# Clinical trial results:
# A Multicenter Open-Label Study of the Long-term Safety and Efficacy of the Human Anti-TNF Monoclonal Antibody Adalimumab in Subjects with Non-infectious Intermediate Uveitis, Posterior Uveitis, or Panuveitis

## Summary

| | |
|---|---|
| EudraCT number | 2009-016196-29 |
| Trial protocol | FR ES BE PT GB DE DK AT IT CZ GR |
| Global end of trial date | 21 May 2018 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 19 April 2019 |
| First version publication date | 19 April 2019 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | M11-327 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01148225 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | AbbVie Deutschland GmbH & Co. KG |
| Sponsor organisation address | AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6-4UB |
| Public contact | Global Medical Services, AbbVie, 001 800-633-9110, |
| Scientific contact | Alexandra Song, AbbVie, Alex.Song@abbvie.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 | 21 May 2018 |
| Is this the analysis of the primary | No |

| completion data? | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 21 May 2018 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the long term efficacy and safety of adalimumab participants with non-infectious intermediate uveitis, posterior uveitis, or panuveitis.

Protection of trial subjects:

Subject and/or legal guardian read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

| Actual start date of recruitment | 23 November 2010 |
|---|---|
| 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 | Spain: 9 |
|---|---|
| Country: Number of subjects enrolled | Switzerland: 10 |
| Country: Number of subjects enrolled | United Kingdom: 22 |
| Country: Number of subjects enrolled | United States: 121 |
| Country: Number of subjects enrolled | Argentina: 21 |
| Country: Number of subjects enrolled | Australia: 16 |
| Country: Number of subjects enrolled | Austria: 9 |
| Country: Number of subjects enrolled | Belgium: 43 |
| Country: Number of subjects enrolled | Brazil: 2 |
| Country: Number of subjects enrolled | Canada: 19 |
| Country: Number of subjects enrolled | Czech Republic: 2 |
| Country: Number of subjects enrolled | Denmark: 5 |
| Country: Number of subjects enrolled | France: 8 |
| Country: Number of subjects enrolled | Germany: 24 |
| Country: Number of subjects enrolled | Greece: 3 |
| Country: Number of subjects enrolled | Israel: 9 |
| Country: Number of subjects enrolled | Italy: 34 |
| Country: Number of subjects enrolled | Japan: 44 |
| Country: Number of subjects enrolled | Mexico: 7 |
| Country: Number of subjects enrolled | Poland: 13 |
| Country: Number of subjects enrolled | Portugal: 3 |
| Worldwide total number of subjects | 424 |
| EEA total number of subjects | 175 |

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) | 390 |
| From 65 to 84 years | 34 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 424 participants were enrolled and received ≥1 dose of study drug (Safety population); 364 participants were included in the intent-to-treat (ITT) population (reasons for exclusion: incomplete efficacy data or GCP compliance issues at 2 sites (n=7); diabetic retinopathy [n=1]; cataract surgery [n=26]; and previous vitrectomy [n=26]).

### Period 1

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

### Arms

| | |
|---|---|
| **Arm title** | Adalimumab |

Arm description:

Participants received open label (OL) adalimumab 40 mg by subcutaneous (SC) injection every other week (eow) until the final visit.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Adalimumab |
| Investigational medicinal product code | |
| Other name | ABT-D2E7, Humira |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Adalimumab, pre-filled syringe, administered by SC injection.

| **Number of subjects in period 1** | Adalimumab |
|---|---|
| Started | 424 |
| Completed | 239 |
| Not completed | 185 |
| Not specified | 185 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Adalimumab |
| Reporting group description: | |
| Participants received open label (OL) adalimumab 40 mg by subcutaneous (SC) injection every other week (eow) until the final visit. | |

| Reporting group values | Adalimumab | Total | |
|---|---|---|---|
| Number of subjects | 424 | 424 | |
| Age categorical<br>Units: Subjects | | | |
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | <br><br>43.44<br>± 14.066 | <br><br><br>- | |
| Gender categorical<br>Units: Subjects | | | |
| Female<br>Male | 249<br>175 | 249<br>175 | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino<br>Not Hispanic or Latino | 77<br>347 | 77<br>347 | |

## End points

### End points reporting groups

| Reporting group title | Adalimumab |
|---|---|

Reporting group description:

Participants received open label (OL) adalimumab 40 mg by subcutaneous (SC) injection every other week (eow) until the final visit.

| Subject analysis set title | Adalimumab |
|---|---|
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Safety analysis set: includes all participants who received at least one dose of study medication.

### Primary: Number of Participants With Adverse Events

| End point title | Number of Participants With Adverse Events[1] |
|---|---|

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. The investigator assessed the relationship of each event to the use of study drug as either probably related, possibly related, probably not related or not related. A serious adverse event (SAE) is an event that results in death, is life-threatening, requires or prolongs hospitalization, results in a congenital anomaly, persistent or significant disability/incapacity or is an important medical event that, based on medical judgment, may jeopardize the subject and may require medical or surgical intervention to prevent any of the outcomes listed above. Treatment-emergent events (TEAEs/TESAEs) are defined as any event with an onset date on or after the first dose of study drug and up to 70 days after the last dose. See the Adverse Event section for details.

| End point type | Primary |
|---|---|

End point timeframe:

Baseline to Final Visit (up to 366 weeks)

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: Descriptive data are summarized for this end point per protocol.

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 424[2] | | | |
| Units: Participants | | | | |
| Any TEAE | 398 | | | |
| Any TESAE | 101 | | | |

Notes:

[2] - Safety analysis set: includes all participants who received at least one dose of study medication.

### Statistical analyses

No statistical analyses for this end point

### Primary: Hematology: Number of Participants With Potentially Clinically Significant (PCS) Values

| End point title | Hematology: Number of Participants With Potentially Clinically Significant (PCS) Values[3] |
|---|---|

End point description:

PCS laboratory values were defined as Common Toxicity Criteria (CTC) according to the National Cancer Institute Common Terminology for Adverse Events (NCI CTCAE) v3.0 ≥ Grade 3. Abbreviations used include g=grams; L=liters.

| End point type | Primary |
|---|---|

End point timeframe:

Baseline to Final Visit (Up to 366 weeks)

Notes:

[3] - 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: Descriptive data are summarized for this end point per protocol.

