Clinical trial results:
A double-blind, placebo-controlled, randomized trial to study the Viaskin® Peanut's Efficacy and Safety for treating peanut allergy in children and adults.

Summary

EudraCT number	2011-002550-32
Trial protocol	NL PL DK
Global end of trial date	31 July 2014

Results information

Result version number	v1 (current)
This version publication date	03 December 2021
First version publication date	03 December 2021

Trial information

Trial identification

Sponsor protocol code	V712-202 (VIPES)

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01675882
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	31 July 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 July 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the efficacy of several doses of Viaskin® Peanut (DBV712) to significantly desensitize peanut-allergic participants to peanut after 12 months of epicutaneous immunotherapy (EPIT).

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: -

Evidence for comparator: -

Actual start date of recruitment	31 July 2012
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: 71
Country: Number of subjects enrolled	France: 37
Country: Number of subjects enrolled	Netherlands: 9
Country: Number of subjects enrolled	Poland: 1
Country: Number of subjects enrolled	United States: 103
Worldwide total number of subjects	221
EEA total number of subjects	47

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	0

months)	
Children (2-11 years)	113
Adolescents (12-17 years)	73
Adults (18-64 years)	35
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study was conducted in participants aged 6 to 55 years old with peanut allergy at 22 study centers in 5 countries. Study had a 4-week screening period, 52-week treatment period and 2-week follow-up period. All participants who completed the VIPES study up to Visit 11 (inclusive) were eligible for participation in the follow-up study (OLFUS-VIPES).

Pre-assignment

Screening details:

A total of 221 participants were randomized in 1:1:1:1 ratio into 4 treatment groups. Each participant underwent dose-escalating double-blind, placebo-controlled food challenge (DBPCFC) at screening and Month 12. At screening, a dose-escalating DBPCFC confirmed peanut allergy to an eliciting dose <=300 milligrams (mg) peanut protein.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Viaskin Peanut 50 µg

Arm description:

Participants applied 1 new Viaskin Peanut 50 micrograms (µg) patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.

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 12 months. The drug substance is an unmodified, lyophilized peanut extract produced from the extraction and freeze drying of defatted peanut flour.

Arm title	Viaskin Peanut 100 µg

Arm description:

Participants applied 1 new Viaskin Peanut 100 µg patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.

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 12 months. The drug substance is an unmodified, lyophilized peanut extract produced from the extraction and freeze drying of defatted peanut flour.

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 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.

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 12 months. The drug substance is an unmodified, lyophilized peanut extract produced from the extraction and freeze drying of defatted peanut flour.

Arm title	Placebo

Arm description:

Participants applied 1 new placebo patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous patch
Routes of administration	Epicutaneous use

Dosage and administration details:

Placebo cutaneous patch applied on intact skin for 24 hours daily for 12 months.

Number of subjects in period 1	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg
Started	53	56	56
Completed	51	49	53
Not completed	2	7	3
Adverse event, non-fatal	-	2	1
Non-compliance	-	-	-
Lost to follow-up	-	1	-
Participant unwilling to continue	2	4	2

Number of subjects in period 1	Placebo
Started	56
Completed	54
Not completed	2
Adverse event, non-fatal	-
Non-compliance	1
Lost to follow-up	-
Participant unwilling to continue	1

Baseline characteristics

Reporting groups	
Reporting group title	Viaskin Peanut 50 µg
Reporting group description:	
Participants applied 1 new Viaskin Peanut 50 micrograms (µg) patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.	
Reporting group title	Viaskin Peanut 100 µg
Reporting group description:	
Participants applied 1 new Viaskin Peanut 100 µg patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.	
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 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.	
Reporting group title	Placebo
Reporting group description:	
Participants applied 1 new placebo patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.	

Reporting group values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg
Number of subjects	53	56	56
Age categorical Units: Subjects			
Children (6-11 years)	28	26	28
Adolescents (12-17 years)	18	19	18
Adults (18-55 years)	7	11	10
Age continuous Units: years			
arithmetic mean	12.3	13.9	13.6
standard deviation	± 6.72	± 6.66	± 7.48
Gender categorical Units: Subjects			
Female	22	23	18
Male	31	33	38
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	39	33	32
Black	1	2	0
Hispanic	1	0	0
Asian	3	9	10
Other	2	4	4
Not applicable	7	8	10

Reporting group values	Placebo	Total	
Number of subjects	56	221	
Age categorical Units: Subjects			
Children (6-11 years)	31	113	
Adolescents (12-17 years)	18	73	
Adults (18-55 years)	7	35	
Age continuous Units: years			
arithmetic mean	12.5		
standard deviation	± 6.84	-	
Gender categorical Units: Subjects			
Female	20	83	
Male	36	138	
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	31	135	
Black	2	5	
Hispanic	2	3	
Asian	5	27	
Other	4	14	
Not applicable	12	37	

End points

End points reporting groups

Reporting group title	Viaskin Peanut 50 µg
Reporting group description:	
Participants applied 1 new Viaskin Peanut 50 micrograms (µg) patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.	
Reporting group title	Viaskin Peanut 100 µg
Reporting group description:	
Participants applied 1 new Viaskin Peanut 100 µg patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.	
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 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.	
Reporting group title	Placebo
Reporting group description:	
Participants applied 1 new placebo patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.	

Primary: Percentage of Treatment Responders at Month 12; Analyzed in Overall Population

End point title	Percentage of Treatment Responders at Month 12; Analyzed in Overall Population
End point description:	
A treatment responder was defined as a participant with a peanut protein eliciting dose equal to or greater than 1,000 mg peanut proteins based on the results of the DBPCFC after 12 months of treatment or a participant with a >=10-fold increase of the eliciting dose at 12 months, compared to the initial eliciting dose. For participants with missing treatment response at Month 12, last observation carried forward (LOCF) imputation was used (i.e., participants were considered as non-responders). The full analysis set included all participants who were randomized.	
End point type	Primary
End point timeframe:	
At Month 12	

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	56	56	56
Units: percentage of participants				
number (confidence interval 95%)	45.3 (31.56 to 59.55)	41.1 (28.10 to 55.02)	50.0 (36.34 to 63.66)	25.0 (14.39 to 38.37)

Statistical analyses

Statistical analysis title	Viaskin peanut 50 µg versus Placebo

Statistical analysis description:

The three pair-wise comparisons of viaskin peanut versus placebo were analyzed using the Bonferroni stepwise procedure, keeping the overall false-positive (alpha) risk below 5%. The comparison of viaskin peanut 250 µg versus placebo is statistically significant at p<0.05. The subsequent comparison of viaskin peanut 100 µg versus placebo is not statistically significant at p<0.05. Thus, no conclusion can be made on the comparison of viaskin peanut 50 µg vs placebo.

