Clinical trial results:
Open-label follow-up study of the VIPES study to evaluate long-term efficacy and safety of the Viaskin Peanut

Summary

EudraCT number	2013-001754-10
Trial protocol	NL
Global end of trial date	29 September 2016

Results information

Result version number	v1 (current)
This version publication date	25 April 2022
First version publication date	25 April 2022

Trial information

Trial identification

Sponsor protocol code	V712-203 (OLFUS-VIPES)

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01955109
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	DBV Technologies
Sponsor organisation address	177-181 avenue Pierre Brossolette, Montrouge, France, 92120
Public contact	Chief Medical Officer, DBV Technologies, 33 1-55-42-78-78, clinicaltrials@dbv-technologies.com
Scientific contact	Chief Medical Officer, DBV Technologies, 33 1-55-42-78-78, clinicaltrials@dbv-technologies.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001481-PIP01-13
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 September 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of Viaskin® Peanut (DBV712) after up to 36 months of epicutaneous immunotherapy (EPIT) in peanut-allergic participants.

Protection of trial subjects:

The investigator was responsible for obtaining informed consent from each participant in the study, in accordance with the International Conference on Harmonisation-Good Clinical Practice (GCP) Guidelines, the Declaration of Helsinki, and applicable regulatory requirements. Before initiating a study, the investigator/institution had to have written and dated approval/favorable opinion from the Independent Ethics Committee (IEC)/Institutional Review Board (IRB) for the study protocol/amendment(s), written informed consent form, any consent form updates, participant recruitment procedures, and any written information to be provided to participants and a statement from the IEC/IRB that they comply with GCP requirements.

Background therapy:

Participants received either Viaskin Peanut 50 micrograms (µg), 100 µg, 250 µg or placebo patch on intact skin for 24 hours daily for 12 months in the VIPES study (V712-202).

Evidence for comparator: -

Actual start date of recruitment	30 August 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 54
Country: Number of subjects enrolled	France: 27
Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	United States: 84
Worldwide total number of subjects	171
EEA total number of subjects	33

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	83
Adolescents (12-17 years)	52
Adults (18-64 years)	36
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants who were previously randomized in and completed the VIPES study were eligible to enroll in this Phase II open-label follow-up study to receive an additional 24 months of Viaskin Peanut EPIT. Participants were enrolled in 21 study centers in 4 countries from 30 August 2013 and the last participant completed 29 September 2016.

Pre-assignment

Screening details:

Participants who received 50, 100 or 250 µg Viaskin Peanut in VIPES continued on same dose in OLFUS-VIPES; those receiving placebo were re-randomized 1:1:1 to 50, 100 or 250 µg Viaskin Peanut. After protocol amendment 1, all participants received 250 µg dose from start of OLFUS-VIPES; those already enrolled were switched to 250 µg at Month 6 visit.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Viaskin Peanut 250 µg

Arm description:

Participants applied 1 new Viaskin Peanut 250 µg patch on intact skin for 24 hours daily for up to 24 months. Each patch contained 250 µg peanut protein extract for epicutaneous administration. For participants who were unresponsive to a cumulative dose of 1440 milligrams (mg) peanut protein or more at Month 24 double-blind placebo-controlled food challenge (DBPCFC), 24 months of treatment was followed by a period of 2 months without treatment while maintaining a peanut-free diet.

Arm type	Experimental
Investigational medicinal product name	Viaskin Peanut
Investigational medicinal product code	
Other name	DBV712
Pharmaceutical forms	Cutaneous patch
Routes of administration	Epicutaneous use

Dosage and administration details:

Viaskin Peanut cutaneous patch containing a dry deposit of a formulation of peanut protein extract applied on intact skin for 24 hours daily for 24 months. The drug substance is an unmodified, lyophilized peanut extract produced from the extraction and freeze drying of defatted peanut flour.