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 424[4] | | | |
| Units: Participants | | | | |
| Hemoglobin (Low: <80-65) | 3 | | | |
| Neutrophils (Low:<1.0-0.5*10^9/L) | 6 | | | |
| Lymphocytes (Low:<0.5-0.2*10^9/L) | 7 | | | |

Notes:

[4] - Safety analysis set: includes all participants who received at least one dose of study medication.

## Statistical analyses

No statistical analyses for this end point

## Primary: Chemistry: Number of Participants With PCS Values

| End point title | Chemistry: Number of Participants With PCS Values[5] |
|---|---|

End point description:

PCS laboratory values were defined as Common Toxicity Criteria (CTC) according to the National Cancer Institute Common Terminology for Adverse Events (NCI CTCAE) v3.0 ≥ Grade 3. Abbreviations include ALT/SGPT=alanine aminotransferase/serum glutamate pyruvate transaminase; AST/SGOT=aspartate aminotransferase/serum glutamate oxaloacetate transaminase; g/L=grams/liter; mmol/L=millimoles/liter; ULN=upper limit of normal.

| End point type | Primary |
|---|---|

End point timeframe:

Baseline to Final Visit (Up to 366 weeks)

Notes:

[5] - 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: Descriptive data are summarized for this end point per protocol.

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 424[6] | | | |
| Units: Participants | | | | |
| ALT/SGPT (High:>5.0-20.0*ULN) | 2 | | | |
| AST/SGOT (High: >5.0-20.0*ULN) | 3 | | | |
| Bilirubin, Total (High: >3.0-10.0*ULN) | 1 | | | |
| Creatinine (High:>3.0-6.0*ULN) | 2 | | | |
| Phosphate Inorganic (Low:<0.6-0.3 mmol/L) | 5 | | | |
| Sodium (Low: <130-120 mmol/L) | 4 | | | |
| Potassium (Low:<3.0-2.5 mmol/L) | 7 | | | |
| Glucose (High: >13.9-27.8 mmol/L) | 18 | | | |
| Albumin (Low: <20.0 g/L) | 2 | | | |

| | | | | |
|---|---|---|---|---|
| Cholesterol (High: >10.34-12.92 mmol/L) | 3 | | | |
| Triglycerides (High: >5.0-10*ULN) | 8 | | | |

Notes:

[6] - Safety analysis set: includes all participants who received at least one dose of study medication.

## Statistical analyses

No statistical analyses for this end point

## Primary: Pulse (Sitting): Mean Change (Beats Per Minute) From Baseline To Final Visit

| End point title | Pulse (Sitting): Mean Change (Beats Per Minute) From Baseline To Final Visit[7] |
|---|---|

End point description:

Heart rate (beats per minute) was measured while the participant was sitting.

| End point type | Primary |
|---|---|

End point timeframe:

Baseline to Final Visit (Up to 366 weeks)

Notes:

[7] - 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: Descriptive data are summarized for this end point per protocol.

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 424[8] | | | |
| Units: beats per minute | | | | |
| arithmetic mean (standard deviation) | | | | |
| beats per minute | -1.0 (± 11.92) | | | |

Notes:

[8] - Safety analysis set: includes all participants who received at least one dose of study medication.

## Statistical analyses

No statistical analyses for this end point

## Primary: Respiratory Rate (Sitting): Mean Change (Respirations Per Minute) From Baseline To Final Visit

| End point title | Respiratory Rate (Sitting): Mean Change (Respirations Per Minute) From Baseline To Final Visit[9] |
|---|---|

End point description:

Respiratory rate (respirations per minute) was measured while the participant was sitting.

| End point type | Primary |
|---|---|

End point timeframe:

Baseline to Final Visit (Up to 366 weeks)

Notes:

[9] - 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: Descriptive data are summarized for this end point per protocol.

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 424[10] | | | |
| Units: respirations per minute | | | | |
| arithmetic mean (standard deviation) | | | | |
| respirations per minute | -0.1 (± 2.94) | | | |

Notes:

[10] - Safety analysis set: includes all participants who received at least one dose of study medication.

### Statistical analyses

No statistical analyses for this end point

## Primary: Temperature (Sitting): Mean Change (Centigrade) From Baseline To Final Visit

| End point title | Temperature (Sitting): Mean Change (Centigrade) From Baseline To Final Visit[11] |
|---|---|

End point description:

Temperature was measured while the participant was sitting.

| End point type | Primary |
|---|---|

End point timeframe:

Baseline to Final Visit (Up to 366 weeks)

Notes:

[11] - 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: Descriptive data are summarized for this end point per protocol.

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 424[12] | | | |
| Units: Centigrade | | | | |
| arithmetic mean (standard deviation) | | | | |
| Centigrade | -0.03 (± 0.516) | | | |

Notes:

[12] - Safety analysis set: includes all participants who received at least one dose of study medication.

### Statistical analyses

No statistical analyses for this end point

## Primary: Diastolic and Systolic Blood Pressure (Sitting): Mean Change (mmHg) From Baseline To Final Visit

| End point title | Diastolic and Systolic Blood Pressure (Sitting): Mean Change (mmHg) From Baseline To Final Visit[13] |
|---|---|

End point description:

Blood pressure was measured while the participant was sitting. Abbreviations used include mmHg=millimeters of mercury.

| End point type | Primary |
|---|---|

End point timeframe:

Baseline to Final Visit (Up to 366 weeks)

Notes:

[13] - 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: Descriptive data are summarized for this end point per protocol.

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 424[14] | | | |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Diastolic Blood Pressure (Sitting) | 1.443 (± 10.4373) | | | |
| Systolic Blood Pressure (Sitting) | 1.955 (± 14.6281) | | | |

Notes:

[14] - Safety analysis set: includes all participants who received at least one dose of study medication.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants in Quiescence Over Time

| End point title | Percentage of Participants in Quiescence Over Time |
|---|---|

End point description:

Quiescence is defined as no active inflammatory lesions and anterior chamber (AC) cell grade ≤ 0.5+ and vitreous haze (VH) grade ≤0.5+. Participants with active uveitis at study entry could have been in quiescence at Week 0 because all participants were evaluated for uveitis status at the Final/Early Termination visit of the lead-in study and the Week 0 visit could have occurred up to 28 days later during which time the participant's disease status may have changed. n=the number of participants at given time point.