Comparison groups	Viaskin Peanut 50 µg v Placebo
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0292
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	1.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.05
upper limit	3.11

Statistical analysis title	Viaskin peanut 100 µg versus Placebo

Statistical analysis description:

The three pair-wise comparisons of viaskin peanut versus placebo were analyzed using the Bonferroni stepwise procedure, keeping the overall false-positive (alpha) risk below 5%. The comparison of viaskin peanut 250 µg versus placebo is statistically significant at p<0.05. The subsequent comparison of viaskin peanut 100 µg versus placebo is not statistically significant at p<0.05.

Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1074
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	2.85

Statistical analysis title	Viaskin peanut 250 µg versus Placebo

Statistical analysis description:

The three pair-wise comparisons of viaskin peanut versus placebo were analyzed using the Bonferroni stepwise procedure, keeping the overall false-positive (alpha) risk below 5%. The comparison of viaskin peanut 250 µg versus placebo is statistically significant at p<0.05.

Comparison groups	Viaskin Peanut 250 µg v Placebo

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0108
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.18
upper limit	3.38

Secondary: Percentage of Treatment Responders at Month 12; Analyzed in Children (6-11 Years of Age)

End point title	Percentage of Treatment Responders at Month 12; Analyzed in Children (6-11 Years of Age)

End point description:

A treatment responder was defined as a participant with a peanut protein eliciting dose equal to or greater than 1,000 mg peanut proteins based on the results of the DBPCFC after 12 months of treatment or a participant with a >=10-fold increase of the eliciting dose at 12 months, compared to the initial eliciting dose. For participants with missing treatment response at Month 12, LOCF imputation was used (i.e., participants were considered as non-responders). The full analysis set included all participants who were randomized. Only participants in the range of 6-11 years of age are reported.

End point type	Secondary

End point timeframe:

At Month 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	26	28	31
Units: percentage of participants				
number (confidence interval 95%)	57.1 (37.18 to 75.54)	46.2 (26.59 to 66.63)	53.6 (33.87 to 72.49)	19.4 (7.45 to 37.47)

Statistical analyses

Statistical analysis title	Viaskin peanut 50 µg versus Placebo
Comparison groups	Viaskin Peanut 50 µg v Placebo

Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0035
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	2.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.34
upper limit	6.49

Statistical analysis title	Viaskin peanut 100 µg versus Placebo
Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0453
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	2.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.04
upper limit	5.47

Statistical analysis title	Viaskin peanut 250 µg versus Placebo
Comparison groups	Viaskin Peanut 250 µg v Placebo
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0076
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	2.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	6.14

Secondary: Percentage of Treatment Responders at Month 12; Analyzed in

Adolescents (12-17 Years of Age)

End point title	Percentage of Treatment Responders at Month 12; Analyzed in Adolescents (12-17 Years of Age)

End point description:

A treatment responder was defined as a participant with a peanut protein eliciting dose equal to or greater than 1,000 mg peanut proteins based on the results of the DBPCFC after 12 months of treatment or a participant with a >=10-fold increase of the eliciting dose at 12 months, compared to the initial eliciting dose. For participants with missing treatment response at Month 12, LOCF imputation was used (i.e., participants were considered as non-responders). The full analysis set included all participants who were randomized. Only participants in the range of 12-17 years of age are reported.

End point type	Secondary

End point timeframe:

At Month 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	18	18
Units: percentage of participants				
number (confidence interval 95%)	33.3 (13.34 to 59.01)	10.5 (1.30 to 33.14)	38.9 (17.30 to 64.25)	22.2 (6.41 to 47.64)

Statistical analyses

Statistical analysis title	Viaskin peanut 50 µg versus Placebo
Comparison groups	Viaskin Peanut 50 µg v Placebo
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7112
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	4.43

Statistical analysis title	Viaskin peanut 100 µg versus Placebo
Comparison groups	Viaskin Peanut 100 µg v Placebo

Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4048
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	2.28

Statistical analysis title	Viaskin peanut 250 µg versus Placebo
Comparison groups	Viaskin Peanut 250 µg v Placebo
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4705
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	1.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	4.95

Secondary: Percentage of Treatment Responders at Month 12; Analyzed in Adults (18-55 Years of Age)

End point title	Percentage of Treatment Responders at Month 12; Analyzed in Adults (18-55 Years of Age)

End point description:

A treatment responder was defined as a participant with a peanut protein eliciting dose equal to or greater than 1,000 mg peanut proteins based on the results of the DBPCFC after 12 months of treatment or a participant with a >=10-fold increase of the eliciting dose at 12 months, compared to the initial eliciting dose. For participants with missing treatment response at Month 12, LOCF imputation was used (i.e., participants were considered as non-responders). The full analysis set included all participants who were randomized. Only participants in the range of 18-55 years of age are reported.

End point type	Secondary

End point timeframe:

At Month 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	11	10	7
Units: percentage of participants				
number (confidence interval 95%)	28.6 (3.67 to 70.96)	81.8 (48.22 to 97.72)	60.0 (26.24 to 87.84)	57.1 (18.41 to 90.10)

Statistical analyses

Statistical analysis title	Viaskin peanut 50 µg versus Placebo
Comparison groups	Viaskin Peanut 50 µg v Placebo
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5921
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.13
upper limit	1.9

Statistical analysis title	Viaskin peanut 100 µg versus Placebo
Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	18
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.326
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	2.88

Statistical analysis title	Viaskin peanut 250 µg versus Placebo
Comparison groups	Viaskin Peanut 250 µg v Placebo

Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Fisher exact
Parameter estimate	Relative risk
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	2.38

Secondary: Mean Eliciting Doses of Peanut Proteins at Month 12; Analyzed in Overall Population

End point title	Mean Eliciting Doses of Peanut Proteins at Month 12; Analyzed in Overall Population

End point description:

The peanut protein eliciting dose was defined as the first dose of peanut protein administered to the participant during the DBPCFC procedure which caused an objective allergic reaction. This was capped to 300 mg at the screening DBPCFC and to 2000 mg at the Month 12 DBPCFC. For participants with missing treatment response at Month 12, LOCF imputation was used (i.e., participants were considered as non-responders). The full analysis set included all participants who were randomized.