Number of subjects in period 1	Viaskin Peanut 250 µg
Started	171
Randomized in OLFUS-VIPES Baseline:50 µg	30 [1]
Randomized in OLFUS-VIPES Baseline:100µg	30 [2]
Randomized in OLFUS-VIPES Baseline:250µg	111 [3]
Switched to 250 µg at Month 6	57 [4]
Completed Study Until Month 12	149

Completed	117
Not completed	54
Physician decision	2
Adverse event, non-fatal	2
Non-compliance	4
Lost to follow-up	4
Participant unwilling to continue	42

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants who had previously received either Viaskin Peanut 50 µg, 100 µg, 250 µg or placebo in the VIPES study and randomized in the OLFUS-VIPES study to receive Viaskin Peanut are presented in the separate milestones.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants who had previously received either Viaskin Peanut 50 µg, 100 µg, 250 µg or placebo in the VIPES study and randomized in the OLFUS-VIPES study to receive Viaskin Peanut are presented in the separate milestones.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants who had previously received either Viaskin Peanut 50 µg, 100 µg, 250 µg or placebo in the VIPES study and randomized in the OLFUS-VIPES study to receive Viaskin Peanut are presented in the separate milestones.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: After protocol amendment 1, participants who were already enrolled were switched to 250 µg at Month 6 visit.

Baseline characteristics

Reporting groups	
Reporting group title	Viaskin Peanut 250 µg

Reporting group description:

Participants applied 1 new Viaskin Peanut 250 µg patch on intact skin for 24 hours daily for up to 24 months. Each patch contained 250 µg peanut protein extract for epicutaneous administration. For participants who were unresponsive to a cumulative dose of 1440 milligrams (mg) peanut protein or more at Month 24 double-blind placebo-controlled food challenge (DBPCFC), 24 months of treatment was followed by a period of 2 months without treatment while maintaining a peanut-free diet.

Reporting group values	Viaskin Peanut 250 µg	Total	
Number of subjects	171	171	
Age categorical			
Participants' ages at OLFUS-VIPES entry.			
Units: Subjects			
Children (2-11 years)	83	83	
Adolescents (12-17 years)	52	52	
Adults (18-64 years)	36	36	
Age continuous			
Mean age at OLFUS-VIPES entry.			
Units: years			
arithmetic mean	13.5		
standard deviation	± 6.61	-	
Gender categorical			
Units: Subjects			
Female	61	61	
Male	110	110	
Race/Ethnicity			
The ethnicity of the participants at French local sites was not collected as it was not applicable as per local law. As such, these participants are included in the category of 'Not applicable'.			
Units: Subjects			
Caucasian	108	108	
Black	5	5	
Hispanic	3	3	
Asian	20	20	
Other	8	8	
Not applicable	27	27	

End points

End points reporting groups

Reporting group title	Viaskin Peanut 250 µg

Reporting group description:

Participants applied 1 new Viaskin Peanut 250 µg patch on intact skin for 24 hours daily for up to 24 months. Each patch contained 250 µg peanut protein extract for epicutaneous administration. For participants who were unresponsive to a cumulative dose of 1440 milligrams (mg) peanut protein or more at Month 24 double-blind placebo-controlled food challenge (DBPCFC), 24 months of treatment was followed by a period of 2 months without treatment while maintaining a peanut-free diet.

Subject analysis set title	VIPES Treatment Group: All Viaskin Peanut Doses
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were randomized in the VIPES study to receive either 50 µg, 100 µg or 250 µg Viaskin Peanut for 12 months. In the follow-up OLFUS-VIPES study, participants received 250 µg Viaskin Peanut for up to 24 months. Participants received treatment with Viaskin Peanut for a total of up to 36 months.

Subject analysis set title	VIPES Treatment Group: Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Participants were randomized in the VIPES study to receive placebo for 12 months. In the follow-up OLFUS-VIPES study, participants received 250 µg Viaskin Peanut for up to 24 months. Participants received treatment with Viaskin Peanut for a total of up to 24 months.

Primary: Percentage of Treatment Responders at Months 12 and 24

End point title	Percentage of Treatment Responders at Months 12 and 24[1]

End point description:

A treatment responder was defined as a participant with a peanut protein eliciting dose (ED) equal to or greater than 1000 mg peanut protein or with at least a 10-fold increase of ED compared to their initial ED observed at VIPES baseline, as determined by DBPCFCs at Months 12 and 24. At Month 12, participants had received 24 months of active treatment for those who received Viaskin Peanut in VIPES study and 12 months of active treatment for those who received placebo in VIPES study. At Month 24, participants had received 36 months of active treatment for those who received Viaskin Peanut in VIPES study and 24 months of active treatment for those who received placebo in VIPES study. Percentage of responders at Months 12 and 24 are presented according to whether participants received Viaskin Peanut or placebo during VIPES study. The full analysis set was the intent-to-treat population which consisted of all participants. Here, n= number of participants analyzed at specific timepoint.

End point type	Primary

End point timeframe:

Month 12 and Month 24 (end of treatment) of the OLFUS-VIPES study

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive statistical analysis was performed for the primary endpoint.

End point values	VIPES Treatment Group: All Viaskin Peanut Doses	VIPES Treatment Group: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	123	48		
Units: percentage of participants				
number (confidence interval 95%)				
Month 12 (n= 103, 46)	64.1 (54.0 to 73.3)	50.0 (34.9 to 65.1)		
Month 24 (n= 83, 41)	67.5 (56.3 to 77.4)	58.5 (42.1 to 73.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Unresponsive to a Cumulative Dose of at Least 1440 mg Peanut Protein at Month 24

End point title	Percentage of Participants Unresponsive to a Cumulative Dose of at Least 1440 mg Peanut Protein at Month 24

End point description:

Participants were considered unresponsive if they showed no objective symptoms leading to stopping the challenge during the Month 24 DBPCFC with a cumulative dose of at least 1440 mg of peanut protein, up to a cumulative dose of 5044 mg peanut protein. The percentage of unresponsive participants is presented according to whether participants received Viaskin Peanut or placebo during the VIPES study. The full analysis set was the intent-to-treat population which consisted of all participants and results are reported for those participants who had the Month 24 DBPCFC performed.

End point type	Secondary

End point timeframe:

Month 24 (end of treatment) of the OLFUS-VIPES study

End point values	VIPES Treatment Group: All Viaskin Peanut Doses	VIPES Treatment Group: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	83	41		
Units: percentage of participants				
number (confidence interval 95%)	31.3 (21.6 to 42.4)	7.3 (1.5 to 19.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Sustained Unresponsiveness to a Cumulative Dose of at Least 1440 mg Peanut Protein at Month 26

End point title	Percentage of Participants With a Sustained Unresponsiveness to a Cumulative Dose of at Least 1440 mg Peanut Protein at Month 26

End point description:

Participants who were unresponsive to a cumulative dose of 1440 mg of peanut protein or above at the Month 24 DBPCFC, had an additional 2-month period without treatment and continued on a peanut-free diet to assess for sustained unresponsiveness by a DBPCFC at Month 26. The percentage of participants with this sustained unresponsiveness, i.e, who showed no objective symptoms leading to stopping the challenge during the DBPCFC to a cumulative dose of 1440 mg of peanut protein or above at Month 26,

are presented according to whether participants received Viaskin Peanut or placebo during the VIPES study. The full analysis set was the intent-to-treat population which consisted of all participants and results are reported for participants who had the Month 26 DBPCFC performed.

End point type	Secondary

End point timeframe:

Month 26 (2 months post-treatment) of the OLFUS-VIPES study

End point values	VIPES Treatment Group: All Viaskin Peanut Doses	VIPES Treatment Group: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	22	3		
Units: percentage of participants				
number (confidence interval 95%)	77.3 (54.6 to 92.2)	100 (29.2 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Median Cumulative Reactive Dose of Peanut Protein at Months 12 and 24

End point title	Median Cumulative Reactive Dose of Peanut Protein at Months 12 and 24

End point description:

The cumulative reactive dose was defined as the sum of all peanut protein doses taken by the participant during the DBPCFC. To distinguish participants who reached the highest dose of the DBPCFC without objective symptoms 1000 mg was added to the cumulative reactive dose to obtain an adjusted value. The median cumulative reactive doses at Months 12 and 24 are presented according to whether participants received Viaskin Peanut or placebo during the VIPES study. The full analysis set was the intent-to-treat population which consisted of all participants. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

Month 12 and Month 24 (end of treatment) of the OLFUS-VIPES study

End point values	VIPES Treatment Group: All Viaskin Peanut Doses	VIPES Treatment Group: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	123	48		
Units: mg				
median (inter-quartile range (Q1-Q3))				
Month 12 (n= 103, 46)	480.0 (140.0 to 2240.0)	365.0 (140.0 to 1440.0)		

Month 24 (n= 83, 41)	440.0 (160.0 to 3040.0)	440.0 (140.0 to 1440.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Cumulative Reactive Dose of Peanut Protein at Months 12 and 24

End point title	Mean Cumulative Reactive Dose of Peanut Protein at Months 12 and 24

End point description:

The cumulative reactive dose was defined as the sum of all peanut protein doses taken by the participant during the DBPCFC. To distinguish participants who reached the highest dose of the DBPCFC without objective symptoms 1000 mg was added to the cumulative reactive dose to obtain an adjusted value. The mean cumulative reactive doses at Months 12 and 24 are presented according to whether participants received Viaskin Peanut or placebo during the VIPES study. The full analysis set was the intent-to-treat population which consisted of all participants. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

Month 12 and Month 24 (end of treatment) of the OLFUS-VIPES study

End point values	VIPES Treatment Group: All Viaskin Peanut Doses	VIPES Treatment Group: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	123	48		
Units: mg				
arithmetic mean (standard deviation)				
Month 12 (n= 103, 46)	1419.6 (± 1595.92)	895.9 (± 1329.14)		
Month 24 (n= 83, 41)	1751.1 (± 1962.12)	758.4 (± 1176.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From VIPES Baseline in Peanut-Specific Immunoglobulin E (IgE) at Months 6, 12, 18 and 24

End point title	Change From VIPES Baseline in Peanut-Specific Immunoglobulin E (IgE) at Months 6, 12, 18 and 24

End point description:

The change from the VIPES Baseline in peanut-specific IgE values at Months 6, 12, 18 and 24 of the OLFUS-VIPES study are presented according to whether participants received Viaskin Peanut or placebo during the VIPES study. The full analysis set was the intent-to-treat population which consisted of all

participants. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

VIPES Baseline to Months 6, 12, 18 and 24 (end of treatment) of the OLFUS-VIPES study

End point values	VIPES Treatment Group: All Viaskin Peanut Doses	VIPES Treatment Group: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	123	48		
Units: kilo units per liter				
median (full range (min-max))				
VIPES Baseline to Month 6 (n= 117, 48)	2.150 (-306.00 to 500.12)	18.900 (-72.37 to 344.79)		
VIPES Baseline to Month 12 (n= 104, 46)	-0.370 (-189.17 to 1168.12)	4.785 (-447.41 to 233.11)		
VIPES Baseline to Month 18 (n= 95, 43)	-1.870 (-1091.88 to 433.97)	-0.710 (-389.03 to 716.20)		
VIPES Baseline to Month 24 (n= 85, 41)	-3.160 (-381.93 to 861.24)	-10.060 (-384.03 to 332.83)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From VIPES Baseline in Peanut-Specific Immunoglobulin G Subtype 4 (IgG4) at Months 6, 12, 18 and 24

End point title	Change From VIPES Baseline in Peanut-Specific Immunoglobulin G Subtype 4 (IgG4) at Months 6, 12, 18 and 24

End point description:

The change from the VIPES Baseline in peanut-specific IgG4 values at Months 6, 12, 18 and 24 of the OLFUS-VIPES study are presented according to whether participants received Viaskin Peanut or placebo during the VIPES study. The full analysis set was the intent-to-treat population which consisted of all participants. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

VIPES Baseline to Months 6, 12, 18 and 24 (end of treatment) of the OLFUS-VIPES study

End point values	VIPES Treatment Group: All Viaskin Peanut Doses	VIPES Treatment Group: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	123	48		
Units: mg/L				
median (full range (min-max))				
VIPES Baseline to Month 6 (n= 118, 46)	1.935 (-6.82 to 28.95)	0.775 (-0.80 to 8.86)		
VIPES Baseline to Month 12 (n= 105, 44)	2.890 (-7.06 to 34.80)	1.510 (-0.61 to 11.93)		
VIPES Baseline to Month 18 (n= 95, 43)	2.780 (-5.04 to 21.90)	2.370 (-0.26 to 16.98)		
VIPES Baseline to Month 24 (n= 85, 41)	2.170 (-5.64 to 27.51)	1.950 (-0.89 to 15.40)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From VIPES Baseline in Wheal Diameter During Skin Prick Testing at Months 6, 12, 18 and 24

End point title	Change From VIPES Baseline in Wheal Diameter During Skin Prick Testing at Months 6, 12, 18 and 24

End point description:

The change from the VIPES Baseline in the wheal diameter from the undiluted skin prick tests at Months 6, 12, 18 and 24 of the OLFUS-VIPES study are presented according to whether participants received Viaskin Peanut or placebo during the VIPES study. The full analysis set was the intent-to-treat population which consisted of all participants. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

VIPES Baseline to Months 6, 12, 18 and 24 (end of treatment) in the OLFUS-VIPES study

End point values	VIPES Treatment Group: All Viaskin Peanut Doses	VIPES Treatment Group: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	123	48		
Units: millimeters				
median (full range (min-max))				
VIPES Baseline to Month 6 (n= 121, 48)	-2.30 (-17.0 to 8.5)	-1.50 (-14.0 to 3.5)		
VIPES Baseline to Month 12 (n= 106, 47)	-3.00 (-15.0 to 7.3)	-1.00 (-14.5 to 22.5)		
VIPES Baseline to Month 18 (n= 97, 45)	-3.00 (-27.6 to 8.0)	-1.40 (-14.5 to 10.5)		
VIPES Baseline to Month 24 (n= 85, 43)	-2.00 (-15.0 to 13.0)	-1.50 (-15.0 to 6.5)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events were collected from OLFUS-VIPES Baseline up to Month 24. Overall time frame of up to 24 months.

Adverse event reporting additional description:

The safety analysis set included all participants who received at least 1 dose of investigational product during the OLFUS-VIPES study. All participants were randomized in the VIPES study to receive either 50 µg, 100 µg or 250 µg Viaskin Peanut or placebo and then received at least 1 dose of 250 µg Viaskin Peanut in the OLFUS-VIPES study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.0

Reporting groups

Reporting group title	Viaskin Peanut 250 µg

Reporting group description:

Participants applied 1 new Viaskin Peanut 250 µg patch on intact skin for 24 hours daily for up to 24 months. Each patch contained 250 µg peanut protein extract for epicutaneous administration.