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

End point timeframe:

Weeks 0, 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 364[15] | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 0 (n=364) | 33.5 (28.7 to 38.6) | | | |
| Week 2 (n=348) | 56.3 (50.9 to 61.6) | | | |
| Week 4 (n=323) | 63.8 (58.3 to 69.0) | | | |
| Week 8 (n=343) | 72.0 (66.9 to 76.7) | | | |
| Week 12 (n=333) | 72.4 (67.2 to 77.1) | | | |
| Week 18 (n=330) | 75.2 (70.1 to 79.7) | | | |

| | | | | |
|---|---|---|---|---|
| Week 30 (n=319) | 79.9 (75.1 to 84.2) | | | |
| Week 42 (n=310) | 81.3 (76.5 to 85.5) | | | |
| Week 54 (n=296) | 81.1 (76.1 to 85.4) | | | |
| Week 66 (n=284) | 85.9 (81.3 to 89.7) | | | |
| Week 78 (n=271) | 86.3 (81.7 to 90.2) | | | |
| Week 90 (n=261) | 87.4 (82.7 to 91.1) | | | |
| Week 102 (n=245) | 87.3 (82.5 to 91.2) | | | |
| Week 114 (n=231) | 87.9 (83.0 to 91.8) | | | |
| Week 126 (n=215) | 88.4 (83.3 to 92.3) | | | |
| Week 138 (n=196) | 89.3 (84.1 to 93.2) | | | |
| Week 150 (n=180) | 85.0 (78.9 to 89.9) | | | |
| Week 162 (n=154) | 87.0 (80.7 to 91.9) | | | |
| Week 174 (n=142) | 87.3 (80.7 to 92.3) | | | |
| Week 186 (n=128) | 90.6 (84.2 to 95.1) | | | |
| Week 198 (n=113) | 89.4 (82.2 to 94.4) | | | |
| Week 210 (n=88) | 88.6 (80.1 to 94.4) | | | |
| Week 222 (n=70) | 92.9 (84.1 to 97.6) | | | |
| Week 234 (n=51) | 96.1 (86.5 to 99.5) | | | |
| Week 246 (n=42) | 95.2 (83.8 to 99.4) | | | |

Notes:

[15] - ITT set: all participants with at least 1 dose of study drug and evaluable data at a given timepoint

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants With Uveitis Flare Among Participants With Inactive Uveitis at Study Start

| End point title | Percentage of Participants With Uveitis Flare Among Participants With Inactive Uveitis at Study Start |
|---|---|

End point description:

Uveitis flare is defined as no quiescence (active inflammatory lesions and AC cell grade > 0.5+ and/or VH grade >0.5+).

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

End point timeframe:

366 Weeks

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 124[16] | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Percentage of Participants | 38.7 (30.1 to 47.9) | | | |

Notes:

[16] - ITT set: all participants with inactive uveitis with evaluable data at a given timepoint.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants With Uveitis Flare From Week 8 Through Last Visit Among Participants With Active Uveitis at Study Start

| End point title | Percentage of Participants With Uveitis Flare From Week 8 Through Last Visit Among Participants With Active Uveitis at Study Start |
|---|---|

End point description:

Uveitis flare is defined as no quiescence (active inflammatory lesions and AC cell grade > 0.5+ and/or VH grade >0.5+).

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

End point timeframe:

Weeks 8 to 246 (238 Weeks)

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 232[17] | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Percentage of Participants | 67.7 (61.2 to 73.6) | | | |

Notes:

[17] - ITT set: all participants with active uveitis at study start and evaluable data at a given timepoint

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants With New Active Inflammatory Lesions or Grade ≥2 in Anterior Chamber (AC) Cells or Grade ≥2 in Vitreous Haze (VH) Over Time

| End point title | Percentage of Participants With New Active Inflammatory Lesions or Grade ≥2 in Anterior Chamber (AC) Cells or Grade ≥2 in Vitreous Haze (VH) Over Time |
|---|---|

End point description:

Dilated indirect ophthalmoscopy is performed to determine both vitreous haze grading and the absence/presence of inflammatory chorioretinal and/or inflammatory retinal vascular lesions. The number of AC cells observed within a 1 mm * 1 mm slit beam was recorded for each eye and this number was used to determine the grade according to Standardization of Uveitis Nomenclature (SUN)

criteria. Grading of VH was based on the National Eye Institute (NEI) publication which was adapted by the SUN working group. The percentage of participants with new active inflammatory lesions or grade ≥2 in AC cells or grade ≥2 in VH are presented. n=the number of participants at given time point.

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

End point timeframe:

Weeks 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 364[18] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 (n=348) | 11.8 (8.6 to 15.6) | | | |
| Week 4 (n=323) | 8.4 (5.6 to 11.9) | | | |
| Week 8 (n=343) | 7.6 (5.0 to 10.9) | | | |
| Week 12 (n=333) | 6.9 (4.4 to 10.2) | | | |
| Week 18 (n=330) | 3.6 (1.9 to 6.3) | | | |
| Week 30 (n=319) | 5.3 (3.1 to 8.4) | | | |
| Week 42 (n=310) | 4.2 (2.3 to 7.1) | | | |
| Week 54 (n=296) | 4.1 (2.1 to 7.0) | | | |
| Week 66 (n= 284) | 1.4 (0.4 to 3.6) | | | |
| Week 78 (n= 271) | 4.1 (2.0 to 7.1) | | | |
| Week 90 (n=261) | 4.6 (2.4 to 7.9) | | | |
| Week 102 (n=245) | 4.1 (2.0 to 7.4) | | | |
| Week 114 (n=231) | 4.8 (2.4 to 8.4) | | | |
| Week 126 (n=215) | 3.3 (1.3 to 6.6) | | | |
| Week 138 (n=196) | 2.0 (0.6 to 5.1) | | | |
| Week 150 (n=180) | 4.4 (1.9 to 8.6) | | | |
| Week 162 (n=154) | 3.2 (1.1 to 7.4) | | | |
| Week 174 (n=142) | 1.4 (0.2 to 5.0) | | | |
| Week 186 (n=128) | 1.6 (0.2 to 5.5) | | | |
| Week 198 (n=113) | 0 (0 to 0) | | | |
| Week 210 (n=88) | 3.4 (0.7 to 9.6) | | | |
| Week 222 (n=70) | 1.4 (0 to 7.7) | | | |
| Week 234 (n=51) | 0 (0 to 0) | | | |
| Week 246 (n=42) | 0 (0 to 0) | | | |

Notes:

[18] - All participants in the ITT analysis set with evaluable data at a given time point.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants With Steroid-free Quiescence Over Time

| End point title | Percentage of Participants With Steroid-free Quiescence Over |
|---|---|

| | Time |
|---|---|

End point description:

Steroid-free quiescence is defined as no active inflammatory lesions and AC cell grade ≤ 0.5+ and VH grade ≤0.5+ and no uveitis-related corticosteroids on the day of assessment. n=the number of participants at given time point. n=the number of participants at given time point.

