobulin G4 (IgG4) were maintained at an 800% increase from the VIPES baseline.

Placebo-treated children in VIPES treated for 12 months with Viaskin Peanut

- New data from children treated for 12 months with Viaskin Peanut were consistent with the previously reported safety and efficacy results observed in this patient population.
- Out of the 31 children who received placebo for 12 months in VIPES, 29 enrolled in OLFUS. One patient was unwilling to continue with treatment, but no other discontinuations were reported.
- A 53.6% response rate after 12 months of treatment with Viaskin Peanut was observed compared to 17.2% at the OLFUS baseline. Patients consumed a mean CRD of 722 mg of peanut protein compared to 190 mg at the OLFUS baseline.
- The evolution of serological markers for patients treated with Viaskin Peanut for 12 months was also consistent with data previously reported from VIPES.

Adolescents and adults treated for 12 and 24 months with Viaskin Peanut 250 µg

- For adolescent and adult patients treated for 24 months, no additional significant clinical response was observed relative to the OLFUS baseline. A response rate consistent with results observed in VIPES was shown in treatment-naïve adolescents and adults who received 12 months of therapy during OLFUS. These results confirm the company’s intention to explore a higher Viaskin Peanut dosing regimen in this patient population.

James R. Baker, Chief Executive Officer and Chief Medical Officer of the Food Allergy Research & Education patient organization (FARE), commented: “These important results extend prior studies showing the ability of DBV’s Viaskin Peanut patch to enhance protection of peanut allergic children. The results also show additional benefit from longer term use of the patch. The safety profile is also impressive as no significant side-effects were noted. If this is confirmed in DBV’s Phase III trial, Viaskin could be a breakthrough therapy for young children with peanut allergy.”

About OLFUS-VIPES

OLFUS enrolled 171 subjects who had previously received either placebo or one of three 12-month dose regimens administered during VIPES. During the first year of OLFUS, patients were to receive a daily application of Viaskin Peanut 50 µg or Viaskin Peanut 100 µg or Viaskin Peanut 250 µg for 12 months. According to a study protocol change implemented in March 2014, all patients were switched to receive Viaskin Peanut 250 µg during OLFUS. Baseline response levels in OLFUS were based on the results of the last double-blind, placebo controlled food challenge (DBPCFC) in VIPES, and adjusted by the number of patients
enrolling in OLFUS. As in VIPES, a responder in the OLFUS trial was defined as a subject who could reach a peanut protein eliciting dose equal to or greater than 1,000 mg peanut protein during the 12-month DBPCFC or a subject with a ≥10-fold increase of the eliciting dose compared to the initial eliciting dose after 12 months of treatment. Patients enrolled in OLFUS who received placebo in VIPES were analyzed separately from subjects who initially received Viaskin Peanut.

About VIPES
The VIPES trial was a double-blind, placebo-controlled, multi-center clinical trial conducted at 22 sites in North America and Europe. 221 peanut-allergic subjects were randomized 1:1:1:1 into four treatment arms to evaluate three doses of Viaskin® Peanut, 50 µg, 100 µg and 250 µg, compared to placebo. Each patient underwent two DBPCFCs: one at screening and one after 12 months of treatment. The challenge was halted once the subject exhibited an objective allergic symptom. Patients in VIPES received a daily application of the Viaskin® Peanut patch over 12 months. Each patch was applied for 24 hours on the upper arm for adults (age 18-55) and adolescents (age 12-17) or on the back of children (age 6-11). The primary efficacy endpoint was the percentage of treatment responders for each active treatment group compared to placebo. With Viaskin Peanut 250 µg, 53.6% of children responded to treatment compared to a 19.4% response rate in the placebo group (p=0.008). The compliance rate was more than 97% across all cohorts, the dropout for related adverse events was less than 1%, and there were no serious adverse events or epinephrine injection related to treatment.

About DBV Technologies
DBV Technologies created the Viaskin® patch, a proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT®, DBV’s method of delivering biologically active compounds to the immune system through intact skin while avoiding compound transfer to the blood. With this new class of self-administered and non-invasive product candidates, the company is dedicated to safely transforming the care of food allergy patients, for which there are currently no approved treatments. DBV’s food allergy programs include ongoing clinical studies with Viaskin Peanut and Viaskin Milk, one experimental program with Viaskin Egg and a human proof concept clinical study in Eosinophilic Esophagitis. DBV is also exploring platform indications in vaccines, and selected immune diseases with unmet medical needs.

DBV Technologies has global headquarters in Paris, France and New York, NY, USA. Company shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, and traded on the Nasdaq Global Select Market in the form of American Depositary Shares (each representing one-half of one ordinary share) (Ticker: DBVT). 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 potential safety and efficacy of Epicutaneous Immunotherapy (EPIT®) via Viaskin® Peanut and DBV’s anticipated clinical development of Viaskin Peanut and other product candidates. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. The Company’s product candidates have not been approved for sale in any jurisdiction. Among the factors that could cause actual results to differ materially from those described or projected herein are uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, the risk that historical preclinical results may not be predictive of future clinical trial results, 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, the Company’s Securities and Exchange Commission filings and reports, including in the Company’s Annual Report on Form 20-F for the year ended December 31, 2014 and future filings and reports by the Company. 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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