End point type	Secondary

End point timeframe:

At Month 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	56	56	56
Units: mg				
arithmetic mean (standard deviation)	453.8 (± 608.16)	539.7 (± 659.31)	621.4 (± 715.03)	283.7 (± 482.04)

Statistical analyses

Statistical analysis title	Viaskin peanut 50 µg versus Placebo

Statistical analysis description:

The least squares (LS) mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 50 µg v Placebo

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0607 [1]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	70.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.41
upper limit	193.69

Notes:

[1] - P-value was based on type III sum of squares from analysis of covariance (ANCOVA) model on log transformed values for peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 100 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.015 [2]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	97.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.45
upper limit	237.82

Notes:

[2] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 250 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 250 µg v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [3]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	242.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	100.03
upper limit	482.65

Notes:

[3] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Secondary: Mean Eliciting Doses of Peanut Proteins at Month 12; Analyzed in Children (6-11 Years of Age)

End point title	Mean Eliciting Doses of Peanut Proteins at Month 12; Analyzed in Children (6-11 Years of Age)

End point description:

The peanut protein eliciting dose was defined as the first dose of peanut protein administered to the participant during the DBPCFC procedure which caused an objective allergic reaction. This was capped to 300 mg at screening DBPCFC and to 2000 mg at the Month 12 DBPCFC. For participants with missing treatment response at Month 12, LOCF imputation was used (i.e., participants were considered as non-responders). The full analysis set included all participants who were randomized. Only participants in the range of 6-11 years of age are reported.

End point type	Secondary

End point timeframe:

At Month 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	26	28	31
Units: mg				
arithmetic mean (standard deviation)	397.1 (± 510.13)	441.2 (± 511.26)	652.5 (± 766.93)	160.5 (± 244.00)

Statistical analyses

Statistical analysis title	Viaskin peanut 50 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 50 µg v Placebo
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0372 [4]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	73.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.96
upper limit	225.85

Notes:

[4] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 100 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0143 [5]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	96.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.92
upper limit	278.11

Notes:

[5] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 250 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 250 µg v Placebo
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [6]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	260.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	89.83
upper limit	625.95

Notes:

[6] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Secondary: Mean Eliciting Doses of Peanut Proteins at Month 12; Analyzed in

Adolescents (12-17 Years of Age)

End point title	Mean Eliciting Doses of Peanut Proteins at Month 12; Analyzed in Adolescents (12-17 Years of Age)

End point description:

The peanut protein eliciting dose was defined as the first dose of peanut protein administered to the participant during the DBPCFC procedure which caused an objective allergic reaction. This was capped to 300 mg at screening DBPCFC and to 2000 mg at the Month 12 DBPCFC. For participants with missing treatment response at Month 12, LOCF imputation was used (i.e., participants were considered as non-responders). The full analysis set included all participants who were randomized. Only participants in the range of 12-17 years of age are reported.

End point type	Secondary

End point timeframe:

At Month 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	18	18
Units: mg				
arithmetic mean (standard deviation)	501.7 (± 726.14)	281.6 (± 472.47)	573.9 (± 716.01)	331.8 (± 511.62)

Statistical analyses

Statistical analysis title	Viaskin peanut 50 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 50 µg v Placebo
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6596 [7]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	26.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-59.58
upper limit	236

Notes:

[7] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 100 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8702 [8]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	8.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.9
upper limit	189.96

Notes:

[8] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 250 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 250 µg v Placebo
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.063 [9]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	158.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.5
upper limit	562.31

Notes:

[9] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Secondary: Mean Eliciting Doses of Peanut Proteins at Month 12; Analyzed in Adults (18-55 Years of Age)

End point title	Mean Eliciting Doses of Peanut Proteins at Month 12; Analyzed in Adults (18-55 Years of Age)

End point description:

The peanut protein eliciting dose was defined as the first dose of peanut protein administered to the participant during the DBPCFC procedure which caused an objective allergic reaction. This was capped to 300 mg at screening DBPCFC and to 2000 mg at the Month 12 DBPCFC. For participants with missing treatment response at Month 12, LOCF imputation was used (i.e., participants were considered as non-responders). The full analysis set included all participants who were randomized. Only participants in the range of 18-55 years of age are reported.

End point type	Secondary

End point timeframe:

At Month 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	11	10	7
Units: mg				
arithmetic mean (standard deviation)	557.1 (± 711.47)	1218.5 (± 822.74)	620.0 (± 619.68)	705.7 (± 893.01)

Statistical analyses

Statistical analysis title	Viaskin peanut 50 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 50 µg v Placebo
Number of subjects included in analysis	14
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6776 [10]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	-80.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-237.22
upper limit	782.24

Notes:

[10] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 100 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	18
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5068 [11]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	158.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-166.1
upper limit	1478.83

Notes:

[11] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 250 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean peanut protein eliciting dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 250 µg v Placebo
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7972 [12]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	53.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-193.9
upper limit	1085.38

Notes:

[12] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the peanut protein eliciting dose at Month 12, including treatment group, baseline eliciting dose, age-strata and country as covariates.

Secondary: Mean Cumulative Reactive Dose of Peanut Proteins at Month 12; Analyzed in Overall Population

End point title	Mean Cumulative Reactive Dose of Peanut Proteins at Month 12; Analyzed in Overall Population

End point description:

The peanut protein cumulative reactive dose was defined as the sum of all peanut protein doses up to and including the eliciting dose ingested during the peanut challenge. For participants with missing treatment response at Month 12, LOCF imputation was used (i.e., participants were considered as non-responders). The full analysis set included all participants who were randomized.

End point type	Secondary

End point timeframe:

At Month 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	56	56	56
Units: mg				
arithmetic mean (standard deviation)	730.8 (± 1020.53)	863.5 (± 1120.43)	1010.6 (± 1223.85)	451.4 (± 807.13)

Statistical analyses

Statistical analysis title	Viaskin peanut 50 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group was the estimated mean peanut protein cumulative reactive dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 50 µg v Placebo
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0444 [13]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	120
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.3
upper limit	321.8

Notes:

[13] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for cumulative reactive dose at Month 12, including treatment group, baseline cumulative reactive dose, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 100 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group was the estimated mean peanut protein cumulative reactive dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0175 [14]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	147.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.67
upper limit	365.51

Notes:

[14] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the cumulative reactive dose at Month 12, including treatment group, baseline cumulative reactive dose, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 250 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group was the estimated mean peanut protein cumulative reactive dose for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 250 µg v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [15]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	386
Confidence interval	
level	95 %
sides	2-sided
lower limit	159.67
upper limit	771.16

Notes:

[15] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the cumulative reactive dose at Month 12, including treatment group, baseline cumulative reactive dose, age-strata and country as covariates.

Secondary: Change From Baseline in Severity of Symptoms Based on the Oral Food Challenge (OFC) Symptom Score Sheet at Month 12; Analyzed in Overall Population

End point title	Change From Baseline in Severity of Symptoms Based on the Oral Food Challenge (OFC) Symptom Score Sheet at Month 12; Analyzed in Overall Population

End point description:

The symptoms of erythematous rash, pruritus, urticaria/angioedema, rash, sneezing/itching, nasal congestion, rhinorrhea, laryngeal symptoms (example, throat clearing, occasional cough, hoarseness, frequent dry cough, inspiratory stridor), wheezing, subjective complaints, objective complaints and cardiovascular symptoms (example, color change, weakness, dizziness, mental status change, tachycardia, decreased blood pressure, etc) were observed. The OFC score ranges from 0 to 3 for each symptom (0=Absent, 1=mild, 2=moderate or 3=severe). The total symptom score for each participant was calculated. Higher scores indicate worst outcome. For participants with missing treatment response at Month 12, LOCF imputation was used (i.e., participants were considered as non-responders). The full analysis set included all participants who were randomized.

End point type	Secondary

End point timeframe:

Baseline and Month 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	56	56	56
Units: units on a scale				
arithmetic mean (standard deviation)	-1.9 (± 4.79)	-0.9 (± 4.21)	0.2 (± 4.65)	-1.4 (± 4.35)

Statistical analyses

Statistical analysis title	Viaskin peanut 50 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean OFC score for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 50 µg v Placebo
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.251 [16]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.55
upper limit	0.52

Notes:

[16] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the OFC symptom scores at Month 12, including treatment group, Baseline OFC symptom scores, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 100 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean OFC score for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.682 [17]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.24
upper limit	1.05

Notes:

[17] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the OFC symptom scores at Month 12, including treatment group, Baseline OFC symptom scores, age-strata and country as covariates.

Statistical analysis title	Viaskin peanut 250 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group is the estimated mean OFC score for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 250 µg v Placebo

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2117 [18]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	2.47

Notes:

[18] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the OFC symptom scores at Month 12, including treatment group, Baseline OFC symptom scores, age-strata and country as covariates.

Secondary: Number of Participants With an Average Wheal Diameter Ratio ≤0.5 and >0.5 at Each Skin Prick Test Dilution at Months 3, 6 and 12; Analyzed in Overall Population

End point title	Number of Participants With an Average Wheal Diameter Ratio ≤0.5 and >0.5 at Each Skin Prick Test Dilution at Months 3, 6 and 12; Analyzed in Overall Population

End point description:

The mean wheal diameter of skin prick test (sum of the orthogonal diameters divided by 2) at each time point is calculated for the 5 skin prick tests at baseline and at each time point, i.e., Months 3, 6 and 12: undiluted, diluted 1:10 millimeter (mm), diluted 1:100 (mm), diluted 1:1,000 (mm), diluted 1:10,000 (mm). The ratio of the mean wheal diameter at each time point for a specific dilution versus the baseline value for that specific dilution was calculated and classified as <=0.5 or >0.5, allowing to assess the number of participants of those mean wheal diameters that have been at least halved from the baseline value. The full analysis set included all participants who were randomized.

End point type	Secondary

End point timeframe:

Baseline and Months 3, 6 and 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	56	56	56
Units: participants				
Month 3: undiluted; <= 0.5	7	9	5	4
Month 3: undiluted; > 0.5	46	47	51	52
Month 3: diluted (1:10); <= 0.5	10	5	8	4
Month 3: diluted (1:10); > 0.5	43	51	48	52
Month 3: diluted (1:100); <= 0.5	13	12	15	6
Month 3: diluted (1:100); > 0.5	39	43	41	50
Month 3: diluted (1:1000); <= 0.5	13	15	24	12
Month 3: diluted (1:1000); > 0.5	35	35	28	40
Month 3: diluted (1:10000); <= 0.5	21	17	22	15
Month 3: diluted (1:10000); > 0.5	21	18	20	24
Month 6: undiluted; <= 0.5	14	7	7	2
Month 6: undiluted; > 0.5	39	49	49	54
Month 6: diluted (1:10); <= 0.5	9	10	9	5

Month 6: diluted (1:10); > 0.5	44	46	47	51
Month 6: diluted (1:100); <= 0.5	15	16	14	4
Month 6: diluted (1:100); > 0.5	37	39	42	52
Month 6: diluted (1:1000); <= 0.5	15	11	23	11
Month 6: diluted (1:1000); > 0.5	33	39	29	41
Month 6: diluted (1:10000); <= 0.5	21	15	22	14
Month 6: diluted (1:10000); > 0.5	21	20	20	25
Month 12: undiluted; <= 0.5	8	4	7	2
Month 12: undiluted; > 0.5	45	52	49	54
Month 12: diluted (1:10); <= 0.5	10	6	15	3
Month 12: diluted (1:10); > 0.5	43	50	41	53
Month 12: diluted (1:100); <= 0.5	11	14	13	7
Month 12: diluted (1:100); > 0.5	41	41	43	49
Month 12: diluted (1:1000); <= 0.5	14	9	18	8
Month 12: diluted (1:1000); > 0.5	34	41	34	44
Month 12: diluted (1:10000); <= 0.5	22	14	24	13
Month 12: diluted (1:10000); > 0.5	20	21	18	26

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Peanut-Specific Immunoglobulin E (IgE) at Months 3, 6 and 12; Analyzed in Overall Population

End point title	Change From Baseline in Peanut-Specific Immunoglobulin E (IgE) at Months 3, 6 and 12; Analyzed in Overall Population

End point description:

Venous blood samples were taken for assessment of the peanut-specific IgE at 3, 6 and 12 months. Results are presented using multiple imputation to replace missing values. The full analysis set included all participants who were randomized.

End point type	Secondary

End point timeframe:

Baseline and Months 3, 6 and 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	56	56	56
Units: kilo units per liter (kU/L)				
median (full range (min-max))				
Month 3	32.3 (-375 to 676)	29.9 (-118 to 1243)	50.7 (-91 to 794)	2.8 (-117 to 445)
Month 6	8.8 (-158 to 348)	22.0 (-65 to 1464)	29.5 (-93 to 747)	-1.1 (-363 to 79)
Month 12	-0.2 (-211 to 305)	4.9 (-146 to 245)	5.2 (-382 to 598)	-1.4 (-327 to 93)

Statistical analyses

Statistical analysis title	Month 12: Viaskin peanut 50 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group was the estimated mean for a participant in that treatment group with the mean value for all Baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 50 µg v Placebo
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0337 [19]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	17.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.17
upper limit	38.82

Notes:

[19] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the immunological marker at Month 12, including treatment group, Baseline marker, age-strata and country as covariates.

Statistical analysis title	Month 12: Viaskin peanut 100 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group was the estimated mean for a participant in that treatment group with the mean value for all Baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [20]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	26.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.38
upper limit	49.45

Notes:

[20] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the immunological marker at Month 12, including treatment group, Baseline marker, age-strata and country as covariates.

Statistical analysis title	Month 12: Viaskin peanut 250 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group was the estimated mean for a participant in that treatment group with the mean value for all Baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 250 µg v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012 [21]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	20
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.85
upper limit	40.91

Notes:

[21] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the immunological marker at Month 12, including treatment group, Baseline marker, age-strata and country as covariates.

Secondary: Change From Baseline in Peanut-Specific IgE at Months 3, 6 and 12; Analyzed in Children (6-11 Years of Age)

End point title	Change From Baseline in Peanut-Specific IgE at Months 3, 6 and 12; Analyzed in Children (6-11 Years of Age)

End point description:

Venous blood samples were taken for assessment of the peanut-specific IgE at 3, 6 and 12 months. Results are presented using multiple imputation to replace missing values. The full analysis set included all participants who were randomized. Only participants in the range of 6-11 years of age are reported.

End point type	Secondary

End point timeframe:

Baseline and Months 3, 6 and 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	26	28	31
Units: kU/L				
median (full range (min-max))				
Month 3	63.6 (-375 to 676)	63.1 (-27 to 1243)	50.7 (-16 to 794)	4.1 (-117 to 445)
Month 6	10.6 (-55 to 348)	48.7 (-9 to 1464)	21.2 (-70 to 291)	-1.8 (-363 to 79)
Month 12	-3.1 (-211 to 305)	3.5 (-146 to 150)	1.0 (-136 to 485)	-12.0 (-327 to 59)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Peanut-Specific IgE at Months 3, 6 and 12; Analyzed in Adolescents (12-17 Years of Age)

End point title	Change From Baseline in Peanut-Specific IgE at Months 3, 6 and 12; Analyzed in Adolescents (12-17 Years of Age)

End point description:

Venous blood samples were taken for assessment of the peanut-specific IgE at 3, 6 and 12 months. Results are presented using multiple imputation to replace missing values. The full analysis set included all participants who were randomized. Only participants in the range of 12-17 years of age are reported.

End point type	Secondary

End point timeframe:

Baseline and Months 3, 6 and 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	18	18
Units: kU/L				
median (full range (min-max))				
Month 3	11.5 (-99 to 248)	62.0 (-118 to 303)	135.5 (0 to 552)	4.8 (-17 to 232)
Month 6	6.0 (-158 to 170)	24.2 (-65 to 239)	90.0 (-10 to 440)	0.0 (-43 to 75)
Month 12	5.2 (-49 to 199)	24.9 (-98 to 163)	39.4 (-382 to 434)	1.0 (-31 to 93)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Peanut-Specific IgE at Months 3, 6 and 12; Analyzed in Adults (18-55 Years of Age)

End point title	Change From Baseline in Peanut-Specific IgE at Months 3, 6 and 12; Analyzed in Adults (18-55 Years of Age)

End point description:

Venous blood samples were taken for assessment of the peanut-specific IgE at 3, 6 and 12 months. Results are presented using multiple imputation to replace missing values. The full analysis set included all participants who were randomized. Only participants in the range of 18-55 years of age are reported.

End point type	Secondary

End point timeframe:

Baseline and Months 3, 6 and 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	11	10	7
Units: kU/L				
median (full range (min-max))				
Month 3	65.3 (-76 to 183)	12.3 (-1 to 169)	3.1 (-91 to 471)	0.1 (-34 to 13)
Month 6	34.4 (-0 to 214)	3.6 (-4 to 377)	1.6 (-93 to 747)	-0.2 (-42 to 40)
Month 12	22.3 (-25 to 163)	0.3 (-9 to 245)	-2.0 (-148 to 598)	0.9 (-107 to 39)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Peanut-Specific Immunoglobulin G Subtype 4 (IgG4) at Months 3, 6 and 12; Analyzed in Overall Population

End point title	Change From Baseline in Peanut-Specific Immunoglobulin G Subtype 4 (IgG4) at Months 3, 6 and 12; Analyzed in Overall Population

End point description:

Venous blood samples were taken for assessment of the peanut-specific IgG4 at 3, 6 and 12 months. Results are presented using multiple imputation to replace missing values. The full analysis set included all participants who were randomized.

End point type	Secondary

End point timeframe:

Baseline and Months 3, 6 and 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	56	56	56
Units: mg per liter (mg/L)				
median (full range (min-max))				
Month 3	0.4 (-1 to 6)	0.4 (-18 to 4)	0.8 (-1 to 14)	0.0 (-3 to 2)
Month 6	0.8 (-2 to 6)	0.8 (-19 to 8)	1.4 (-6 to 19)	0.0 (-2 to 3)
Month 12	1.0 (-2 to 12)	0.9 (-9 to 10)	1.6 (-3 to 17)	0.0 (-3 to 1)

Statistical analyses

Statistical analysis title	Month 12: Viaskin peanut 50 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group was the estimated mean for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 50 µg v Placebo

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [22]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.9

Notes:

[22] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the immunological marker at Month 12, including treatment group, Baseline marker, age-strata and country as covariates.

Statistical analysis title	Month 12: Viaskin peanut 100 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group was the estimated mean for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 100 µg v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [23]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	2.01

Notes:

[23] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the immunological marker at Month 12, including treatment group, Baseline marker, age-strata and country as covariates.

Statistical analysis title	Month 12: Viaskin peanut 250 µg versus Placebo

Statistical analysis description:

The LS mean for any given treatment group was the estimated mean for a participant in that treatment group with the mean value for all baseline covariates in the analysis set.

Comparison groups	Viaskin Peanut 250 µg v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [24]
Method	ANCOVA
Parameter estimate	Difference in LS mean
Point estimate	2.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.39
upper limit	3.11

Notes:

[24] - P-value was based on type III sum of squares from an ANCOVA model on log transformed values for the immunological marker at Month 12, including treatment group, Baseline marker, age-strata and country as covariates.

Secondary: Change From Baseline in Peanut-Specific IgG4 at Months 3, 6 and 12; Analyzed in Children (6-11 Years of Age)

End point title	Change From Baseline in Peanut-Specific IgG4 at Months 3, 6 and 12; Analyzed in Children (6-11 Years of Age)

End point description:

Venous blood samples were taken for assessment of the peanut-specific IgG4 at 3, 6 and 12 months. Results are presented using multiple imputation to replace missing values. The full analysis set included all participants who were randomized. Only participants in the range of 6-11 years of age are reported.

End point type	Secondary

End point timeframe:

Baseline and Months 3, 6 and 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	26	28	31
Units: mg/L				
median (full range (min-max))				
Month 3	0.6 (-1 to 6)	0.4 (-18 to 4)	1.7 (-1 to 14)	0.0 (-1 to 1)
Month 6	1.1 (-2 to 6)	1.1 (-19 to 8)	4.4 (0 to 19)	-0.1 (-1 to 2)
Month 12	2.0 (-2 to 12)	1.6 (-9 to 10)	6.3 (-1 to 17)	-0.0 (-2 to 1)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Peanut-Specific IgG4 at Months 3, 6 and 12; Analyzed in Adolescents (12-17 Years of Age)

End point title	Change From Baseline in Peanut-Specific IgG4 at Months 3, 6 and 12; Analyzed in Adolescents (12-17 Years of Age)

End point description:

Venous blood samples were taken for assessment of the peanut-specific IgG4 at 3, 6 and 12 months. Results are presented using multiple imputation to replace missing values. The full analysis set included all participants who were randomized. Only participants in the range of 12-17 years of age are reported.

End point type	Secondary

End point timeframe:

Baseline and Months 3, 6 and 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	19	18	18
Units: mg/L				
median (full range (min-max))				
Month 3	0.1 (-0 to 2)	0.6 (-0 to 2)	0.7 (-0 to 4)	0.1 (-3 to 2)
Month 6	0.3 (-1 to 3)	0.8 (0 to 2)	0.7 (-6 to 6)	0.1 (-2 to 3)
Month 12	0.4 (-1 to 8)	0.7 (-1 to 3)	0.9 (-3 to 9)	0.1 (-3 to 1)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Peanut-Specific IgG4 at Months 3, 6 and 12; Analyzed in Adults (18-55 Years of Age)

End point title	Change From Baseline in Peanut-Specific IgG4 at Months 3, 6 and 12; Analyzed in Adults (18-55 Years of Age)

End point description:

Venous blood samples were taken for assessment of the peanut-specific IgG4 at 3, 6 and 12 months. Results are presented using multiple imputation to replace missing values. The full analysis set included all participants who were randomized. Only participants in the range of 18-55 years of age are reported.

End point type	Secondary

End point timeframe:

Baseline and Months 3, 6 and 12

End point values	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	11	10	7
Units: mg/L				
median (full range (min-max))				
Month 3	0.2 (0 to 3)	0.5 (-0 to 2)	0.4 (-0 to 1)	0.1 (-0 to 0.4)
Month 6	0.5 (-0 to 3)	0.5 (-0 to 1)	0.6 (-0 to 6)	0.0 (-0 to 1)
Month 12	0.6 (0 to 3)	0.3 (0 to 1)	0.9 (-0 to 8)	0.1 (-0 to 0.4)

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 Day 1, throughout the 52-week treatment period and additional 2-week follow-up period. Overall time frame of up to 54 weeks.

Adverse event reporting additional description:

The safety analysis set included all participants who were randomized and received at least 1 dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.0

Reporting groups

Reporting group title	Viaskin Peanut 50 µg

Reporting group description:

Participants applied 1 new Viaskin Peanut (DBV712) 50 µg patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.

Reporting group title	Viaskin Peanut 100 µg

Reporting group description:

Participants applied 1 new Viaskin Peanut 100 µg patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.

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 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.

Reporting group title	Placebo

Reporting group description:

Participants applied 1 new placebo patch on intact skin for 24 hours daily for 12 months. To better ensure the safety of the patch at the initiation of treatment, the application duration was progressively increased to a duration of 24 hours daily over a 21-day graduated dosing period.

Serious adverse events	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 53 (3.77%)	1 / 56 (1.79%)	2 / 56 (3.57%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	2 / 53 (3.77%)	0 / 56 (0.00%)	1 / 56 (1.79%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			

subjects affected / exposed	0 / 53 (0.00%)	0 / 56 (0.00%)	1 / 56 (1.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food allergy			
subjects affected / exposed	0 / 53 (0.00%)	1 / 56 (1.79%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 56 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaphylactic shock			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Food allergy			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Viaskin Peanut 50 µg	Viaskin Peanut 100 µg	Viaskin Peanut 250 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 53 (100.00%)	55 / 56 (98.21%)	56 / 56 (100.00%)
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	1 / 53 (1.89%)	1 / 56 (1.79%)	0 / 56 (0.00%)
occurrences (all)	1	1	0
Ligament sprain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 56 (0.00%)	3 / 56 (5.36%)
occurrences (all)	0	0	4
Nervous system disorders			
Headache			
subjects affected / exposed	11 / 53 (20.75%)	8 / 56 (14.29%)	8 / 56 (14.29%)
occurrences (all)	17	16	14
General disorders and administration site conditions			
Application site dermatitis			
subjects affected / exposed	5 / 53 (9.43%)	6 / 56 (10.71%)	8 / 56 (14.29%)
occurrences (all)	5	6	9
Application site discolouration			
subjects affected / exposed	1 / 53 (1.89%)	2 / 56 (3.57%)	4 / 56 (7.14%)
occurrences (all)	1	2	4
Application site dryness			
subjects affected / exposed	0 / 53 (0.00%)	0 / 56 (0.00%)	3 / 56 (5.36%)
occurrences (all)	0	0	3
Application site eczema			
subjects affected / exposed	7 / 53 (13.21%)	8 / 56 (14.29%)	10 / 56 (17.86%)
occurrences (all)	9	12	17
Application site erythema			
subjects affected / exposed	39 / 53 (73.58%)	33 / 56 (58.93%)	32 / 56 (57.14%)
occurrences (all)	53	68	61
Application site irritation			
subjects affected / exposed	2 / 53 (3.77%)	1 / 56 (1.79%)	3 / 56 (5.36%)
occurrences (all)	2	1	3
Application site oedema			
subjects affected / exposed	1 / 53 (1.89%)	2 / 56 (3.57%)	3 / 56 (5.36%)
occurrences (all)	1	2	3
Application site pain			
subjects affected / exposed	0 / 53 (0.00%)	3 / 56 (5.36%)	0 / 56 (0.00%)
occurrences (all)	0	5	0
Application site papules			

subjects affected / exposed	6 / 53 (11.32%)	8 / 56 (14.29%)	9 / 56 (16.07%)
occurrences (all)	6	8	12
Application site pruritus			
subjects affected / exposed	18 / 53 (33.96%)	23 / 56 (41.07%)	23 / 56 (41.07%)
occurrences (all)	23	52	38
Application site rash			
subjects affected / exposed	7 / 53 (13.21%)	1 / 56 (1.79%)	1 / 56 (1.79%)
occurrences (all)	11	1	2
Application site reaction			
subjects affected / exposed	2 / 53 (3.77%)	2 / 56 (3.57%)	4 / 56 (7.14%)
occurrences (all)	2	4	6
Application site swelling			
subjects affected / exposed	5 / 53 (9.43%)	8 / 56 (14.29%)	12 / 56 (21.43%)
occurrences (all)	6	8	15
Application site urticaria			
subjects affected / exposed	2 / 53 (3.77%)	5 / 56 (8.93%)	5 / 56 (8.93%)
occurrences (all)	3	6	7
Pyrexia			
subjects affected / exposed	9 / 53 (16.98%)	7 / 56 (12.50%)	6 / 56 (10.71%)
occurrences (all)	15	8	7
Immune system disorders			
Food allergy			
subjects affected / exposed	8 / 53 (15.09%)	11 / 56 (19.64%)	7 / 56 (12.50%)
occurrences (all)	11	22	11
Hypersensitivity			
subjects affected / exposed	4 / 53 (7.55%)	3 / 56 (5.36%)	1 / 56 (1.79%)
occurrences (all)	5	3	1
Seasonal allergy			
subjects affected / exposed	5 / 53 (9.43%)	3 / 56 (5.36%)	6 / 56 (10.71%)
occurrences (all)	9	6	7
Eye disorders			
Eye swelling			
subjects affected / exposed	1 / 53 (1.89%)	2 / 56 (3.57%)	3 / 56 (5.36%)
occurrences (all)	1	3	3
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	2 / 53 (3.77%)	4 / 56 (7.14%)	3 / 56 (5.36%)
occurrences (all)	2	4	3
Abdominal pain upper			
subjects affected / exposed	5 / 53 (9.43%)	3 / 56 (5.36%)	2 / 56 (3.57%)
occurrences (all)	9	6	2
Diarrhoea			
subjects affected / exposed	2 / 53 (3.77%)	1 / 56 (1.79%)	3 / 56 (5.36%)
occurrences (all)	6	1	3
Nausea			
subjects affected / exposed	5 / 53 (9.43%)	2 / 56 (3.57%)	1 / 56 (1.79%)
occurrences (all)	5	2	1
Oral pruritus			
subjects affected / exposed	0 / 53 (0.00%)	1 / 56 (1.79%)	3 / 56 (5.36%)
occurrences (all)	0	1	3
Vomiting			
subjects affected / exposed	5 / 53 (9.43%)	3 / 56 (5.36%)	2 / 56 (3.57%)
occurrences (all)	8	3	2
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	4 / 53 (7.55%)	8 / 56 (14.29%)	4 / 56 (7.14%)
occurrences (all)	6	9	4
Cough			
subjects affected / exposed	6 / 53 (11.32%)	7 / 56 (12.50%)	5 / 56 (8.93%)
occurrences (all)	9	7	5
Nasal congestion			
subjects affected / exposed	6 / 53 (11.32%)	5 / 56 (8.93%)	7 / 56 (12.50%)
occurrences (all)	11	7	7
Oropharyngeal pain			
subjects affected / exposed	5 / 53 (9.43%)	4 / 56 (7.14%)	7 / 56 (12.50%)
occurrences (all)	7	4	7
Rhinitis allergic			
subjects affected / exposed	6 / 53 (11.32%)	9 / 56 (16.07%)	1 / 56 (1.79%)
occurrences (all)	6	14	1
Rhinorrhoea			

subjects affected / exposed	1 / 53 (1.89%)	2 / 56 (3.57%)	0 / 56 (0.00%)
occurrences (all)	4	2	0
Throat irritation			
subjects affected / exposed	3 / 53 (5.66%)	1 / 56 (1.79%)	0 / 56 (0.00%)
occurrences (all)	3	1	0
Wheezing			
subjects affected / exposed	4 / 53 (7.55%)	0 / 56 (0.00%)	3 / 56 (5.36%)
occurrences (all)	4	0	7
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	6 / 53 (11.32%)	3 / 56 (5.36%)	5 / 56 (8.93%)
occurrences (all)	6	3	7
Erythema			
subjects affected / exposed	3 / 53 (5.66%)	1 / 56 (1.79%)	2 / 56 (3.57%)
occurrences (all)	3	1	2
Pruritus			
subjects affected / exposed	4 / 53 (7.55%)	1 / 56 (1.79%)	5 / 56 (8.93%)
occurrences (all)	5	1	5
Urticaria			
subjects affected / exposed	8 / 53 (15.09%)	3 / 56 (5.36%)	8 / 56 (14.29%)
occurrences (all)	16	5	9
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 53 (0.00%)	2 / 56 (3.57%)	3 / 56 (5.36%)
occurrences (all)	0	2	3
Infections and infestations			
Ear infection			
subjects affected / exposed	3 / 53 (5.66%)	5 / 56 (8.93%)	1 / 56 (1.79%)
occurrences (all)	5	7	1
Gastroenteritis			
subjects affected / exposed	2 / 53 (3.77%)	3 / 56 (5.36%)	6 / 56 (10.71%)
occurrences (all)	3	4	6
Gastroenteritis viral			
subjects affected / exposed	6 / 53 (11.32%)	4 / 56 (7.14%)	4 / 56 (7.14%)
occurrences (all)	8	4	4
Influenza			

subjects affected / exposed	4 / 53 (7.55%)	3 / 56 (5.36%)	2 / 56 (3.57%)
occurrences (all)	4	3	2
Nasopharyngitis			
subjects affected / exposed	12 / 53 (22.64%)	9 / 56 (16.07%)	10 / 56 (17.86%)
occurrences (all)	13	17	15
Pharyngitis			
subjects affected / exposed	5 / 53 (9.43%)	1 / 56 (1.79%)	3 / 56 (5.36%)
occurrences (all)	8	1	3
Pharyngitis streptococcal			
subjects affected / exposed	3 / 53 (5.66%)	4 / 56 (7.14%)	2 / 56 (3.57%)
occurrences (all)	4	5	2
Rhinitis			
subjects affected / exposed	0 / 53 (0.00%)	3 / 56 (5.36%)	1 / 56 (1.79%)
occurrences (all)	0	5	1
Sinusitis			
subjects affected / exposed	3 / 53 (5.66%)	1 / 56 (1.79%)	3 / 56 (5.36%)
occurrences (all)	3	1	3
Upper respiratory tract infection			
subjects affected / exposed	14 / 53 (26.42%)	11 / 56 (19.64%)	12 / 56 (21.43%)
occurrences (all)	23	18	17
Urinary tract infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 56 (0.00%)	1 / 56 (1.79%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	1 / 53 (1.89%)	5 / 56 (8.93%)	1 / 56 (1.79%)
occurrences (all)	1	6	1
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 53 (3.77%)	2 / 56 (3.57%)	1 / 56 (1.79%)
occurrences (all)	5	3	2

Non-serious adverse events	Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	51 / 56 (91.07%)		
Injury, poisoning and procedural complications			
Contusion			

subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	3		
Ligament sprain			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	3		
Nervous system disorders			
Headache			
subjects affected / exposed	13 / 56 (23.21%)		
occurrences (all)	27		
General disorders and administration site conditions			
Application site dermatitis			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	4		
Application site discolouration			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Application site dryness			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Application site eczema			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Application site erythema			
subjects affected / exposed	14 / 56 (25.00%)		
occurrences (all)	21		
Application site irritation			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Application site oedema			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Application site pain			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Application site papules			

subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Application site pruritus			
subjects affected / exposed	7 / 56 (12.50%)		
occurrences (all)	15		
Application site rash			
subjects affected / exposed	6 / 56 (10.71%)		
occurrences (all)	6		
Application site reaction			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	6		
Application site swelling			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	5		
Application site urticaria			
subjects affected / exposed	2 / 56 (3.57%)		
occurrences (all)	2		
Pyrexia			
subjects affected / exposed	10 / 56 (17.86%)		
occurrences (all)	12		
Immune system disorders			
Food allergy			
subjects affected / exposed	10 / 56 (17.86%)		
occurrences (all)	14		
Hypersensitivity			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	2		
Seasonal allergy			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	5		
Eye disorders			
Eye swelling			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	7 / 56 (12.50%)		
occurrences (all)	8		
Abdominal pain upper			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	6		
Diarrhoea			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	4		
Nausea			
subjects affected / exposed	2 / 56 (3.57%)		
occurrences (all)	2		
Oral pruritus			
subjects affected / exposed	0 / 56 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	4 / 56 (7.14%)		
occurrences (all)	4		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	5 / 56 (8.93%)		
occurrences (all)	6		
Cough			
subjects affected / exposed	5 / 56 (8.93%)		
occurrences (all)	15		
Nasal congestion			
subjects affected / exposed	6 / 56 (10.71%)		
occurrences (all)	7		
Oropharyngeal pain			
subjects affected / exposed	4 / 56 (7.14%)		
occurrences (all)	6		
Rhinitis allergic			
subjects affected / exposed	6 / 56 (10.71%)		
occurrences (all)	12		
Rhinorrhoea			

subjects affected / exposed	4 / 56 (7.14%)		
occurrences (all)	9		
Throat irritation			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Wheezing			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	10		
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	4 / 56 (7.14%)		
occurrences (all)	4		
Erythema			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	4 / 56 (7.14%)		
occurrences (all)	4		
Urticaria			
subjects affected / exposed	8 / 56 (14.29%)		
occurrences (all)	18		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Infections and infestations			
Ear infection			
subjects affected / exposed	5 / 56 (8.93%)		
occurrences (all)	6		
Gastroenteritis			
subjects affected / exposed	8 / 56 (14.29%)		
occurrences (all)	8		
Gastroenteritis viral			
subjects affected / exposed	2 / 56 (3.57%)		
occurrences (all)	2		
Influenza			

subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	3		
Nasopharyngitis			
subjects affected / exposed	18 / 56 (32.14%)		
occurrences (all)	30		
Pharyngitis			
subjects affected / exposed	1 / 56 (1.79%)		
occurrences (all)	1		
Pharyngitis streptococcal			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	4		
Rhinitis			
subjects affected / exposed	2 / 56 (3.57%)		
occurrences (all)	3		
Sinusitis			
subjects affected / exposed	2 / 56 (3.57%)		
occurrences (all)	3		
Upper respiratory tract infection			
subjects affected / exposed	12 / 56 (21.43%)		
occurrences (all)	25		
Urinary tract infection			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	4		
Viral infection			
subjects affected / exposed	4 / 56 (7.14%)		
occurrences (all)	6		
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 56 (5.36%)		
occurrences (all)	4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 May 2013	Study design modified to include an open-label follow-up study or extension study to the VIPES study (OLFUS-VIPES study). The OLFUS-VIPES study is for participants who were previously randomized and completed the VIPES study. Participants were offered enrollment in OLFUS-VIPES study to receive 24 months of Viaskin Peanut treatment. Participants formerly randomized to the placebo treatment group in the VIPES study crossed over to receive one of the 3 active doses of Viaskin Peanut.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported