Evaluate Vantage

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Nestlé’s peanut exit makes DBV look brittle

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The $2.6bn that Nestlé paid for the peanut allergy therapy developer Aimmune always looked a little bit nuts. Now reality is biting for the food giant, with the company announcing today that it is "exploring strategic options" for Palforzia following poor sales. While Aimmune investors got their exit, the same cannot be said for backers of the group’s peanut allergy rival, DBV, which now looks like it could have an even harder task of making its patch project, Viaskin Peanut, a success. Not that the French company has had an easy ride so far, with its latest setback a partial clinical hold for its new pivotal trial, Vitesse. Nestlé’s latest move suggests that even if Viaskin Peanut can make it past regulators – hardly a dead cert given its tortuous development path so far – it will have trouble drumming up demand. DBV stock fell only 2% today, but it is not far off all-time lows. Other players in peanut allergy might also want to take note: Novartis’s ligelizumab is in phase 3 here, although it has already failed in urticaria.

Selected projects in development for peanut allergy

Project	Company	Mechanism	Status
Ligelizumab	Novartis	Anti-immunoglobin E antibody	Ph3 ends Jan 2025
PRT120	Prota Therapeutics	IgE/Th2 inhibitor	Ph2b completed in Australia; company seeking funds for further development
Remibrutinib	Novartis	BTK inhibitor	Ph2 ends Sep 2024
PVX108	Aravax	"Next-generation, allergen-specific immunotherapy"	Ph2 ends Nov 2024
ADP101	Alladapt Immunotherapeutics	Oral immunotherapy	Ph1/2 ends Nov 2022
VE416	Vedanta	Oral immunotherapy	Ph1/2* ends Jan 2023
CNP-201	Cour Pharmaceuticals	Nanoparticle encapsulating purified peanut protein extract	Ph1/2 ends May 2023

**Investigator-sponsored study. Source: Evaluate Pharma & clinicaltrials.gov.*

The recent history of DBV's Viaskin peanut	
Date	**Event**
Dec 2018	DBV pulls US filing for Viaskin Peanut
Oct 2019	FDA accepts refiling of Viaskin Peanut in 4-11 year olds; target action date Aug 5 2020
Aug 2020	CRL for Viaskin Peanut; FDA cites need for patch modifications and subsequent new human factor study
Jan 2021	DBV says FDA only requires two short studies to support new application
Dec 2021	DBV changes plan & starts pivotal study of modified Viaskin Peanut patch in children; withdraws EU marketing application
Sep 2022	DBV starts ph3 Vitesse trial using modified Viaskin Peanut patch; expects to screen 1st pt in Q4 2022 & topline results in Q1 2025
Sep 2022	FDA puts Vitesse on partial clinical hold, requesting protocol changes
Nov 2022	DBV says it will not meet target of screening 1st pt in Vitesse by YE 2022; has $213m cash
Source: Company releases.	