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

End point timeframe:

Weeks 0, 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 364[19] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 0 (n=364) | 30.5 (25.8 to 35.5) | | | |
| Week 2 (n=348) | 34.8 (29.8 to 40.0) | | | |
| Week 4 (n=323) | 35.6 (30.4 to 41.1) | | | |
| Week 8 (n=343) | 41.4 (36.1 to 46.8) | | | |
| Week 12 (n=333) | 44.4 (39.0 to 50.0) | | | |
| Week 18 (n=330) | 47.6 (42.1 to 53.1) | | | |
| Week 30 (n=319) | 52.4 (46.7 to 57.9) | | | |
| Week 42 (n=310) | 55.8 (50.1 to 61.4) | | | |
| Week 54 (n=296) | 55.7 (49.9 to 61.5) | | | |
| Week 66 (n=284) | 56.7 (50.7 to 62.5) | | | |
| Week 78 (n=272) | 57.7 (51.6 to 63.7) | | | |
| Week 90 (n=261) | 60.2 (53.9 to 66.1) | | | |
| Week 102 (n=245) | 65.7 (59.4 to 71.6) | | | |
| Week 114 (n=231) | 66.2 (59.7 to 72.3) | | | |
| Week 126 (n=215) | 66.0 (59.3 to 72.3) | | | |
| Week 138 (n=196) | 67.9 (60.8 to 74.3) | | | |
| Week 150 (n=180) | 65.0 (57.6 to 71.9) | | | |
| Week 162 (n=154) | 63.0 (54.8 to 70.6) | | | |
| Week 174 (n=142) | 65.5 (57.1 to 73.3) | | | |
| Week 186 (n=128) | 68.0 (59.1 to 75.9) | | | |

| | | | | |
|---|---|---|---|---|
| Week 198 (n=113) | 64.6 (55.0 to 73.4) | | | |
| Week 210 (n=89) | 64.0 (53.2 to 73.9) | | | |
| Week 222 (n=71) | 69.0 (56.9 to 79.5) | | | |
| Week 234 (n=51) | 78.4 (64.7 to 88.7) | | | |
| Week 246 (n=42) | 83.3 (68.6 to 93.0) | | | |

Notes:

[19] - All participants in the ITT set in steroid-free quiescence with evaluable data at a given timepoint.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants in Non-quiescence (With/Without Change in Concomitant Medications Within 5 Days and With/Without Quiescence at Next Visit at Least 8 Weeks After Non-quiescence) Among Participants With Inactive Uveitis at Study Start

| | |
|---|---|
| End point title | Percentage of Participants in Non-quiescence (With/Without Change in Concomitant Medications Within 5 Days and With/Without Quiescence at Next Visit at Least 8 Weeks After Non-quiescence) Among Participants With Inactive Uveitis at Study Start |

End point description:

Percentage of participants, without quiescence, with/without change in concomitant medications within 5 days after non-quiescence and with/without quiescence at next visit at least 8 weeks after non-quiescence among participants with inactive uveitis at study start. Quiescence is defined as no active inflammatory lesions and AC cell grade ≤ 0.5+ and VH grade ≤0.5+. Abbreviations used are as follows: CM=concomitant medications; NQ=non-quiescence.

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

End point timeframe:

366 Weeks

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 124[20] | | | |
| Units: Percentage of Participants | | | | |
| number (not applicable) | | | | |
| NQ With CM Change and quiescence at next visit | 10.5 | | | |
| NQ With CM Change and nonquiescence at next visit | 2.4 | | | |
| NQ Without CM Change and quiescence at next visit | 13.7 | | | |
| NQ Without CM Change and NQ at next visit | 8.9 | | | |
| NQ With Premature Discontinuation | 3.2 | | | |
| NQ And Completion | 0.8 | | | |

Notes:

[20] - ITT set: all with inactive uveitis at Week 0 in nonquiescence with evaluable data at given timepoint

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants in Non-quiescence (With/Without Change in Concomitant Medications Within 5 Days and With/Without Quiescence at Next Visit at Least 8 Weeks After Non-quiescence) Among Participants With Active Uveitis at Study Start

| End point title | Percentage of Participants in Non-quiescence (With/Without Change in Concomitant Medications Within 5 Days and With/Without Quiescence at Next Visit at Least 8 Weeks After Non-quiescence) Among Participants With Active Uveitis at Study Start |
|---|---|

End point description:

Percentage of participants, without quiescence, with/without change in concomitant medications within 5 days after non-quiescence and with/without quiescence at next visit at least 8 weeks after non-quiescence, among participants with active uveitis at study start. Quiescence is defined as no active inflammatory lesions and AC cell grade ≤ 0.5+ and VH grade ≤0.5+. Abbreviations used include: CM=concomitant medications, NQ=non-quiescence.

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

End point timeframe:

366 Weeks

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 240[21] | | | |
| Units: Percentage of Participants | | | | |
| number (not applicable) | | | | |
| NQ With CM Change and quiescence at next visit | 19.2 | | | |
| NQ With CM Change and nonquiescence at next visit | 10.8 | | | |
| NQ Without CM Change and quiescence at next visit | 15.0 | | | |
| NQ Without CM Change and NQ at next visit | 15.4 | | | |
| NQ With Premature Discontinuation | 6.7 | | | |
| NQ And Completion | 0.4 | | | |

Notes:

[21] - ITT set: all with active uveitis at Week 0 in nonquiescence with evaluable data at given timepoint

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Who Started Uveitis-related Systemic Corticosteroids During the Study

| End point title | Percentage of Participants Who Started Uveitis-related Systemic Corticosteroids During the Study |
|---|---|

End point description:

Percentage of participants who started uveitis-related systemic corticosteroids during the study.

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

End point timeframe:

366 Weeks

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 364[22] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Percentage of Participants | 20.3 (16.3 to 24.8) | | | |

Notes:

[22] - ITT set: all without systemic corticosteroids at baseline with evaluable data at a given timepoint

### Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Daily Dose in Milligrams (mg) of Uveitis-related Systemic Corticosteroids in Participants With Active Uveitis Over Time

| End point title | Mean Daily Dose in Milligrams (mg) of Uveitis-related Systemic Corticosteroids in Participants With Active Uveitis Over Time |
|---|---|

End point description:

Corticosteroid doses were converted into prednisone equivalents. Participants with uveitis-related systemic corticosteroid that could not be converted to prednisone equivalents were excluded. Individual mean daily doses were calculated within the respective visit windows. For Week 0, only uveitis-related systemic corticosteroids at Baseline (Day 1 for all participants) were considered. Baseline was defined as Week 0 for all participants. n=the number of participants at given time point.

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

End point timeframe:

Weeks 0, 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 235[23] | | | |
| Units: Milligrams | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 0 (n=235) | 13.6 (± 19.21) | | | |
| Week 2 (n=235) | 14.8 (± 17.12) | | | |
| Week 4 (n=230) | 10.1 (± 12.27) | | | |

| | | | | |
|---|---|---|---|---|
| Week 8 (n=227) | 7.3 (± 9.75) | | | |
| Week 12 (n=222) | 6.0 (± 9.34) | | | |
| Week 18 (n=216) | 5.1 (± 8.47) | | | |
| Week 30 (n=207) | 4.4 (± 7.12) | | | |
| Week 42 (n=196) | 3.5 (± 5.54) | | | |
| Week 54 (n=188) | 3.5 (± 6.71) | | | |
| Week 66 (n=179) | 3.1 (± 6.32) | | | |
| Week 78 (n=171) | 2.6 (± 5.10) | | | |
| Week 90 (n=164) | 2.2 (± 4.47) | | | |
| Week 102 (n=155) | 2.1 (± 4.80) | | | |
| Week 114 (n=148) | 1.8 (± 4.50) | | | |
| Week 126 (n=139) | 1.6 (± 4.16) | | | |
| Week 138 (n=132) | 2.2 (± 5.65) | | | |
| Week 150 (n=122) | 2.0 (± 4.49) | | | |
| Week 162 (n=115) | 1.9 (± 4.31) | | | |
| Week 174 (n=109) | 1.9 (± 4.46) | | | |
| Week 186 (n=96) | 1.6 (± 4.27) | | | |
| Week 198 (n=86) | 1.6 (± 4.05) | | | |
| Week 210 (n=74) | 1.4 (± 3.57) | | | |
| Week 222 (n=59) | 2.3 (± 8.48) | | | |
| Week 234 (n=42) | 1.1 (± 3.17) | | | |
| Week 246 (n=35) | 0.6 (± 1.69) | | | |

Notes:

[23] - ITT set: active uveitis, daily dose of uveitis-related systemic corticosteroids, and evaluable data

### Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Daily Dose (mg) of Uveitis-related Systemic Corticosteroids in Participants With Inactive Uveitis Over Time

| End point title | Mean Daily Dose (mg) of Uveitis-related Systemic Corticosteroids in Participants With Inactive Uveitis Over Time |
|---|---|

End point description:

Corticosteroid doses were converted into prednisone equivalents. Participants with uveitis-related systemic corticosteroid that could not be converted to prednisone equivalents were excluded. Individual mean daily doses were calculated within the respective visit windows. For Week 0, only uveitis-related systemic corticosteroids at Baseline (Day 1 for all participants) were considered. Baseline was defined as Week 0 for all participants. n=the number of participants at given time point. n=the number of participants at given time point.

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

End point timeframe:

Weeks 0, 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 124[24] | | | |
| Units: Milligrams | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 0 (n=124) | 1.5 (± 7.32) | | | |
| Week 2 (n=124) | 1.6 (± 6.65) | | | |
| Week 4 (n=123) | 1.4 (± 4.89) | | | |
| Week 8 (n=117) | 0.9 (± 3.41) | | | |
| Week 12 (n=115) | 0.9 (± 4.12) | | | |
| Week 18 (n=114) | 0.8 (± 3.29) | | | |
| Week 30 (n=113) | 0.7 (± 2.74) | | | |
| Week 42 (n=112) | 0.7 (± 2.64) | | | |
| Week 54 (n=108) | 1.8 (± 7.09) | | | |
| Week 66 (n=103) | 1.3 (± 5.32) | | | |
| Week 78 (n=99) | 1.1 (± 4.36) | | | |
| Week 90 (n=95) | 1.2 (± 4.54) | | | |
| Week 102 (n=91) | 0.6 (± 2.63) | | | |
| Week 114 (n=84) | 0.6 (± 2.67) | | | |
| Week 126 (n=77) | 0.7 (± 2.95) | | | |
| Week 138 (n=64) | 0.5 (± 2.09) | | | |
| Week 150 (n=59) | 0.5 (± 1.91) | | | |
| Week 162 (n=39) | 0.2 (± 1.00) | | | |
| Week 174 (n=34) | 0.2 (± 1.07) | | | |
| Week 186 (n= 31) | 0.3 (± 1.12) | | | |
| Week 198 (n=26) | 0.3 (± 1.23) | | | |
| Week 210 (n=16) | 0.4 (± 1.50) | | | |
| Week 222 (n=12) | 0.5 (± 1.73) | | | |
| Week 234 (n=9) | 0.5 (± 1.57) | | | |
| Week 246 (n=7) | 0.0 (± 0.00) | | | |

Notes:

[24] - ITT set: inactive uveitis, daily dose uveitis-related systemic corticosteroids, and evaluable data

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percent Change in Mean Daily Dose of Uveitis-related Systemic Corticosteroids Relative to Week 0 in Participants With Inactive Uveitis Using Systemic Corticosteroids at Week 0 Over Time

| End point title | Percent Change in Mean Daily Dose of Uveitis-related Systemic Corticosteroids Relative to Week 0 in Participants With Inactive Uveitis Using Systemic Corticosteroids at Week 0 Over Time |
|---|---|

End point description:

Corticosteroid doses were converted into prednisone equivalents. Participants with uveitis-related systemic corticosteroid that could not be converted to prednisone equivalents were excluded. Individual mean daily doses were calculated within the respective visit windows. For Week 0, only uveitis-related systemic corticosteroids at Baseline (Day 1 for all participants) were considered. Baseline was defined as Week 0 for all participants. Data not presented after Week 198 as no participants remained on study as of Week 198. n=the number of participants at given time point.

