Press Release

Montrouge, France, November 9, 2023

DBV Technologies Announces 2-Year Results from Ongoing Phase 3 Open-Label Extension to the EPITOPE Trial (EPOPEX) of Viaskin™ Peanut in Toddlers

- Viaskin Peanut showed improvement between months 12 and 24 of treatment across all efficacy parameters. Notably, 81.3% of subjects who completed the oral food challenge reached an eliciting dose of ≥1,000 mg after 24 months of treatment.
- 55.9% of subjects completed the oral food challenge at a cumulative dose of 3,444 mg without meeting stopping criteria.
- Among treatment-arm subjects from EPITOPE, there were no treatment-related anaphylactic or serious treatment-related adverse events in the second year of active treatment.
- DBV to highlight EPOPEX results in late-breaking oral abstract presentation at the American College of Allergy, Asthma, and Immunology (ACAAI) annual meeting on Saturday, November 11th at 9:35AM PT.
- Company to host investor conference call and webcast at 5:00pm ET today, Thursday, November 9th, to discuss the results.

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced positive interim results from its ongoing Open-Label Extension (OLE) Study of EPITOPE (Phase 3 trial of Viaskin™ Peanut 250 µg [VP250] in toddlers ages 1 to 3 years), which is named EPOPEX. After completing participation in the EPITOPE study, eligible subjects could enroll in EPOPEX to receive a total of three years of Viaskin Peanut treatment. Double-blind placebo-controlled food challenges (DBPCFC) are conducted at the end of each year of treatment with safety assessed throughout the entire OLE. Importantly, all subjects remained blinded to their treatment assignment in EPITOPE until every patient completed EPITOPE and the database was locked; therefore, the decision to enter the OLE was not biased by the unblinding of the randomized treatment.

Twelve-Month EPITOPE OLE Interim Results:

- 244 subjects were randomized to the active arm of EPITOPE with 208 completing the study. 85% of eligible subjects (175 of 208) entered the OLE with 95% (166 of 175) participating in the DBPCFC at Month 24 of Viaskin™ Peanut 250 µg ("VP250") treatment. Similar percentages were observed for the subjects randomized to the placebo arm of EPITOPE: 92% of eligible subjects (91 of 99) entered the OLE with 86% (78 of 91) participating in the DBPCFC at Month 12 of VP 250 treatment.
- The 175 and 91 subjects presented in the OLE cohorts (24 months and 12 months of VP250 treatment, respectively) are a subset of the subjects presented in the EPITOPE 12-month results (e.g., drop-outs, incomplete DBPCFC etc.).
- After 24 months of VP250, all efficacy parameters demonstrated an increase in treatment response relative to the corresponding EPITOPE 12-month results:
    - 81.3% of participants reached an eliciting dose (ED) ≥1000 mg, or approximately 3 – 4 whole peanut kernels (64.2% in EPITOPE, n=244).
    - 63.8% reached an ED ≥2000 mg (37.0% in EPITOPE, n=244).
    - 55.9% completed the cumulative 3,444 mg DBPCFC without meeting stopping criteria (30.7% in EPITOPE, n=244).
    - Using the EPITOPE primary endpoint definition, 83.9% of subjects were responders (67.0% in EPITOPE, n=244).
- Month-12 assessment of the efficacy parameters in the EPITOPE subjects (n=175) that entered the OLE further demonstrates the improvement in treatment response following an additional 12 months of treatment (24 months total)
    - At month 12, 74.7%, reached an eliciting dose (ED) ≥1000 mg relative to 81.3% at Month 24.
    - At month 12, 52.4% reached an ED ≥2000 mg relative to 63.8% at Month 24.
    - The proportion who completed the cumulative 3,444 mg DBPCFC without meeting stopping criteria was 39.5% and 55.9%, at months 12 and 24, respectively.
    - Using the EPITOPE primary endpoint definition, 77.4% were responders at Month 12 relative to 83.9% at month 24.
    - 47.2% (17 of 36) of subjects that did not meet EPITOPE responder criteria at Month 12 did meet the responder criteria at Month 24.
- No treatment-related anaphylaxis or serious treatment-related adverse events occurred in the second year of active treatment. The frequency of local application site reaction decreased in the second year of treatment.
- Efficacy results for subjects that entered the OLE from the placebo arm of

EPITOPE (i.e., crossed-over to VP250 and received 12-months of treatment and were thus 2-4 years-old at VP250 treatment initiation): 62.7% reached an ED ≥1000 mg, 36.5% reached an ED ≥2000 mg, 28.4% completed the DBPCFC without meeting stopping criteria and 68.0% met the EPITOPE responder definition. These results were consistent with the EPITOPE VP250 arm results. The safety data for this group were consistent with what was observed in EPITOPE. There was a single event of treatment-related anaphylaxis (after 12 months of active treatment).

