Phase 2 Study to Evaluate the Sensitivity, Specificity, and Safety of DBV1605 as a Diagnostic Tool for Non–IgE-Mediated Cow's Milk Allergy in Children (APTITUDE)

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Rationale

- Non–immunoglobulin E (IgE)-mediated cow's milk allergy (CMA) is typically a clinical diagnosis based on history[1]
- No validated diagnostic test currently exists; a tool that provides early, reliable diagnosis may aid in appropriate management and lessen burden for families[2]
- Atopy patch tests (APTs) are of interest for this purpose[3]

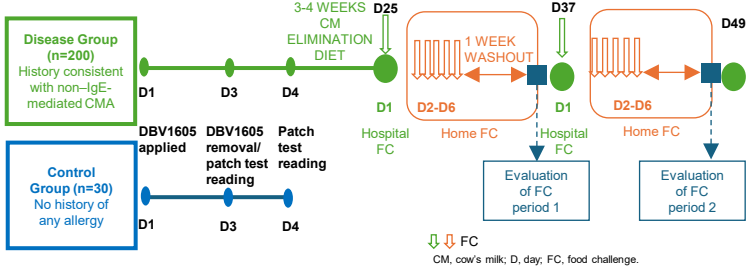
Objective

- Assess the performance and safety of DBV1605, a ready-to-use APT as a diagnostic tool in children aged >28 days to ≤24 months with suspected non–IgE-mediated CMA

Methods

- APTITUDE (NCT04492683) was a multicenter, phase 2 study conducted across 32 sites in Canada, Italy, and the US (**Figure 1**)

Figure 1. APTITUDE Study Design Diagram



CM, cow's milk; D, day; FC, food challenge.

- Participants applied active and control patches to the upper back for 48 hours, followed by skin assessments after 48 and 72 hours
- The Disease group underwent a cow's milk (CM)-elimination diet followed by double-blind, placebo-controlled food challenges (DBPCFCs) to CM
- Sensitivity and specificity were evaluated by comparing skin assessments to DBPCFC results
- Safety was assessed throughout the study

References: 1. Indinnimeo L et al. *BMC Pediatr*. 2013;13:203. 2. Fiocchi A et al. *J Allergy Clin Immunol*. 2010;126(6):1119-1128.e12. 3. Canani RB et al. *Allergy*. 2007;62(7):738-743.

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Key Points

- DBV1605 was well tolerated, with no identified safety concerns and high compliance
- Results suggest the potential of DBV1605 in the diagnosis of non–IgE-mediated cow's milk allergy; however, future investigations will consider the recruitment challenges encountered in this study
- The decision to terminate the study was not related to any safety concerns or inadequate performance of DBV1605

Results

- The study was terminated early in November 2023 due to recruitment challenges. This decision was not related to any safety concerns or inadequate performance of the patch
- The study included 95 participants (median age: 7.55 months); 57/65 (87.7%) participants in the Disease group and 30/30 (100%) participants in the Control group completed the study

Efficacy

Figure 2. Primary Efficacy Analysis

		Final interpretation of DBPCFC		
		CMA +	CMA -	Subtotal
Patch reading of skin reactivity	Patch reading +	29	5	34
	Patch reading -	5	7	12
	Subtotal	34	12	46

Sensitivity: TP/(TP+FN)	29/34	85.3% [71.5, 94.0]
Specificity: TN/(TN+FP)	7/12	58.3% [31.5, 81.9]

FN, false negative; FP, false positive; TN, true negative; TP, true positive.

- DBV1605 showed a specificity of 58.3 (90% CI: 31.5, 81.9) and a sensitivity of 85.3 (90% CI: 71.5, 94.0) in the diagnosis of non–IgE-mediated CMA (**Figure 2**)

Safety

- 24 (36.9%) participants in the Disease group and 5 (16.7%) in the Control group experienced at least 1 treatment-emergent adverse event (TEAE); all were mild and unrelated to DBV1605 (**Table 1**)
- No serious TEAE, TEAE leading to discontinuation, adverse event of special interest (local or systemic), TEAE leading to epinephrine intake, or TEAE leading to death were reported

Table 1. Overview of TEAEs

Adverse event category	Disease safety analysis set (N=65) n (%) m	Control set (N=30) n (%) m
Any TEAE	24 (36.9) 49	5 (16.7) 5
Patch application and reading	3 (4.6) 3	5 (16.7) 5
CM elimination diet	18 (27.7) 29	-
Food challenge	13 (20.0) 17	-

m, number of events.