



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) | EMA-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: 100 µg | 30 ^[2] |
| Randomized in OLFUS-VIPES Baseline: 250 µg | 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

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|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 15.0 |
|--------------------|------|

Reporting groups

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

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