"We are thrilled with the results generated from the two-year open-label extension to the Phase 3 EPITOPE trial. This OLE aimed to evaluate the continued efficacy, safety, and tolerability of Viaskin Peanut in toddlers in a real-world setting," stated Daniel Tassé, Chief Executive Officer of DBV Technologies. "*The data show that nearly 56% of subjects were able to consume a cumulative dose of 12 – 14 peanut kernels without meeting the pre-defined stopping criteria and more than 81% of subjects reached an eliciting dose of 3 – 4 peanut kernels. Recall that these are toddlers that began the study with an equivalent eliciting dose ranging from fractions of a peanut kernel to roughly one peanut kernel. This is a promising outcome for a community of peanut allergic toddlers where accidental exposure poses significant risk, and the current best practice – avoidance – places a daily burden on patients and families. These data further our belief that Viaskin Peanut has the potential to be the first FDA approved treatment for peanut allergic toddlers.*"

The interim data from the EPOPEX OLE will be presented at the American College of Allergy, Asthma & Immunology (ACAAI) Annual Scientific Meeting, which is being held November 9-13, 2023, in Anaheim, CA. The data were submitted in as a late-breaking abstract and accepted for an oral abstract presentation.

The presentation and abstract details interim 12-month results from subjects previously enrolled in EPITOPE, a study of one year of epicutaneous immunotherapy with a patch containing 250 µg of peanut protein vs a placebo patch. The EPITOPE study resulted in a statistically significant treatment response vs placebo in 1-3-year-old peanut-allergic toddlers, as featured in a *New England Journal of Medicine* publication and editorial in May 2023.

"These interim data from the first 12 months of follow-up from the OLE demonstrate that Viaskin Peanut continued to generate a treatment effect beyond what was

observed in EPITOPE," stated **Dr. Matthew Greenhawt, Children's Hospital Colorado, lead author and study investigator**. *"As a clinician, I am pleased that Viaskin Peanut showed improvement between months 12 and 24 of treatment across all evaluated efficacy parameters. It is even more encouraging that this was achieved with no new safety signals and with fewer local application site reactions in year two versus year one. I look forward to progressing the EPITOPE OLE to its conclusion with the goal of assessing the long-term efficacy, safety, and tolerability of Viaskin Peanut."*

Late-Breaking Abstract (poster presentation):

"**EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: 1-year Open-Label Extension to EPITOPE**"

- Presenter: Matthew C. Greenhawt, MD, MSc, MBA, FACAAI, Children's Hospital Colorado, Anschutz Medical Campus, Aurora, CO.
- Session: Late-breaking Oral Abstracts - Session 1: Food Allergy
- Day: **Saturday, November 11**
- Time: 9:35 – 10:00 AM (PT)
- Location: Exhibit Hall C – ePoster Area – LIVE Presentation Stage

"*On behalf of the food allergy community, we are so pleased to see the results from the open-label extension to the EPITOPE study*" said **Eleanor Garrow-Holding, CEO, Food Allergy and Anaphylaxis Connection Team**. "*Patients and families are eagerly awaiting FDA-approved options that may be appropriate for their unique medical needs and lifestyle. Viaskin Peanut, if approved, has the potential to be an efficacious and well-tolerated treatment with a promising safety profile. We look forward to DBV's continued regulatory progress and the initiation of the COMFORT Toddlers safety study to support a future BLA submission and FDA's potential review of this innovative product."*

Investor Conference Call and Webcast

DBV management will host an investor conference call and webcast today, November 9th, at 5:00pm EST, to discuss the EPOPEX data. This call is accessible via the below teleconferencing numbers and requesting the DBV Technologies call.

- United States: +1-844-481-2866
- International: +1-412-317-1859

A live webcast of the call will be available on the Investors & Media section of the Company's website: https://www.dbv-technologies.com/investor-relations/. A replay of the presentation will also be available on DBV's website after the event.

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).

Forward Looking Statements

This press release may contain forward-looking statements and estimates, including, but not limited to, statements regarding the therapeutic potential of Viaskin™ Peanut and EPIT™ and DBV's planned regulatory and clinical efforts including timing and results of communications with regulatory agencies, and the ability of any of DBV's product candidates, if approved, to improve the lives of patients with food allergies. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties. At this stage, DBV's product candidates have not been authorized for sale in any country. Among the factors that could cause actual results to differ materially from those described or project herein include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals. A further list and description of risks and uncertainties that could cause actual results to differ materially from those set forth herein can be found in DBV Technologies' regulatory filings with the Autorité des Marchés Financiers ("AMF"), DBV Technologies' filings and reports with the U.S. Securities and Exchange Commission ("SEC"), and future filings and reports made with the AMF and SEC. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak only as of the date hereof. Other than as required by applicable law, DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release.

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