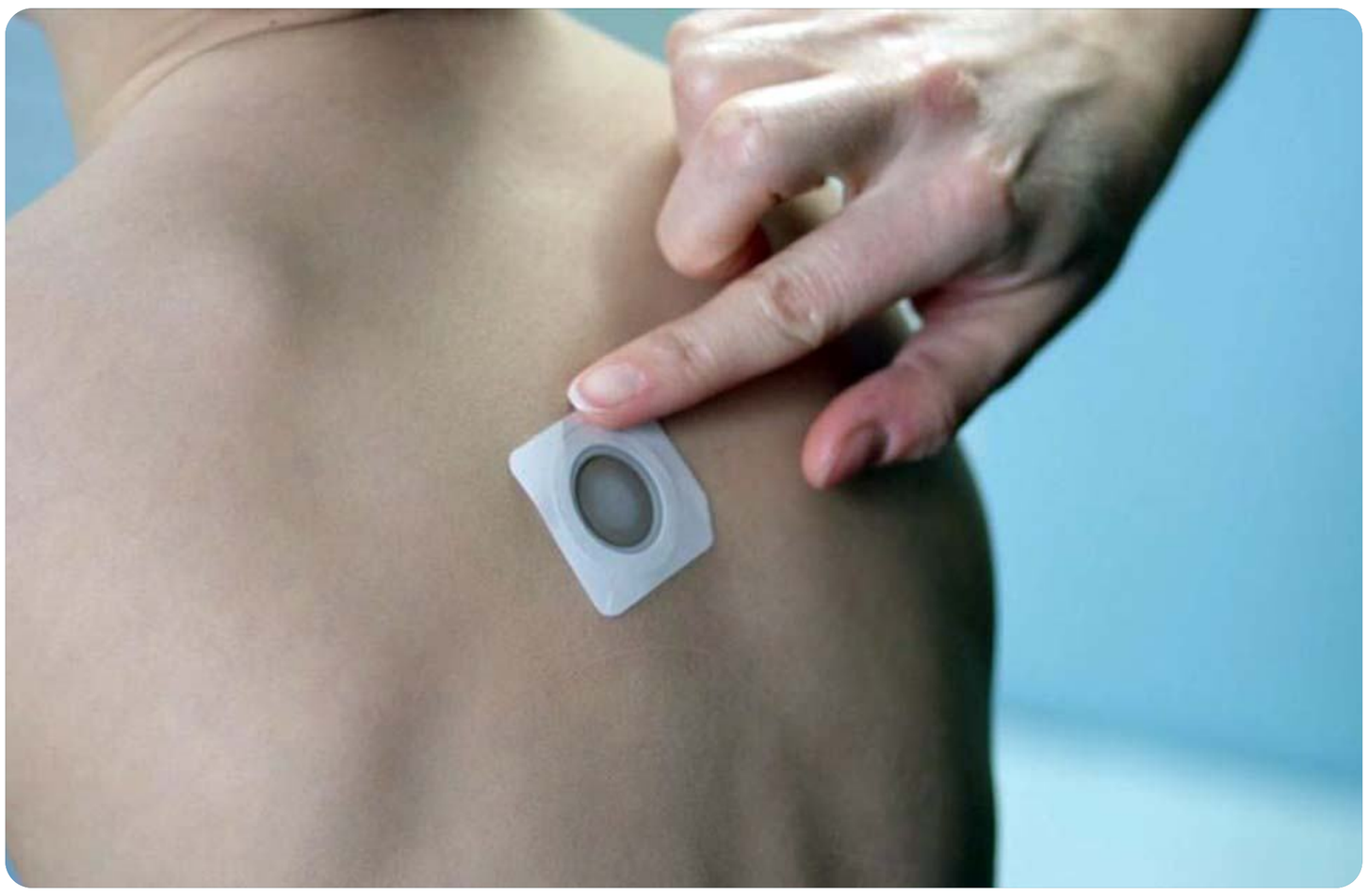
Peanut Blog

An ounce of information



DBV Technologies Provides Updates on the Viaskin Peanut Program in Children and Toddlers and Reports Second Quarter and Half-Year 2024 Financial Results

- ITESSE enrollment in peanut allergic 4-7-year-olds is on-track and recruitment is expected to be complete by end of Q3 2024
- DBV submitted a labeling proposal, informed by the EPITOPE efficacy data, to the Food and Drug Administration (FDA) to address the FDA's protocol queries regarding patch wear-time in COMFORT Toddlers

- DBV closes Q2 2024 with a cash balance of $66.2 million; due to cost-saving measures, the Company's cash runway is extended into Q1 2025

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today shared an update on the Phase 3 study, VITESSE (Viaskin Peanut Immunotherapy Trial to Evaluate Safety, Simplicity and Efficacy), using the modified Viaskin Peanut Patch, in children ages 4 – 7 years old with peanut allergy. The Company also provided a status update on the COMFORT (Characterization of the Optimal Management of FOod allergy Relief and Treatment) Toddlers supplemental safety study in 1 – 3-year-olds with peanut allergy. DBV reported financial results for the second quarter and the first half of 2024. The quarterly and half-year financial statements were approved by the Board of Directors on July 30, 2024.

Business Update

VITESSE

DBV Technologies reports that enrollment for the VITESSE Phase 3 pivotal study in children 4 - 7-year-olds with a peanut allergy continues to be on track to screen the last subject by the end of Q3 2024. VITESSE is a trial evaluating efficacy and safety of the modified Viaskin® Peanut patch in approximately 600 subjects (randomized 2:1) with 86 participating sites in US, Canada, Europe, UK and Australia.

"We are pleased that sites in the U.S., Canada, Europe, Australia, and the UK are working hard to continue screening and enrolling subjects so that we are on-track to reach our goal of last subject into VITESSE by the end of Q3 2024," said Pharis Mohideen, M.D. Chief Medical Officer at DBV Technologies. "We are seeing great momentum via our engagements at medical conferences and through our outreach efforts via the patient advocacy community and with study investigators. I look forward to the completion of study recruitment in the months to come."

COMFORT Toddlers

DBV Technologies and the FDA have been engaged in ongoing dialogue since May 2023 on the COMFORT Toddlers supplemental safety study in 1 – 3-year-olds with a peanut allergy. The study protocol was submitted on November 9, 2023, with comments provided by FDA on March 11, 2024. Since March, much of the dialogue between DBV and FDA regarding the COMFORT Toddlers supplemental study has focused on patch wear-time experience, including how prescribers would advise parents and caregivers to manage day-to-day variability in patch wear time.

In this context, DBV proposed an approach, informed by the EPITOPE efficacy data, that focuses on the user experience during the first 90-days of treatment. DBV submitted to the FDA draft labeling for Section 2 – Dosing and Administration, for a potential Viaskin Peanut Prescribing Information (PI), along with comprehensive supportive data and analyses. Within the first 90-days of treatment (excluding the lead-in dosing period) it is possible to identify those patients who are very likely to have a robust clinical efficacy response based on patch wear time experience (i.e., "Label-in" patients). The proposed PI recommends continuation of treatment for these patients. With the same 90-day approach, patients less likely to have a robust clinical efficacy response, identified by their patch wear-time experience, would be identified as "Label-out" patients. In these instances, the PI would recommend a shared decision-making process, between the health care provider and the parent or caregiver, to determine whether treatment should be discontinued.

Importantly, the data shows that the "Label-in" and "Label-out" populations have similar immunological characteristics at baseline and have a similar safety profile while on treatment. However, there is clearly a difference in immune physiology (i.e., local application site sensitivity to the allergen, peanut protein) which impacts an individual patient's wear time experience.

"DBV is and always has been dedicated to families in the food allergy community—our future patients are our top priority," said Daniel Tasse, Chief Executive Officer of DBV Technologies. "We have offered a robust proposal to the FDA with the goal of expediting and finalizing a path forward for Viaskin Peanut in 1–3-year-olds. We believe the proposed labeling solution, which identifies patients to label-in and label-out of treatment with the Viaskin Peanut patch, will provide data-driven instructions to prescribers, and thus optimize Viaskin Peanut treatment for toddlers suffering from peanut allergy.

"On April 29th, the FDA Office of Vaccine Research and Review stated that non-COVID related backlogs were behind them, that the Division was caught-up, allowing more time for interactions with sponsors. We have indeed seen more engagement from FDA, particularly on CMC and our clinical program. DBV looks forward to continued dialogue with FDA in advancing a regulatory pathway for Viaskin Peanut in 1–3-year-olds."

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