Serious adverse events	Viaskin Peanut 250 µg		
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 171 (5.85%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	1 / 171 (0.58%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	1 / 171 (0.58%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	1 / 171 (0.58%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ulna fracture			

subjects affected / exposed	1 / 171 (0.58%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	2 / 171 (1.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Food allergy			
subjects affected / exposed	1 / 171 (0.58%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	1 / 171 (0.58%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 171 (0.58%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 171 (0.58%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 171 (0.58%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral pericarditis			

subjects affected / exposed	1 / 171 (0.58%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Viaskin Peanut 250 µg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	159 / 171 (92.98%)		
Nervous system disorders			
Headache			
subjects affected / exposed	37 / 171 (21.64%)		
occurrences (all)	124		
General disorders and administration site conditions			
Application site dermatitis			
subjects affected / exposed	13 / 171 (7.60%)		
occurrences (all)	17		
Application site eczema			
subjects affected / exposed	21 / 171 (12.28%)		
occurrences (all)	27		
Application site erythema			
subjects affected / exposed	97 / 171 (56.73%)		
occurrences (all)	334		
Application site oedema			
subjects affected / exposed	10 / 171 (5.85%)		
occurrences (all)	18		
Application site papules			
subjects affected / exposed	16 / 171 (9.36%)		
occurrences (all)	17		
Application site pruritus			
subjects affected / exposed	90 / 171 (52.63%)		
occurrences (all)	311		
Application site rash			
subjects affected / exposed	18 / 171 (10.53%)		
occurrences (all)	32		

Application site swelling subjects affected / exposed occurrences (all) Application site urticaria subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	 48 / 171 (28.07%) 178 10 / 171 (5.85%) 32 24 / 171 (14.04%) 39		
Immune system disorders Food allergy subjects affected / exposed occurrences (all) Hypersensitivity subjects affected / exposed occurrences (all) Seasonal allergy subjects affected / exposed occurrences (all)	 18 / 171 (10.53%) 41 10 / 171 (5.85%) 14 13 / 171 (7.60%) 24		
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	 9 / 171 (5.26%) 10		
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) Abdominal pain upper subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting	 16 / 171 (9.36%) 24 14 / 171 (8.19%) 24 10 / 171 (5.85%) 13 13 / 171 (7.60%) 17		

subjects affected / exposed	20 / 171 (11.70%)		
occurrences (all)	22		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	15 / 171 (8.77%)		
occurrences (all)	27		
Cough			
subjects affected / exposed	35 / 171 (20.47%)		
occurrences (all)	57		
Nasal congestion			
subjects affected / exposed	21 / 171 (12.28%)		
occurrences (all)	41		
Oropharyngeal pain			
subjects affected / exposed	23 / 171 (13.45%)		
occurrences (all)	30		
Rhinitis allergic			
subjects affected / exposed	26 / 171 (15.20%)		
occurrences (all)	34		
Rhinorrhoea			
subjects affected / exposed	10 / 171 (5.85%)		
occurrences (all)	18		
Throat irritation			
subjects affected / exposed	12 / 171 (7.02%)		
occurrences (all)	16		
Wheezing			
subjects affected / exposed	12 / 171 (7.02%)		
occurrences (all)	34		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	10 / 171 (5.85%)		
occurrences (all)	14		
Rash			
subjects affected / exposed	9 / 171 (5.26%)		
occurrences (all)	11		
Urticaria			

subjects affected / exposed	23 / 171 (13.45%)		
occurrences (all)	29		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	10 / 171 (5.85%)		
occurrences (all)	12		
Infections and infestations			
Influenza			
subjects affected / exposed	12 / 171 (7.02%)		
occurrences (all)	12		
Nasopharyngitis			
subjects affected / exposed	39 / 171 (22.81%)		
occurrences (all)	71		
Pharyngitis streptococcal			
subjects affected / exposed	9 / 171 (5.26%)		
occurrences (all)	10		
Rhinitis			
subjects affected / exposed	10 / 171 (5.85%)		
occurrences (all)	19		
Sinusitis			
subjects affected / exposed	9 / 171 (5.26%)		
occurrences (all)	10		
Upper respiratory tract infection			
subjects affected / exposed	28 / 171 (16.37%)		
occurrences (all)	63		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 December 2013	Protocol was amended to treat all participants in the OLFUS-VIPES study at the highest safe dose administered during the VIPES study (i.e., 250 µg Viaskin Peanut), which may maximize their chances of clinical response.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported