



## Clinical trial results:

### A PHASE 3 RANDOMIZED, DOUBLE-BLIND, PLACEBOCONTROLLED STUDY ASSESSING THE EFFICACY OF ANTI-BET V 1 MONOCLONAL ANTIBODIES TO REDUCE SYMPTOMS OF SEASONAL ALLERGIC RHINITIS

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2020-004094-52 |
| Trial protocol           | DE DK BE       |
| Global end of trial date | 24 August 2021 |

#### Results information

|                                |                   |
|--------------------------------|-------------------|
| Result version number          | v1 (current)      |
| This version publication date  | 08 September 2022 |
| First version publication date | 08 September 2022 |

#### Trial information

##### Trial identification

|                       |                          |
|-----------------------|--------------------------|
| Sponsor protocol code | R5713-5714-5715-ALG-2001 |
|-----------------------|--------------------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04709575 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Regeneron Pharmaceuticals, Inc   |
| Sponsor organisation address | 777 Old Saw Mill River Road, Tarrytown, NY, United States, 10591   |
| Public contact               | Clinical Trials Administrator, Regeneron Pharmaceuticals, Inc., 001 844-734-6643, clinicaltrials@regeneron.com |
| Scientific contact           | Clinical Trial Management, Regeneron Pharmaceuticals, Inc, 001 1-844-734-6643, clinicaltrials@regeneron.com    |

Notes:

#### Paediatric regulatory details

|  |    |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP)       | No |
| 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? | No |

Notes:

## Results analysis stage

|  |                |
|--|----------------|
| Analysis stage                                       | Final          |
| Date of interim/final analysis                       | 24 August 2021 |
| Is this the analysis of the primary completion data? | Yes            |
| Primary completion date                              | 24 August 2021 |
| Global end of trial reached?                         | Yes            |
| Global end of trial date                             | 24 August 2021 |
| Was the trial ended prematurely?                     | No             |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective is to assess the reduction of allergic symptoms as measured by combined symptom and medication score (CSMS) during birch pollen season after a single dose of REGN5713-5714-5715 versus placebo

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the International Council for Harmonisation (ICH) guidelines for Good Clinical Practice (GCP) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

|   |                 |
|---|-----------------|
| Actual start date of recruitment                          | 14 January 2021 |
| 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 | Belgium: 31       |
| Country: Number of subjects enrolled | Canada: 118       |
| Country: Number of subjects enrolled | Denmark: 37       |
| Country: Number of subjects enrolled | Germany: 130      |
| Country: Number of subjects enrolled | United States: 37 |
| Worldwide total number of subjects   | 353               |
| EEA total number of subjects         | 198               |

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)                     | 0 |
| Adolescents (12-17 years)                 | 0 |

|                      |     |
|----------------------|-----|
| Adults (18-64 years) | 336 |
| From 65 to 84 years  | 17  |
| 85 years and over    | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

589 participants screened, 353 randomized and from these 349 treated. 4 participants were randomized but not treated. Reasons not randomized: 235 did not meet I/E criteria, 1 withdrew consent.

### 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, Data analyst, Assessor |

### Arms

|                              |                    |
|------------------------------|--------------------|
| Are arms mutually exclusive? | Yes                |
| <b>Arm title</b>             | REGN5713-5714-5715 |

Arm description:

REGN5713-5714-5715 administered subcutaneously

|  |                    |
|--|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | REGN5713-5714-5715 |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Cutaneous powder   |
| Routes of administration               | Subcutaneous use   |

Dosage and administration details:

Single SC dose, 900 mg

|  |                            |
|--|----------------------------|
| Investigational medicinal product name | REGN5713-5714-5715 placebo |
| Investigational medicinal product code |                            |
| Other name                             |                            |
| Pharmaceutical forms                   | Cutaneous powder           |
| Routes of administration               | Subcutaneous use           |

Dosage and administration details:

Single SC dose, 600 mg

|                  |              |
|------------------|--------------|
| <b>Arm title</b> | Placebo Only |
|------------------|--------------|

Arm description:

Placebo matching REGN5713-5714-5715 administered subcutaneously

|   |         |
|---|---------|
| Arm type  | Placebo |
| No investigational medicinal product assigned in this arm |         |

| <b>Number of subjects in period 1</b> | REGN5713-5714-5715 | Placebo Only |
|---------------------------------------|--------------------|--------------|
| Started                               | 176                | 177          |
| Completed                             | 166                | 172          |
| Not completed                         | 10                 | 5            |
| Consent withdrawn by subject          | 6                  | 2            |
| Adverse event, non-fatal              | 1                  | -            |
| Lost to follow-up                     | 2                  | 2            |
| Protocol deviation                    | 1                  | 1            |

## Baseline characteristics

### Reporting groups

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | REGN5713-5714-5715 |
|-----------------------|--------------------|

Reporting group description:

REGN5713-5714-5715 administered subcutaneously

|                       |              |
|-----------------------|--------------|
| Reporting group title | Placebo Only |
|-----------------------|--------------|

Reporting group description:

Placebo matching REGN5713-5714-5715 administered subcutaneously

| Reporting group values                             | REGN5713-5714-5715 | Placebo Only | Total |
|--|--------------------|--------------|-------|
| Number of subjects                                 | 176                | 177          | 353   |
| Age categorical<br>Units: Subjects                 |                    |              |       |
| In utero   | 0                  | 0            | 0     |
| Preterm newborn infants (gestational age < 37 wks) | 0                  | 0            | 0     |
| Newborns (0-27 days)                               | 0                  | 0            | 0     |
| Infants and toddlers (28 days-23 months)           | 0                  | 0            | 0     |
| Children (2-11 years)                              | 0                  | 0            | 0     |
| Adolescents (12-17 years)                          | 0                  | 0            | 0     |
| Adults (18-64 years)                               | 167                | 169          | 336   |
| From 65-84 years                                   | 9                  | 8            | 17    |
| 85 years and over                                  | 0                  | 0            | 0     |
| Age Continuous<br>Units: years                     |                    |              |       |
| arithmetic mean                                    | 39.6               | 42.1         |       |
| standard deviation                                 | ± 14.15            | ± 14.36      | -     |
| Sex: Female, Male<br>Units: Participants           |                    |              |       |
| Female   | 102                | 102          | 204   |
| Male   | 74                 | 75           | 149   |
| Ethnicity (NIH/OMB)<br>Units: Subjects             |                    |              |       |
| Hispanic or Latino                                 | 2                  | 2            | 4     |
| Not Hispanic or Latino                             | 172                | 174          | 346   |
| Unknown or Not Reported                            | 2                  | 1            | 3     |
| Race (NIH/OMB)<br>Units: Subjects                  |                    |              |       |
| American Indian or Alaska Native                   | 0                  | 1            | 1     |
| Asian  | 3                  | 10           | 13    |
| Native Hawaiian or Other Pacific Islander          | 1                  | 0            | 1     |
| Black or African American                          | 1                  | 2            | 3     |
| White  | 165                | 161          | 326   |
| More than one race                                 | 0                  | 0            | 0     |
| Unknown or Not Reported                            | 6                  | 3            | 9     |



## End points

### End points reporting groups

|                              |   |
|------------------------------|---|
| Reporting group title        | REGN5713-5714-5715  |
| Reporting group description: | REGN5713-5714-5715 administered subcutaneously                  |
| Reporting group title        | Placebo Only  |
| Reporting group description: | Placebo matching REGN5713-5714-5715 administered subcutaneously |

### Primary: Combined symptom and medication score (CSMS) in participants who receive a single dose of REGN5713-5714-5715 versus placebo

|                        |   |
|------------------------|---|
| End point title        | Combined symptom and medication score (CSMS) in participants who receive a single dose of REGN5713-5714-5715 versus placebo                                 |
| End point description: | CSMS is calculated by adding the Daily Medication Score (DMS) and Total Symptom Score (TSS) together, with scores ranging between 0 (none) and 38 (severe). |
| End point type         | Primary   |
| End point timeframe:   | Until the end of Birch Pollen Season, up to Week 16   |

| End point values                    | REGN5713-5714-5715    | Placebo Only          |  |  |
|-------------------------------------|-----------------------|-----------------------|--|--|
| Subject group type                  | Reporting group       | Reporting group       |  |  |
| Number of subjects analysed         | 171                   | 172                   |  |  |
| Units: Scores on a Scale            |                       |                       |  |  |
| least squares mean (standard error) | 7.503 ( $\pm$ 0.6545) | 8.498 ( $\pm$ 0.6534) |  |  |

### Statistical analyses

|   |                                   |
|---|-----------------------------------|
| Statistical analysis title              | Linear-Mixed Effect Model         |
| Comparison groups                       | REGN5713-5714-5715 v Placebo Only |
| Number of subjects included in analysis | 343                               |
| Analysis specification                  | Pre-specified                     |
| Analysis type                           | superiority                       |
| P-value                                 | = 0.0497                          |
| Method                                  | LS Mean Difference                |
| Parameter estimate                      | linear mixed-effect model         |
| Point estimate                          | -0.995                            |



|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -1.9886 |
| upper limit         | -0.0011 |

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**Secondary: Total symptom score (TSS), averaged over the duration of the birch pollen season, in participants who receive a single dose of REGN5713-5714-5715 versus placebo**

|  |  |
|--|--|
| End point title  | Total symptom score (TSS), averaged over the duration of the birch pollen season, in participants who receive a single dose of REGN5713-5714-5715 versus placebo |
| End point description:<br>TSS is a combined score of TOSS and TNSS. TNSS and TOSS are scored as in part 1 each for a combined TSS of 0 (none) to 18 (severe) |  |
| End point type   | Secondary  |
| End point timeframe:<br>Until the end of Birch Pollen Season, up to Week 16  |  |

| End point values                    | REGN5713-5714-5715 | Placebo Only    |  |  |
|-------------------------------------|--------------------|-----------------|--|--|
| Subject group type                  | Reporting group    | Reporting group |  |  |
| Number of subjects analysed         | 171                | 172             |  |  |
| Units: Percentage of Participants   |                    |                 |  |  |
| least squares mean (standard error) | 5.19 (± 0.397)     | 5.62 (± 0.396)  |  |  |

**Statistical analyses**

No statistical analyses for this end point

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**Secondary: Total nasal symptom score (TNSS), averaged over the duration of the birch pollen season, in participants who receive a single dose of REGN5713-5714-5715 versus placebo**

|  |   |
|--|---|
| End point title  | Total nasal symptom score (TNSS), averaged over the duration of the birch pollen season, in participants who receive a single dose of REGN5713-5714-5715 versus placebo |
| End point description:<br>Total nasal symptom score (TNSS) is from 0 to 12 and is based on assessment of 4 nasal symptoms graded on a Likert scale ranging from 0 (none) to 3 (severe) for congestion, itching, and rhinorrhea, and from 0 (none) to 3 (5 or more sneezes) for sneezing. |   |
| End point type   | Secondary   |
| End point timeframe:<br>Until the end of Birch Pollen Season, up to Week 16  |   |

| End point values                    | REGN5713-5714-5715  | Placebo Only        |  |  |
|-------------------------------------|---------------------|---------------------|--|--|
| Subject group type                  | Reporting group     | Reporting group     |  |  |
| Number of subjects analysed         | 171                 | 172                 |  |  |
| Units: Percentage of Participants   |                     |                     |  |  |
| least squares mean (standard error) | 3.76 ( $\pm$ 0.278) | 4.00 ( $\pm$ 0.277) |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Total ocular symptom score (TOSS), averaged over the duration of the birch pollen season, in participants who receive a single dose of REGN5713-5714-5715 versus placebo

|                 |  |
|-----------------|--|
| End point title | Total ocular symptom score (TOSS), averaged over the duration of the birch pollen season, in participants who receive a single dose of REGN5713-5714-5715 versus placebo |
|-----------------|--|

End point description:

Total ocular symptom score is 0 to 6 and is based on itching/redness/gritty feeling and tearing/watering; each of the 2 symptoms is graded 0 (absent), 1 (mild), 2 (moderate), and 3 (severe)

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Until the end of Birch Pollen Season, up to Week 16

| End point values                    | REGN5713-5714-5715  | Placebo Only        |  |  |
|-------------------------------------|---------------------|---------------------|--|--|
| Subject group type                  | Reporting group     | Reporting group     |  |  |
| Number of subjects analysed         | 171                 | 172                 |  |  |
| Units: Percentage of Participants   |                     |                     |  |  |
| least squares mean (standard error) | 1.43 ( $\pm$ 0.150) | 1.62 ( $\pm$ 0.150) |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Daily medication score (DMS), averaged over the duration of the birch pollen season, in participants who receive a single dose of REGN5713-5714-5715 versus placebo

|                 |   |
|-----------------|---|
| End point title | Daily medication score (DMS), averaged over the duration of the birch pollen season, in participants who receive a single dose of REGN5713-5714-5715 versus placebo |
|-----------------|---|

End point description:

The Daily Medication Score (DMS) is calculated by adding points for each pre-specified medication taken as follows: desloratadine 5 mg 6 points/dose; maximum daily score 6 points, olopatadine 1 mg/mL each drop 1.5 points/drop; maximum daily score 6 points, mometasone furoate 50 ug/dose 2.0 points/spray; maximum daily score 8 points). The scale is 0 (minimum) to 20 (maximum)

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Until the end of Birch Pollen Season, up to Week 16

|                                     |                       |                       |  |  |
|-------------------------------------|-----------------------|-----------------------|--|--|
| <b>End point values</b>             | REGN5713-5714-5715    | Placebo Only          |  |  |
| Subject group type                  | Reporting group       | Reporting group       |  |  |
| Number of subjects analysed         | 171                   | 172                   |  |  |
| Units: Percentage of Participants   |                       |                       |  |  |
| least squares mean (standard error) | 2.316 ( $\pm$ 0.3993) | 2.882 ( $\pm$ 0.3986) |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants with Treatment-Emergent Adverse Events (TEAEs) throughout the study

|                 |  |
|-----------------|--|
| End point title | Number of Participants with Treatment-Emergent Adverse Events (TEAEs) throughout the study |
|-----------------|--|

End point description:

Number of participants with any Treatment Emergent Adverse Events (TEAEs)

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 127

|                              |                    |                 |  |  |
|------------------------------|--------------------|-----------------|--|--|
| <b>End point values</b>      | REGN5713-5714-5715 | Placebo Only    |  |  |
| Subject group type           | Reporting group    | Reporting group |  |  |
| Number of subjects analysed  | 173                | 176             |  |  |
| Units: Count of Participants | 92                 | 85              |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants with Serious TEAEs throughout the study

|                 |  |
|-----------------|--|
| End point title | Number of Participants with Serious TEAEs throughout the study |
|-----------------|--|

End point description:

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 127

| End point values             | REGN5713-5714-5715 | Placebo Only    |  |  |
|------------------------------|--------------------|-----------------|--|--|
| Subject group type           | Reporting group    | Reporting group |  |  |
| Number of subjects analysed  | 173                | 176             |  |  |
| Units: Count of Participants | 3                  | 0               |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from baseline to the end of study in birch SPT mean wheal diameter in participants who receive a single dose of REGN5713-5714-5715 versus placebo

|                          |  |
|--------------------------|--|
| End point title          | Change from baseline to the end of study in birch SPT mean wheal diameter in participants who receive a single dose of REGN5713-5714-5715 versus placebo |
| End point description:   |  |
| End point type           | Secondary  |
| End point timeframe:     |  |
| Baseline through Day 127 |  |

| End point values                    | REGN5713-5714-5715     | Placebo Only          |  |  |
|-------------------------------------|------------------------|-----------------------|--|--|
| Subject group type                  | Reporting group        | Reporting group       |  |  |
| Number of subjects analysed         | 171                    | 172                   |  |  |
| Units: millimeters                  |                        |                       |  |  |
| least squares mean (standard error) | -3.139 ( $\pm$ 0.5086) | 0.553 ( $\pm$ 0.5067) |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percent change from baseline to the end of study in birch SPT mean wheal diameter in participants who receive a single dose of REGN5713-5714-5715 versus placebo

|                        |  |
|------------------------|--|
| End point title        | Percent change from baseline to the end of study in birch SPT mean wheal diameter in participants who receive a single dose of REGN5713-5714-5715 versus placebo |
| End point description: |  |
| End point type         | Secondary  |

End point timeframe:  
Baseline through Day 127

|                                     |                       |                     |  |  |
|-------------------------------------|-----------------------|---------------------|--|--|
| <b>End point values</b>             | REGN5713-5714-5715    | Placebo Only        |  |  |
| Subject group type                  | Reporting group       | Reporting group     |  |  |
| Number of subjects analysed         | 171                   | 172                 |  |  |
| Units: Percentage                   |                       |                     |  |  |
| least squares mean (standard error) | -26.38 ( $\pm$ 5.179) | 8.17 ( $\pm$ 5.160) |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Serum concentration of REGN5713 over the study duration

End point title Serum concentration of REGN5713 over the study duration<sup>[1]</sup>

End point description:

End point type Secondary

End point timeframe:

Up to Day 127

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: No statistical analysis was presented for this endpoint

|                                      |                    |  |  |  |
|--------------------------------------|--------------------|--|--|--|
| <b>End point values</b>              | REGN5713-5714-5715 |  |  |  |
| Subject group type                   | Reporting group    |  |  |  |
| Number of subjects analysed          | 172                |  |  |  |
| Units: mg/L                          |                    |  |  |  |
| arithmetic mean (standard deviation) |                    |  |  |  |
| Day 0                                | 0 ( $\pm$ 0)       |  |  |  |
| Day 56                               | 10.0 ( $\pm$ 3.97) |  |  |  |
| Day 112                              | 2.53 ( $\pm$ 1.57) |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Serum concentration of REGN5714 over the study duration

End point title Serum concentration of REGN5714 over the study duration<sup>[2]</sup>

End point description:

|   |                    |  |  |  |
|---|--------------------|--|--|--|
| End point type  | Secondary          |  |  |  |
| End point timeframe:  |                    |  |  |  |
| Up to Day 127   |                    |  |  |  |
| Notes:  |                    |  |  |  |
| [2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. |                    |  |  |  |
| Justification: No statistical analysis was presented for this endpoint  |                    |  |  |  |
| End point values  | REGN5713-5714-5715 |  |  |  |
| Subject group type  | Reporting group    |  |  |  |
| Number of subjects analysed   | 172                |  |  |  |
| Units: mg/L   |                    |  |  |  |
| arithmetic mean (standard deviation)  |                    |  |  |  |
| Day 0   | 0 (± 0)            |  |  |  |
| Day 56  | 14.7 (± 4.68)      |  |  |  |
| Day 112   | 4.82 (± 2.16)      |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Serum concentration of REGN5715 over the study duration

|   |  |  |  |  |
|---|--|--|--|--|
| End point title   | Serum concentration of REGN5715 over the study duration <sup>[3]</sup> |  |  |  |
| End point description:  |  |  |  |  |
|   |  |  |  |  |
| End point type  | Secondary  |  |  |  |
| End point timeframe:  |  |  |  |  |
| Up to Day 127   |  |  |  |  |
| Notes:  |  |  |  |  |
| [3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. |  |  |  |  |
| Justification: No statistical analysis was presented for this endpoint  |  |  |  |  |
| End point values  | REGN5713-5714-5715   |  |  |  |
| Subject group type  | Reporting group  |  |  |  |
| Number of subjects analysed   | 172  |  |  |  |
| Units: mg/L   |  |  |  |  |
| arithmetic mean (standard deviation)  |  |  |  |  |
| Day 0   | 0 (± 0)  |  |  |  |
| Day 56  | 16.6 (± 5.34)  |  |  |  |
| Day 112   | 5.34 (± 2.35)  |  |  |  |

### Statistical analyses

No statistical analyses for this end point

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**Secondary: Percentage of Participants with treatment emergent anti-drug antibodies to REGN5713 throughout the study**

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|                 |  |
|-----------------|--|
| End point title | Percentage of Participants with treatment emergent anti-drug antibodies to REGN5713 throughout the study |
|-----------------|--|

End point description:

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 127

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|                                   |                    |                 |  |  |
|-----------------------------------|--------------------|-----------------|--|--|
| <b>End point values</b>           | REGN5713-5714-5715 | Placebo Only    |  |  |
| Subject group type                | Reporting group    | Reporting group |  |  |
| Number of subjects analysed       | 168                | 171             |  |  |
| Units: Percentage of Participants | 0                  | 0               |  |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Percentage of Participants with treatment emergent anti-drug antibodies to REGN5715 throughout the study**

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|                 |  |
|-----------------|--|
| End point title | Percentage of Participants with treatment emergent anti-drug antibodies to REGN5715 throughout the study |
|-----------------|--|

End point description:

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 127

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|                                   |                    |                 |  |  |
|-----------------------------------|--------------------|-----------------|--|--|
| <b>End point values</b>           | REGN5713-5714-5715 | Placebo Only    |  |  |
| Subject group type                | Reporting group    | Reporting group |  |  |
| Number of subjects analysed       | 168                | 171             |  |  |
| Units: Percentage of Participants | 0                  | 0               |  |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Percentage of Participants with treatment emergent anti-drug antibodies to REGN5714 throughout the study**

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|                        |  |
|------------------------|--|
| End point title        | Percentage of Participants with treatment emergent anti-drug antibodies to REGN5714 throughout the study |
| End point description: |  |
| End point type         | Secondary  |
| End point timeframe:   |  |
| Up to Day 127          |  |

|                                   |                    |                 |  |  |
|-----------------------------------|--------------------|-----------------|--|--|
| <b>End point values</b>           | REGN5713-5714-5715 | Placebo Only    |  |  |
| Subject group type                | Reporting group    | Reporting group |  |  |
| Number of subjects analysed       | 168                | 171             |  |  |
| Units: Percentage of Participants | 0                  | 0               |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of "Well Days"

|   |                       |
|---|-----------------------|
| End point title   | Number of "Well Days" |
| End point description:  |                       |
| "Well Days" are defined as days when rescue medication is not utilized and the Total symptom score (TSS) is $\leq 2/18$ |                       |
| End point type  | Secondary             |
| End point timeframe:  |                       |
| Until the end of Birch Pollen Season, up to Week 16   |                       |

|                                     |                    |                   |  |  |
|-------------------------------------|--------------------|-------------------|--|--|
| <b>End point values</b>             | REGN5713-5714-5715 | Placebo Only      |  |  |
| Subject group type                  | Reporting group    | Reporting group   |  |  |
| Number of subjects analysed         | 171                | 172               |  |  |
| Units: Days                         |                    |                   |  |  |
| least squares mean (standard error) | 8.3 ( $\pm$ 1.42)  | 8.6 ( $\pm$ 1.42) |  |  |

### Statistical analyses

No statistical analyses for this end point



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

28 weeks

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 24.0 |
|--------------------|------|

### Reporting groups

|                       |                        |
|-----------------------|------------------------|
| Reporting group title | R5713-5714-5715 900 mg |
|-----------------------|------------------------|

Reporting group description:

REGN5713-5714-5715 administered subcutaneously

|                       |         |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Placebo matching REGN5713-5714-5715 administered subcutaneously

| Serious adverse events  | R5713-5714-5715<br>900 mg | Placebo         |  |
|---|---------------------------|-----------------|--|
| Total subjects affected by serious adverse events                   |                           |                 |  |
| subjects affected / exposed   | 3 / 173 (1.73%)           | 0 / 176 (0.00%) |  |
| number of deaths (all causes)                                       | 0                         | 0               |  |
| number of deaths resulting from adverse events                      | 0                         | 0               |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                           |                 |  |
| Breast cancer   |                           |                 |  |
| subjects affected / exposed   | 1 / 173 (0.58%)           | 0 / 176 (0.00%) |  |
| occurrences causally related to treatment / all                     | 0 / 1                     | 0 / 0           |  |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0           |  |
| Injury, poisoning and procedural complications                      |                           |                 |  |
| Thermal burn  |                           |                 |  |
| subjects affected / exposed   | 1 / 173 (0.58%)           | 0 / 176 (0.00%) |  |
| occurrences causally related to treatment / all                     | 0 / 1                     | 0 / 0           |  |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0           |  |
| Infections and infestations   |                           |                 |  |
| Appendicitis  |                           |                 |  |
| subjects affected / exposed   | 1 / 173 (0.58%)           | 0 / 176 (0.00%) |  |
| occurrences causally related to treatment / all                     | 0 / 1                     | 0 / 0           |  |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0           |  |

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

| <b>Non-serious adverse events</b>                     | <b>R5713-5714-5715<br/>900 mg</b> | <b>Placebo</b>    |  |
|---|-----------------------------------|-------------------|--|
| Total subjects affected by non-serious adverse events |                                   |                   |  |
| subjects affected / exposed                           | 32 / 173 (18.50%)                 | 43 / 176 (24.43%) |  |
| Injury, poisoning and procedural complications        |                                   |                   |  |
| Vaccination complication                              |                                   |                   |  |
| subjects affected / exposed                           | 17 / 173 (9.83%)                  | 22 / 176 (12.50%) |  |
| occurrences (all)                                     | 26                                | 29                |  |
| Nervous system disorders                              |                                   |                   |  |
| Headache  |                                   |                   |  |
| subjects affected / exposed                           | 15 / 173 (8.67%)                  | 19 / 176 (10.80%) |  |
| occurrences (all)                                     | 19                                | 22                |  |
| Infections and infestations                           |                                   |                   |  |
| Nasopharyngitis                                       |                                   |                   |  |
| subjects affected / exposed                           | 5 / 173 (2.89%)                   | 9 / 176 (5.11%)   |  |
| occurrences (all)                                     | 5                                 | 9                 |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported