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A Phase 2, Open-Label Study to Assess Consumption of Peanut in Infants Aged 6-12 Months With Peanut Allergy Treated With Epicutaneous Peanut Immunotherapy

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Disclosures

Author disclosures:

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Epicutaneous Immunotherapy for Peanut Allergy

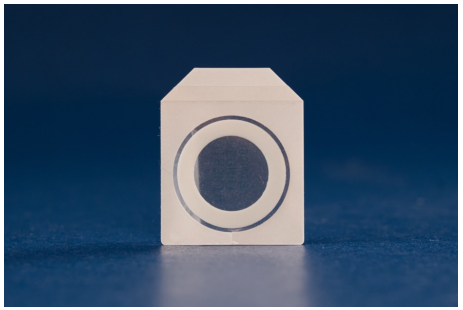
Peanut allergy typically presents in infancy, is usually lifelong, and carries a high risk of severe, potentially life-threatening reactions[1]

Early initiation of immunotherapy may improve treatment outcomes, as increased immune plasticity in young children may support more robust and durable immunomodulation[2-4]

Epicutaneous immunotherapy with VIASKIN® Peanut Patch involves administering a patch containing 250 µg of peanut protein to desensitize children with peanut allergy and reduce the risk of reaction to accidental ingestion[5,6]

In Phase 3 trials, a significantly greater proportion of children with peanut allergy aged 1 through 3 years, and 4 through 7 years achieved desensitization with VIASKIN® Peanut Patch vs placebo ($p<0.001$)*[,7,8]

VIASKIN® Peanut Patch



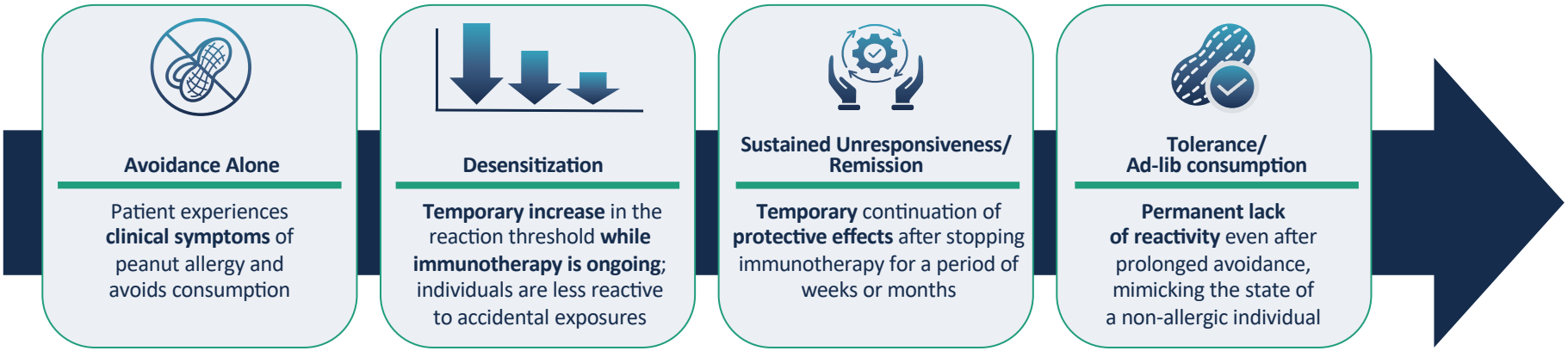
The VIASKIN® Peanut Patch is 34 mm/side.
Figure from DBV Technologies.

*In both studies (EPITOPE and VITESSE), the statistical significance value was $p<0.001$.

1. Patel R, Koterba AP. Peanut allergy. In: *StatPearls [Internet]*. Updated July 4, 2023. Accessed June 10, 2026. https://www.ncbi.nlm.nih.gov/books/NBK538526; **2.** Jones SM, et al. *Lancet*. 2022;399(10322):359-371;
3. Kim EH, et al. *J Allergy Clin Immunol*. 2024;153(1):173-181.e10; **4.** Nguyen A, et al. *Clin Exp Allergy*. 2024;54(3):169-184; **5.** Fleischer DM, et al. *JAMA*. 2019;321(10):946-955; **6.** Fleischer DM, et al. *J Allergy Clin Immunol*. 2020;146(4):863-874;
7. Greenhawt M, et al. *N Engl J Med*. 2023;388(19):1755-1766; **8.** Fleischer, D et al. Presented at: American Academy of Allergy, Asthma & Immunology (AAAAI) Congress; February 26-28, 2026; Philadelphia, PA, USA.

Potential for Ad-Lib Consumption of Peanut in Infants With Peanut Allergy

- Peanut allergy is associated with significant patient and caregiver burden including risk of anaphylactic reactions, dietary restrictions, limitations on daily activities, anxiety, and social isolation, which lead to impaired quality of life[1,2]
- Food allergy immunotherapy studies typically focus on desensitization or sustained unresponsiveness outcomes; however, for some patients and caregivers, **ad-lib consumption is the ultimate treatment goal**[3-6]



Ad-lib consumption may offer benefits beyond protection from accidental exposure, including reduced treatment burden, increased dietary flexibility, and improvements in child and caregiver quality of life[3]

1. Lieberman JA, et al. *Allergy*. 2021;76(5):1367-1384; **2.** Chan E, et al. *Ann Allergy Asthma Immunol*. 2020;124(5):479-486; **3.** Anagnostou A. *Expert Rev Clin Immunol*. 2023;19(6):561-563; **4.** Moran TP, et al. *Curr Opin Immunol*. 2013;25(6):781-787; **5.** Wasserman RL. *J Food Allergy*. 2022;4(2):102-105; **6.** Flom JD, et al. *J Allergy Clin Immunol Pract*. 2025;13(4):741-744.

THRIVE Study Design: 48-Month, Phase 2, Single-Arm, Open-Label Trial[1]

Objective: To assess the efficacy and safety of the VIASKIN® Peanut Patch in achieving ad-lib consumption of peanut in infants with peanut allergy in a Phase 2 trial[1,2]

Participants

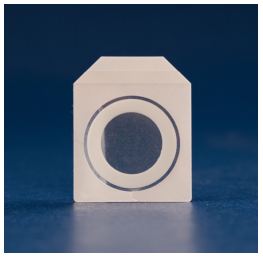
Infants aged 6 through 12 months with peanut allergy, currently following a strict peanut-free diet

Anticipated enrollment

250 participants

Screening period

Open-label treatment period with VIASKIN® Peanut Patch
(250 µg of peanut protein)



Peanut consumption period
Dietary peanut consumption regimens will be based on the month 36 food challenge results

Group 1: Consume entire month 36 food challenge without dose-limiting symptoms (DLS)*
- Discontinue VIASKIN® Peanut Patch
- Begin peanut consumption†

Group 2: Consume a single dose of 600-650 mg without DLS* but have DLS above that dose
- Continue VIASKIN® Peanut Patch
- Begin peanut consumption‡

Group 3: Did not reach a dose of at least 600 mg of peanut without DLS*
- Discontinue VIASKIN® Peanut Patch

Follow-up period
(+2 weeks)

Day 1 — Enrollment/ start treatment

Month 12

Month 24

Month 36 — Open food challenge (maximum dose: 2500 mg)

Month 48 — Group 2 subset:§ Mandatory open food challenge (maximum dose: 2500 mg)

Primary endpoint:
Achievement of ad-lib dietary peanut consumption assessed at month 48

*Consortium for Food Allergy Research DLS as defined in protocol. †Group 1 participants will consume ≥2 g of peanut protein every 2 weeks during the peanut consumption period.
‡Group 2 participants will consume ≥1 g of peanut protein every 2 weeks during the peanut consumption period. §Group 2 subset that undergoes month 48 food challenge, as defined in protocol.

DLS, dose-limiting symptoms.

1. International Standard Randomised Controlled Trial Number (ISRCTN) Registry. ISRCTN63504081. Updated June 9, 2026. Accessed June 10, 2026. https://www.isrctn.com/ISRCTN63504081; **2.** DBV Technologies. Data on file.

Infants Aged 6 Through 12 Months With a Confirmed Diagnosis of Peanut Allergy Will Be Enrolled in THRIVE

Confirmation of peanut allergy diagnosis will be based on clinical history and diagnostic assessments

CLINICAL HISTORY

- No history of peanut ingestion **OR**
- History of peanut ingestion reaction (CoFAR grade 1 or 2) **OR**
- History of peanut ingestion with anaphylaxis (CoFAR grade 3 or 4) **OR**
- History of peanut ingestion reaction on food challenge*

CONFIRMATION OF PEANUT ALLERGY

- Skin prick test
- Peanut-specific IgE†
- Ara h 2–specific IgE†
- Positive screening food challenge‡

*Food challenge within 3 months of visit 1 with eliciting dose ≤2500 mg using CoFAR dose-limiting symptoms as described in the study protocol. †Peanut-specific serum IgE and Ara h 2 measured within 3 months of entry, including during screening. ‡Food challenge during screening, with eliciting dose ≤2500 mg as outlined in the study protocol.

Ara h, *Arachis hypogaea*; CoFAR, Consortium for Food Allergy Research; Ig, immunoglobulin.

DBV Technologies. Data on file.

Peanut Consumption Regimens Will Be Based on the Month 36 Food Challenge (FC) Outcome

Participants will be assigned to **one** of **three** groups based on the month 36 FC outcome; consumption regimens during months 37-48 will be based on participants' group allocation

Group 1

Participant consumes the entire FC (maximum cumulative dose: 4998 mg of peanut protein) without dose limiting symptoms (DLS)

Ad-Lib Regimen

- Discontinue VIASKIN® Peanut Patch
- Begin peanut consumption (≥2 g of peanut protein every 2 weeks)

Group 2

Participant tolerates the 600-650 mg of peanut protein dose at month 36 FC without DLS, but has DLS at higher doses, including partial consumption of those doses

Ad-Lib Regimen

- Continue VIASKIN® Peanut Patch
- Begin peanut consumption (≥1 g of peanut protein every 2 weeks)

Group 3

Participants have DLS at or below the 600-650 mg of peanut protein dose of the FC

No Ad-Lib Regimen

- Discontinue VIASKIN® Peanut Patch
- Continue peanut avoidance

DLS, dose-limiting symptoms; FC, food challenge.

DBV Technologies. Data on file.

THRIVE Primary Endpoint Will Assess Efficacy and Safety of VIASKIN® Peanut Patch in Achieving Ad-Lib Consumption of Peanut

Primary endpoint: Participants in Group 1 and Group 2 will be considered to have met ad-lib consumption of dietary peanut if any **one** of the following **three** criteria are met at the end of the peanut consumption period (month 48)

Group 1: Consumed and tolerated ≥4 g of peanut protein in a single sitting on at least two separate occasions, at least once between months 43 and 48

Group 2: Consumed and tolerated at least the month 36 FC single highest tolerated dose in a single sitting on at least two separate occasions, at least once between months 43 and 48

OR

Participant tolerated and was compliant with peanut consumption ≥75% of the time

OR

Caregiver/parent-reported outcome assessment indicates **satisfaction with the participant's treatment outcome**

- **Other efficacy endpoints:** change in health-related QoL; change in caregiver assessment of treatment experience; month 36 FC outcomes, month 48 FC outcome (for group 2); change from baseline in psIgE, psIgG4, and peanut SPT wheal diameter
- **Safety endpoints:** AEs, serious AEs, AEs associated with accidental peanut consumption, AEs associated with peanut consumption during the consumption period
- THRIVE will also provide insights into the acceptability and feasibility of long-term EPIT and dietary incorporation strategies during infancy and early childhood

AE, adverse event; EPIT, epicutaneous immunotherapy; FC, food challenge; psIgE, peanut-specific immunoglobulin E; psIgG4, peanut-specific immunoglobulin G4; QoL, quality of life; SPT, skin prick test.

DBV Technologies. Data on file.

Summary

The THRIVE trial is investigating the efficacy and safety of daily EPIT via the VIASKIN® Peanut Patch to achieve ad-lib consumption of peanuts in infants with peanut allergy

- Enrollment in THRIVE is ongoing – anticipated completion in 2031

Results are expected to inform future immunotherapy protocols and improve understanding of whether EPIT with VIASKIN® Peanut Patch can support meaningful dietary incorporation of peanut alongside clinically relevant patient- and caregiver-centered outcomes in young children with peanut allergy

VIASKIN® Peanut Patch

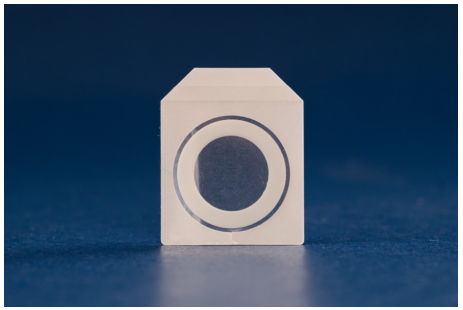


Figure from DBV Technologies.

EPIT, epicutaneous immunotherapy.

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Thank you

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