

PATIENT EXPERIENCES WITH EPICUTANEOUS IMMUNOTHERAPY FOR PEANUT ALLERGY IN OLFUS-VIPES AND REALISE TRIALS: QUALITATIVE STUDIES

Gordon Sussman¹, Amarjit Cheema², Daren Siri³, Terri Brown-Whitehorn⁴, Daniel Petroni⁵, Kari Nadeau⁶, Béatrice Tugaut⁷, Benoit Arnould⁷, Joseph M. Chalil^{8,9}, Jacqueline A. Pongracic¹⁰

¹Gordon Sussman Clinical Research, Toronto, ON, Canada; ²Cheema Research Inc, Mississauga, ON, Canada; ³Midwest Allergy Sinus Asthma, SC/SWIA Clinical Research Center, Normal, IL, USA; ⁴Allergy/Immunology Clinic, Children's Hospital of Philadelphia, Philadelphia, PA, USA; ⁵Asthma, Inc, Clinical Research Center, Seattle, WA, USA; ⁶Stanford University School of Medicine, Stanford, CA, USA; ⁷Patient-Centered Outcomes, ICON, Lyon, France; ⁸DBV Technologies SA, Montrouge, France; ⁹Nova Southeastern University, Fort Lauderdale, FL, USA; ¹⁰Ann and Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, USA

RATIONALE

- Peanut allergy, one of the most common food allergies, can result in severe, potentially life-threatening reactions¹
- Because there is no cure, avoidance of peanut and emergency treatment are key management approaches, and accidental ingestion remains a major concern for patients and their caregivers^{2,3}
- Risks and concerns associated with accidental ingestion can lead to significantly diminished health-related quality of life (HRQL) for peanut-allergic patients and their caregivers³
- Immunotherapy, including investigational peanut epicutaneous immunotherapy (EPIT), is an emerging treatment strategy for reducing the risk of reactions from accidental ingestion, which may also help to improve HRQL⁴
- The efficacy, safety, and tolerability of EPIT with a 250-µg peanut protein patch, DBV712 250 µg, have been studied in multiple placebo-controlled double-blind clinical trials^{2,5,6}
- In order to optimize patient care and prioritize HRQL, it is important to understand patients' and caregivers' experiences with DBV712 250 µg and the potential effects it may have on HRQL

OBJECTIVE

- To assess HRQL trajectories and trial participants' experiences with DBV712 250 µg

METHODS

- Qualitative interviews were conducted with families who participated in 2 clinical trials with DBV712 250 µg
 - OLFUS-VIPES was a 2-year, open-label extension of the 12-month, Phase 2b, double-blind VIPES trial²
 - *Select results from this qualitative analysis for OLFUS-VIPES have been previously presented⁷*
 - REALISE was a 2-part, Phase 3 trial; the first 6 months was a double-blind, placebo-controlled trial, which was followed by a 36-month open-label period⁸
 - Children were aged 6–11 years (OLFUS-VIPES) or 4–11 years (REALISE) at trial enrollment
- Interviews were conducted retrospectively with participants in OLFUS-VIPES and prospectively at 6 and 12 months for REALISE participants
- Approximately 1-hour-long interviews with children aged 4–11 years (~15 minutes) and caregivers (~45–60 minutes) were conducted by telephone or in person by trained researchers
- Interviews were conducted using a semi-structured interview guide with open-ended questions and probes that included the following topics:
 - Impact of peanut allergy on daily life (eg, safety practices and emotional, physical, and social impacts)
 - Experiences using DBV712 250 µg (eg, treatment expectations, treatment preferences, and the impact of DBV712 250 µg on daily life)
- Interviews were audio-recorded, transcribed verbatim, and de-identified
- Interview transcripts were analyzed qualitatively using a thematic approach to identify concepts and subconcepts.⁹ Transcript coding was carried out using ATLAS.ti software.^{10,11} Demographic information was summarized descriptively

RESULTS

Participants

- A total of 18 families (19 caregivers) from OLFUS-VIPES and 29 families from REALISE participated in the qualitative interview (**Table 1** and **Table 2**)

Table 1. Patient Characteristics

CHARACTERISTICS		OLFUS-VIPES (n=18)	REALISE (n=29)*
Sex (n)	Male	9	15
	Female	9	14
Age (years)	Median (minimum–maximum)	13 (9–16)	7 (4–11)
Ethnicity (n)	White	9	20
	Black	5	1
	Asian	2	7
	Other†	2	1
Country (n)*	USA	9	17
	Canada	9	12
Responder at 24 months (n)	Responder	11	–
	Non-responder	7	–
Treatment group (n)§	DBV712 250 µg	13	22
	Placebo	5	7

*Data from 6-month timepoint. †Including multiracial. ‡Based on site enrollment. §Treatment group assignment during the randomized placebo-controlled blinded period of each trial.

Table 2. Caregiver Sociodemographic Data

CHARACTERISTICS		OLFUS-VIPES (n=18)	REALISE (n=29)*
Relationship with child (n)	Mother	13	24
	Father	6	5
Age (years)	Median (minimum–maximum)	47 (37–60)	43 (32–50)
Education level (n)	Completed high school	1	2
	Associate degree/some college	2	5
	Bachelor's degree	7	7
	Post-graduate degree	9	14
Working status (n)	Other	–	1
	Working full time	7	16
	Working part time	8	4
	Stay at home/full-time parent	1	8
	Unemployed	2	–
	Other†	1	1

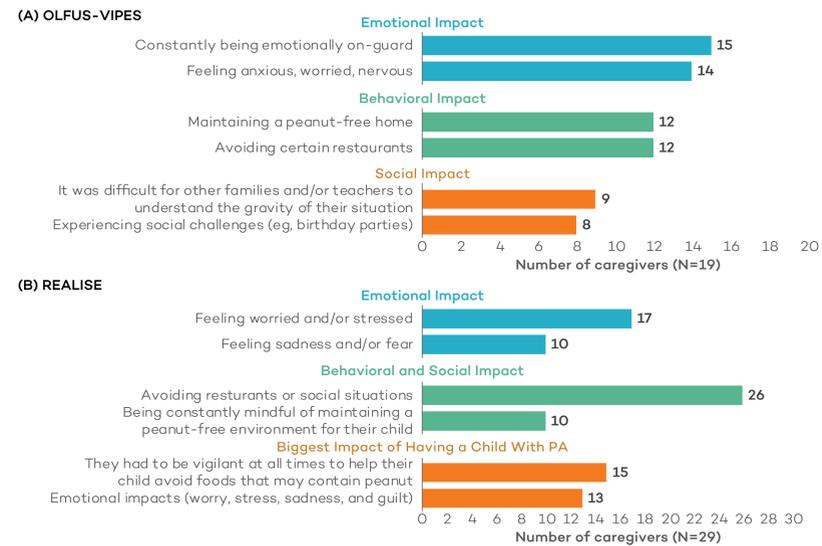
*Data from 6-month timepoint. †Including students.

Impact of Peanut Allergy and DBV712 250 µg on HRQL

- Overall, parents reported substantial emotional, behavioral, and social impacts of peanut allergy on HRQL in both OLFUS-VIPES and REALISE (**Figure 1**)
- In both studies, caregivers also noted positive expectations and experiences with DBV712 250 µg (**Figure 2**)
 - Most caregivers expected treatment with DBV712 250 µg would reduce their child's peanut sensitivity and risks associated with accidental peanut exposure (**Figure 2A**)
 - Overall, most caregivers were satisfied with DBV712 250 µg and reported that they would try DBV712 250 µg with their child again in the future (**Figure 2B**)
- Caregivers also reported positive changes in their family's HRQL with DBV712 250-µg treatment
 - Following DBV712 250-µg use in OLFUS-VIPES, caregivers reported feeling less worried (n=16), as well as more comfortable and confident (n=7). They also reported that their child was able to eat possible cross-contaminated foods (n=9) and permitted their child to be less careful in regard to where they carried their adrenaline autoinjector (n=7). Caregivers also allowed some small shifts in peanut safety practices within the family (n=7)

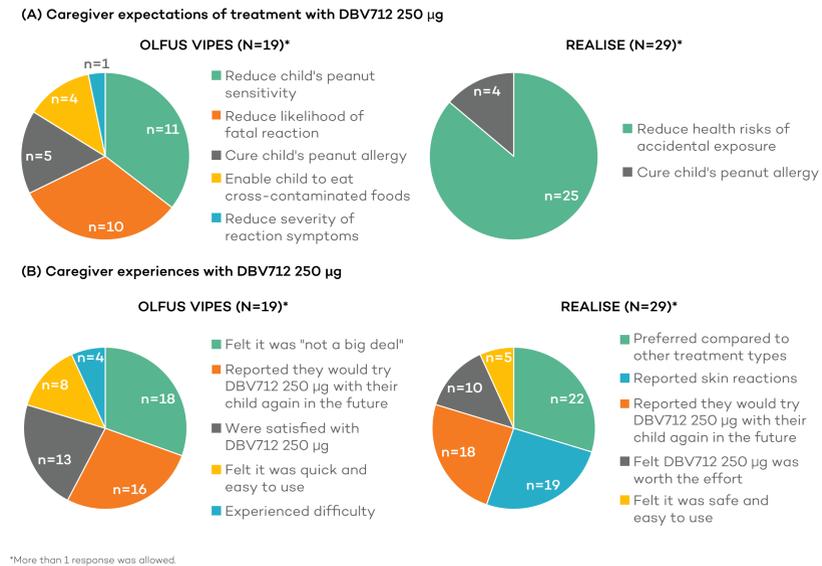
- At the 12-month interview of REALISE, caregivers reported feeling less concerned compared with the 6-month interview. They reported DBV712 250 µg helped them to feel alleviated (n=8), they saw improvement either in their child's skin reaction to DBV712 250 µg (n=5) and/or in their child's peanut allergy (n=5), and felt that their child had more freedom, in the sense that they felt safer if there was a possibility of exposure to peanuts (n=3)

Figure 1. Emotional, Behavioral, and Social Impacts of Peanut Allergy (PA) on Family HRQL in OLFUS-VIPES (N=19) and REALISE (N=29) as Reported by Caregivers*



*Top 2 responses/concepts from caregivers for each category.

Figure 2. Caregiver Expectations and Experiences With DBV712 250 µg in OLFUS-VIPES (n=19) and REALISE (N=29)



*More than 1 response was allowed.

Quotations From Caregivers' Participating in OLFUS-VIPES or REALISE

- Verbatim responses from this qualitative research capture the diverse HRQL impacts that face peanut-allergic children and their families (**Table 3**)

Table 3. Sample of Quotations From Caregivers Participating in OLFUS-VIPES or REALISE With Children Treated With DBV712 250 µg

CONCEPTS	CAREGIVER QUOTATIONS
Impacts of PA on Families' HRQL	
Emotional impacts	"I mean, you can always think, 'Okay, what if I'm wrong and all these reactions she's had are not it and the one time she's going to react respiratory and...the worst is going to happen.' So that can always be in the back of your mind" "Every minute of every day. Literally, when she's not in my sight, I worry about it"
Behavioral impacts	"We've got to always check the label. If you have a party at school, don't eat the food. Bring it home first. Let Mommy read the ingredients" "We just don't go to certain restaurants"
Social impacts	"It's hard to go to a party and tell them there's a cake, but you can't have that. You got to have this cupcake that we have from home that you've had 20 times before"
DBV712 250 µg: expectations and experiences	"Honestly, at the end, I don't expect that he'll be able to eat peanuts, but I'm hoping that, like, we can go somewhere and not fear the 'may contain.'" "It wasn't that he was gonna be able to go have a peanut butter and jelly sandwich one day, but that... [we could] worry less about accidental ingestion, because chances are he's not gonna accidentally eat a whole sandwich, but he might take a bite of something before realizing there's nuts in it. That was really what we were expecting out of it, and I think that's what we got"
Change in families' HRQL with DBV712 250 µg	"It's amazing. It really is. It just feels like some of the weight's been lifted off my shoulders" "Before the study, he had needed an EpiPen after only 33 milligrams, which is about a fifth of a peanut. And now he is able to get to half a peanut. That was right after the patch" "Well, it has helped alleviate. I mean, I still have a little bit of a nervous feeling sometimes. I mean, he's very careful with checking labels, but I still have a little bit of a concern when he's not in my care and he's with other people or an overnight camp situation. I still have a positive apprehension, but it's definitely weaned. I don't have it as much as I used to. Definitely before a year ago, I was much more nervous"

CONCLUSIONS

- Most families in OLFUS-VIPES and REALISE reported emotional, social, and behavioral impacts of peanut allergy on HRQL. The most reported concerns were having to always be mindful of food, the struggle associated with social occasions, and stress due to risk of accidental exposure
- Caregivers' expectations of EPIT with DBV712 250 µg were focused on risk reduction and ability to feel less concerned about their child's health. Additionally, most families reported skin irritation during treatment
- Overall, DBV712 250 µg was well accepted and perceived as easy to use by participating patients/caregivers and helped alleviate caregivers' concerns regarding their child's peanut allergy

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