

DBV Technologies to Participate in Upcoming EAACI Congress 2023

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced upcoming participation in the European Academy of Allergy and Clinical Immunology (EAACI) Congress, June 9 – 11, 2023, in Hamburg, Germany. DBV will present three posters and will also host a symposium and exhibit booth in the EAACI exhibit hall.

Data to be presented during the scientific sessions will describe the current burden of peanut allergy and treatment management strategies for children in the U.K. DBV will also present data from its completed EPITOPE Phase 3 study assessing the efficacy and safety of epicutaneous immunotherapy (EPIT) using Viaskin Peanut™ in toddlers aged 1-3 years with or without concomitant asthma. The toddler age-group represents the age range in which many peanut-allergic children are diagnosed, yet there are currently no approved therapies for this patient population.

“We know that there is an urgent unmet need for treatment options in toddlers living with a peanut allergy, and that no FDA or EMA approved therapies currently exist for those under the age of four years old,” said Daniel Tasse, Chief Executive Officer, DBV Technologies. *“That is why we are working hard to advance our science for this patient population and are pleased to have a significant presence at EAACI again this year to share our progress and participate in academic discussions with the many global allergy and immunology thought leaders who will be in attendance.”*

DBV’s symposium, “Addressing the Burden of Patients Living with Peanut Allergy”, will be co-chaired by Stefania Arasi, MD, PhD, MSc, Pediatric Allergist & Researcher at Paediatric Allergy Unit, Bambino Gesù Children Research Hospital (IRCCS) in Rome, EAACI Pediatric Section Chair and Susanne Lau, MD, PhD, Deputy Head of Pediatric Respiratory Medicine, Immunology and Critical Care Medicine Department, Charité Medical University of Berlin. It will include lectures by Sabine Schnadt, of the German Allergy and Asthma Association, Mönchengladbach, Germany, on the value of thresholds of reaction and Dr. George du Toit, of King’s College London, on data from the Company’s Phase 3 EPITOPE study, respectively.

“We look forward to presenting the EPITOPE Phase 3 data at EAACI this year. The development of a well-tolerated and convenient treatment option continues to be a primary focus for DBV, and we believe the data to be presented will show our

ongoing commitment and efforts to progress the development of this potential treatment option for underserved patients,” said Dr. Pharis Mohideen, Chief Medical Officer, DBV Technologies. “Our symposium will address a theme that peanut-allergy caregivers know well: the burdens that patients face in living with their condition. As a food allergy parent, I believe it is critical that we continue to engage in this open dialogue on how we can help improve lives for patients and families in a meaningful way.”

Symposium

“Addressing the Burden of Patients Living with Peanut Allergy” will be chaired by Dr. Stefania Arasi and Dr. Susanne Lau

- Date and location: Saturday, 10 June, 12:00 – 13:00 CEST, Hall E
- Lectures:
 - “Introduction,” Dr. Stefania Arasi
 - “Managing the risk of patients with peanut allergy: the value of thresholds of reaction,” Dr. Sabine Schnadt
 - “Epicutaneous Immunotherapy for peanut allergy: an update,” Dr. George du Toit
 - “Conclusion,” Susanne Lau

Scientific Presentations

“Characteristics and current management strategies of children diagnosed with peanut allergy (PA) in the United Kingdom (UK)”

- Session title: Food allergy 1
- Session date and time: Friday, 9 June, 2023, 12:00 – 13:00 CEST

“Health state utilities in children with peanut allergy and their parents: a UK vignette study”

- Session title: Food allergy 2
- Session date and time: Saturday, 10 June, 2023, 12:00 – 13:00 CEST

“Efficacy and Safety of Epicutaneous Immunotherapy (EPIT) for Peanut Allergy in Subjects Aged 1-3 Years With and Without Concomitant Asthma in the EPITOPE Study”

- Session title: Asthma 3
- Session date and time: Sunday, 11 June, 2023, 12:45 – 13:45 CEST

About EPITOPE



EPITOPE ([NCT03211247](#)) enrolled 413 subjects (51 in Part A and 362 in Part B) in approximately 50 centers across North America (Canada and the United States), Europe and Australia. The EPITOPE trial was a two-part trial: Part A was designed to assess the safety of Viaskin Peanut 100 µg and 250 µg and to determine the highest safe dose, and Part B was designed to assess the efficacy and safety of the selected dose. Based on the results of Part A, the 250 µg dose was selected for Part B. In Part B, subjects were randomized 2:1 to receive Viaskin Peanut 250 µg or placebo.

The primary endpoint was based on a responder analysis after 12 months of treatment with the selected dose of Viaskin Peanut. As a secondary efficacy endpoint, cumulative reactive dose (CRD) was also evaluated in EPITOPE to establish the total quantity of peanut protein that triggers subject reactions at month 12 of active treatment versus placebo. Serological markers were also measured at baseline, 3, 6 and 12 months in order to characterize the immunological changes in subjects. There were no limitations on activities of daily living in this trial. Participants were able to go about their normal lives without restrictions, including playing, showering, or swimming.

Following the completion of EPITOPE, all eligible subjects had the option to rollover into EPOPEX, a long-term, open-label extension study of Viaskin Peanut 250 µg. Now that the EPITOPE study results are publicly available, subjects enrolled in the EPOPEX study will be unblinded to their respective treatment group in EPITOPE.

In June 2022, DBV Technologies announced positive topline results from EPITOPE. Viaskin Peanut demonstrated a statistically significant treatment effect ($p < 0.001$), with 67.0% of subjects in the Viaskin Peanut arm meeting the treatment responder criteria after 12 months, as compared to 33.5% of subjects in the placebo arm (difference in response rates = 33.4%; 95% CI = 22.4% - 44.5%). The EPITOPE safety results were generally consistent with the safety profile of Viaskin Peanut 250 µg observed in children with peanut allergy ages 4 years and older in prior clinical trials. No imbalance in the overall adverse event (AE) rate was observed in the trial between the active and placebo arms. For more information on the EPITOPE results see the [DBV press release](#).

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 contains forward-looking statements and estimates, including statements regarding DBV Technologies' clinical development and regulatory plans with respect to Viaskin™ Peanut for the treatment of toddlers ages 1-3 years old, the therapeutic potential of Viaskin™ Peanut as a treatment for peanut-allergic children more broadly, the ability of any of the Company's product candidates, if approved, to improve the lives of patients with food allergies, designs of the Company's anticipated clinical trials, safety studies and HF studies, and the timing and anticipated results of interactions with regulatory agencies. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties, including risks inherent to the clinical development and regulatory process, as well as market conditions and other risks and uncertainties set forth 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.

Investor Contact

Katie Matthews
DBV Technologies
+1 857-529-2563
katie.matthews@dbv-technologies.com

Media Contact

Angela Marcucci
DBV Technologies
+1 646-842-2393
angela.marcucci@dbv-technologies.com

Viaskin and EPIT are trademarks of DBV Technologies.