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

End point timeframe:

Weeks 0, 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, and 198

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 7[25] | | | |
| Units: Percent Change from Baseline | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 2 (n=7) | -11.8 (-21.6 to -2.1) | | | |
| Week 4 (n=7) | -46.6 (-64.2 to -29.0) | | | |
| Week 8 (n=7) | -64.5 (-88.1 to -40.8) | | | |
| Week 12 (n=7) | -29.7 (-91.5 to 32.1) | | | |
| Week 18 (n=7) | -30.8 (-128.4 to 66.7) | | | |
| Week 30 (n=6) | -25.0 (-159.6 to 109.5) | | | |
| Week 42 (n=6) | -36.7 (-150.4 to 76.9) | | | |
| Week 54 (n=5) | -11.9 (-186.2 to 162.5) | | | |
| Week 66 (n=5) | -25.1 (-156.9 to 106.6) | | | |
| Week 78 (n=5) | -28.3 (-157.9 to 101.2) | | | |
| Week 90 (n=5) | -27.5 (-162.6 to 107.6) | | | |
| Week 102 (n=4) | -78.1 (-120.7 to -35.4) | | | |
| Week 114 (n=4) | -84.2 (-96.8 to -67.2) | | | |
| Week 126 (n=4) | -88.9 (-113.9 to -63.9) | | | |
| Week 138 (n=2) | -95.9 (-148.4 to -43.3) | | | |
| Week 150 (n=2) | -99.5 (-106.3 to -92.7) | | | |
| Week 162 (n=1) | -100.0 (-100.0 to -100.0) | | | |
| Week 174 (n=1) | -100.0 (-100.0 to -100.0) | | | |
| Week 186 (n=1) | -100.0 (-100.0 to -100.0) | | | |
| Week 198 (n=1) | -100.0 (-100.0 to -100.0) | | | |

Notes:

[25] - ITT set who received systemic corticosteroids at Week 0 with evaluable data at a given timepoint

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percent Change in Mean Daily Dose of Uveitis-related Systemic

## Corticosteroids Relative to Week 0 in Participants With Active Uveitis Using Systemic Corticosteroids at Week 0 Over Time

| End point title | Percent Change in Mean Daily Dose of Uveitis-related Systemic Corticosteroids Relative to Week 0 in Participants With Active Uveitis Using Systemic Corticosteroids at Week 0 Over Time |
|---|---|

End point description:

Corticosteroid doses were converted into prednisone equivalents. Participants with uveitis-related systemic corticosteroid that could not be converted to prednisone equivalents were excluded. Individual mean daily doses were calculated within the respective visit windows. For Week 0, only uveitis-related systemic corticosteroids at Baseline (Day 1 for all participants) were considered. Baseline was defined as Week 0 for all participants. n=the number of participants at given time point.

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

End point timeframe:

Weeks 0, 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 114[26] | | | |
| Units: Percent Change from Baseline | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 2 (n=114) | -4.6 (-14.2 to 5.0) | | | |
| Week 4 (n=112) | -25.0 (-38.6 to -11.4) | | | |
| Week 8 (n=112) | -41.7 (-55.0 to -28.4) | | | |
| Week 12 (n=107) | -46.3 (-65.0 to -27.7) | | | |
| Week 18 (n=106) | -55.1 (-73.1 to -37.1) | | | |
| Week 30 (n=102) | -62.8 (-78.1 to -47.5) | | | |
| Week 42 (n=96) | -73.4 (-85.0 to -61.9) | | | |
| Week 54 (n=93) | -73.2 (-85.3 to -61.0) | | | |
| Week 66 (n=87) | -77.1 (-89.3 to -64.9) | | | |
| Week 78 (n=84) | -77.3 (-90.2 to -64.4) | | | |
| Week 90 (n=80) | -82.1 (-93.3 to -70.9) | | | |
| Week 102 (n=76) | -78.8 (-95.7 to -62.0) | | | |
| Week 114 (n=72) | -82.0 (-96.8 to -66.9) | | | |
| Week 126 (n=65) | -82.8 (-98.6 to -66.9) | | | |
| Week 138 (n=62) | -87.8 (-94.2 to -81.4) | | | |
| Week 150 (n=57) | -86.9 (-94.5 to -79.2) | | | |
| Week 162 (n=55) | -90.7 (-94.9 to -86.4) | | | |

| | | | | |
|---|---|---|---|---|
| Week 174 (n=52) | -91.4 (-95.8 to -86.9) | | | |
| Week 186 (n=47) | -90.3 (-95.9 to -84.7) | | | |
| Week 198 (n=42) | -91.0 (-96.6 to -85.5) | | | |
| Week 210 (n=38) | -89.9 (-96.8 to -82.9) | | | |
| Week 222 (n=30) | -87.1 (-102.0 to -72.2) | | | |
| Week 234 (n=20) | -93.8 (-103.8 to -83.9) | | | |
| Week 246 (n=18) | -98.3 (-101.3 to -95.4) | | | |

Notes:

[26] - ITT set who received systemic corticosteroids at Week 0 with evaluable data at a given timepoint

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Not Using Systemic Corticosteroids Over Time

| End point title | Percentage of Participants Not Using Systemic Corticosteroids Over Time |
|---|---|

End point description:

Corticosteroid doses were converted into prednisone equivalents. Participants with uveitis-related systemic corticosteroid that could not be converted to prednisone equivalents were excluded. Individual mean daily doses were calculated within the respective visit windows. For Week 0, only uveitis-related systemic corticosteroids at Baseline (Day 1 for all participants) were considered. Baseline was defined as Week 0 for all participants. Data presented for participants not using systemic corticosteroids at each timepoint. n=the number of participants at given time point.

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

End point timeframe:

Weeks 0, 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 359[27] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 0 (n=359) | 66.3 (61.1 to 71.2) | | | |
| Week 2 (n=358) | 58.7 (53.4 to 63.8) | | | |
| Week 4 (n=349) | 60.2 (54.8 to 65.3) | | | |
| Week 8 (n=339) | 61.9 (56.5 to 67.1) | | | |
| Week 12 (n=334) | 64.7 (59.3 to 69.8) | | | |
| Week 18 (n=328) | 68.3 (63.0 to 73.3) | | | |
| Week 30 (n=312) | 70.2 (64.8 to 75.2) | | | |

| | | | | |
|---|---|---|---|---|
| Week 42 (n=306) | 70.9 (65.5 to 75.9) | | | |
| Week 54 (n=292) | 71.9 (66.4 to 77.0) | | | |
| Week 66 (n=275) | 73.1 (67.4 to 78.2) | | | |
| Week 78 (n=266) | 75.2 (69.5 to 80.3) | | | |
| Week 90 (n=257) | 77.0 (71.4 to 82.0) | | | |
| Week 102 (n=239) | 80.8 (75.2 to 85.6) | | | |
| Week 114 (n=225) | 83.6 (78.1 to 88.1) | | | |
| Week 126 (n=209) | 84.2 (78.5 to 88.9) | | | |
| Week 138 (n=190) | 82.1 (75.9 to 87.3) | | | |
| Week 150 (n= 173) | 81.5 (74.9 to 87.0) | | | |
| Week 162 (n=149) | 80.5 (73.3 to 86.6) | | | |
| Week 174 (n=136) | 79.4 (71.6 to 85.9) | | | |
| Week 186 (n=123) | 80.5 (72.4 to 87.1) | | | |
| Week 198 (n=97) | 80.4 (71.1 to 87.8) | | | |
| Week 210 (n=82) | 81.7 (71.6 to 89.4) | | | |
| Week 222 (n=59) | 86.4 (75.0 to 94.0) | | | |
| Week 234 (n=48) | 89.6 (77.3 to 96.5) | | | |
| Week 246 (n=34) | 94.1 (80.3 to 99.3) | | | |

Notes:

[27] - All participants in the ITT analysis set with evaluable data at each timepoint.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Without Worsening of Best Corrected Visual Acuity (BCVA) by ≥15 Letters on Early Treatment Diabetic Retinopathy Study (ETDRS) in Both Eyes Relative to Baseline Over Time Among Participants Who Had Inactive Uveitis at Study Entry

| | |
|---|---|
| End point title | Percentage of Participants Without Worsening of Best Corrected Visual Acuity (BCVA) by ≥15 Letters on Early Treatment Diabetic Retinopathy Study (ETDRS) in Both Eyes Relative to Baseline Over Time Among Participants Who Had Inactive Uveitis at Study Entry |

End point description:

Percentage of participants at each study time point without a worsening of Best Corrected Visual Acuity (BCVA) by ≥15 letters on the Early Treatment Diabetic Retinopathy Study (ETDRS) in both eyes relative to Baseline for participants who had inactive uveitis when they entered the study. n=the number of participants at given time point.

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

End point timeframe:

Weeks 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222,

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 124[28] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 (n=118) | 100 (96.9 to 100) | | | |
| Week 4 (n=108) | 99.1 (94.9 to 100) | | | |
| Week 8 (n=113) | 100 (96.8 to 100) | | | |
| Week 12 (n=112) | 100 (96.8 to 100) | | | |
| Week 18 (n=112) | 100 (96.8 to 100) | | | |
| Week 30 (n=112) | 99.1 (95.1 to 100) | | | |
| Week 42 (n=112) | 98.2 (93.7 to 99.8) | | | |
| Week 54 (n=107) | 97.2 (92.0 to 99.4) | | | |
| Week 66 (n=103) | 98.1 (93.2 to 99.8) | | | |
| Week 78 (n=99) | 97.0 (91.4 to 99.4) | | | |
| Week 90 (n=95) | 98.9 (94.3 to 100) | | | |
| Week 102 (n=89) | 97.8 (92.1 to 99.7) | | | |
| Week 114 (n=84) | 97.6 (91.7 to 99.7) | | | |
| Week 126 (n=76) | 96.1 (88.9 to 99.2) | | | |
| Week 138 (n=64) | 96.9 (89.2 to 99.6) | | | |
| Week 150 (n=57) | 100 (93.7 to 100) | | | |
| Week 162 (n=39) | 100 (91.0 to 100) | | | |
| Week 174 (n=34) | 100 (89.7 to 100) | | | |
| Week 186 (n=31) | 100 (88.8 to 100) | | | |
| Week 198 (n=26) | 100 (86.8 to 100) | | | |
| Week 210 (n=16) | 100 (79.4 to 100) | | | |
| Week 222 (n=12) | 91.7 (61.5 to 99.8) | | | |
| Week 234 (n=9) | 88.9 (51.8 to 99.7) | | | |
| Week 246 (n=7) | 85.7 (42.1 to 99.6) | | | |

Notes:

[28] - All participants in the ITT analysis set with evaluable data at each timepoint.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Without Worsening of BCVA by ≥15 Letters on the ETDRS in Both Eyes Relative to Week 8 Over Time Among Participants With Active Uveitis at Study Entry

| End point title | Percentage of Participants Without Worsening of BCVA by ≥15 Letters on the ETDRS in Both Eyes Relative to Week 8 Over Time Among Participants With Active Uveitis at Study Entry |
|---|---|

End point description:

Percentage of participants at each study time point without a worsening of BCVA by ≥15 letters on the ETDRS in both eyes relative to Week 8 for participant who had active uveitis when they entered the study. n=the number of participants at given time point.

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

End point timeframe:

Weeks 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 222[29] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 12 (n=219) | 96.8 (93.5 to 98.7) | | | |
| Week 18 (n=214) | 96.3 (92.8 to 98.4) | | | |
| Week 30 (n=206) | 96.6 (93.1 to 98.6) | | | |
| Week 42 (n=196) | 94.9 (90.8 to 97.5) | | | |
| Week 54 (n=188) | 94.7 (90.4 to 97.4) | | | |
| Week 66 (n=179) | 93.3 (88.6 to 96.5) | | | |
| Week 78 (n=172) | 93.6 (88.8 to 96.8) | | | |
| Week 90 (n=165) | 96.4 (92.3 to 98.7) | | | |
| Week 102 (n=153) | 94.8 (90.0 to 97.7) | | | |
| Week 114 (n=146) | 93.8 (88.6 to 97.1) | | | |
| Week 126 (n=140) | 95.0 (90.0 to 98.0) | | | |
| Week 138 (n=131) | 93.9 (88.3 to 97.3) | | | |

| | | | | |
|---|---|---|---|---|
| Week 150 (n=123) | 92.7 (86.6 to 96.6) | | | |
| Week 162 (n=114) | 93.9 (87.8 to 97.5) | | | |
| Week 174 (n=107) | 91.6 (84.6 to 96.1) | | | |
| Week 186 (n=96) | 92.7 (85.6 to 97.0) | | | |
| Week 198 (n=86) | 95.3 (88.5 to 98.7) | | | |
| Week 210 (n=71) | 95.8 (88.1 to 99.1) | | | |
| Week 222 (n=58) | 96.6 (88.1 to 99.6) | | | |
| Week 234 (n=42) | 95.2 (83.8 to 99.4) | | | |
| Week 246 (n=34) | 91.2 (76.3 to 98.1) | | | |

Notes:

[29] - All participants in the ITT analysis set with evaluable data at each timepoint

### Statistical analyses

No statistical analyses for this end point

## Secondary: Mean of Both Eyes of the Logarithm of the Minimum Angle of Resolution (LogMAR) BCVA Over Time

| End point title | Mean of Both Eyes of the Logarithm of the Minimum Angle of Resolution (LogMAR) BCVA Over Time |
|---|---|

End point description:

Using corrective lenses based on that visit's refraction testing, participant's BCVA was measured using an ETDRS logMAR chart. On the logMAR scale, 0 is equivalent to 20/20 visual acuity, the range of normal vision is considered to be from -0.2 to 0.1; higher values indicate visual impairment. Data presented includes the mean of both eyes for all participants (active or inactive uveitis) for all study time points. n=the number of participants at given time point.

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

End point timeframe:

Weeks 0, 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 364[30] | | | |
| Units: Log (Mar) BCVA Both Eyes | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 0 (n=364) | 0.20 (± 0.275) | | | |
| Week 2 (n=348) | 0.17 (± 0.265) | | | |
| Week 4 (n=325) | 0.15 (± 0.248) | | | |
| Week 8 (n=342) | 0.14 (± 0.247) | | | |
| Week 12 (n=333) | 0.13 (± 0.244) | | | |
| Week 18 (n=329) | 0.12 (± 0.240) | | | |
| Week 30 (n=319) | 0.12 (± 0.249) | | | |
| Week 42 (n=309) | 0.12 (± 0.227) | | | |

| | | | | |
|---|---|---|---|---|
| Week 54 (n=296) | 0.11 (± 0.238) | | | |
| Week 66 (n=284) | 0.11 (± 0.241) | | | |
| Week 78 (n=272) | 0.11 (± 0.238) | | | |
| Week 90 (n=261) | 0.90 (± 0.214) | | | |
| Week 102 (n=244) | 0.90 (± 0.219) | | | |
| Week 114 (n=231) | 0.90 (± 0.233) | | | |
| Week 126 (n=217) | 0.90 (± 0.231) | | | |
| Week 138 (n=197) | 0.90 (± 0.224) | | | |
| Week 150 (n=181) | 0.10 (± 0.255) | | | |
| Week 162 (n=154) | 0.90 (± 0.249) | | | |
| Week 174 (n=142) | 0.90 (± 0.261) | | | |
| Week 186 (n=128) | 0.90 (± 0.244) | | | |
| Week 198 (n=113) | 0.70 (± 0.205) | | | |
| Week 210 (n=88) | 0.70 (± 0.211) | | | |
| Week 222 (n=71) | 0.70 (± 0.218) | | | |
| Week 234 (n=51) | 0.70 (± 0.222) | | | |
| Week 246 (n=41) | 0.80 (± 0.217) | | | |

Notes:

[30] - All participants in the ITT analysis set with evaluable data at each study timepoint.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percent Change in Left Eye in Central Retinal Thickness (1 mm Subfield) From Baseline to Each Study Time Point Relative to Baseline for Participants Who Had Inactive Uveitis at Study Entry Over Time

| | |
|---|---|
| End point title | Percent Change in Left Eye in Central Retinal Thickness (1 mm Subfield) From Baseline to Each Study Time Point Relative to Baseline for Participants Who Had Inactive Uveitis at Study Entry Over Time |

End point description:

Central retinal thickness was measured using optical coherence tomography (OCT) and assessed by a central reader. Percent change in left eye from baseline (Week 0) to each study time point relative to baseline for participants who had inactive uveitis at study entry is presented. n=the number of participants at given time point.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 111[31] | | | |
| Units: Percent Change from Baseline | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 2 (n=111) | 0.3 (-1.41 to 1.97) | | | |
| Week 4 (n=100) | -0.2 (-2.03 to 1.56) | | | |

| | | | | |
|---|---|---|---|---|
| Week 8 (n=106) | -0.7 (-2.07 to 0.72) | | | |
| Week 12 (n=105) | -1.0 (-2.27 to 0.23) | | | |
| Week 18 (n=105) | -0.5 (-2.02 to 1.07) | | | |
| Week 30 (n=104) | -1.9 (-3.25 to -0.60) | | | |
| Week 42 (n=103) | -1.3 (-2.83 to 0.17) | | | |
| Week 54 (n=101) | -2.1 (-3.90 to -0.22) | | | |
| Week 66 (n=96) | -1.9 (-3.95 to 0.11) | | | |
| Week 78 (n=88) | -1.4 (-4.54 to 1.70) | | | |
| Week 90 (n=85) | -2.9 (-4.51 to -1.22) | | | |
| Week 102 (n=82) | -3.1 (-4.95 to -1.34) | | | |
| Week 114 (n=75) | -2.8 (-4.44 to -1.14) | | | |
| Week 126 (n=67) | -3.7 (-5.66 to -1.68) | | | |
| Week 138 (n=58) | -3.4 (-5.38 to -1.46) | | | |
| Week 150 (n=52) | -3.5 (-5.48 to -1.58) | | | |
| Week 162 (n=32) | -3.3 (-6.25 to -0.29) | | | |
| Week 174 (n=29) | -3.0 (-5.45 to -0.52) | | | |
| Week 186 (n=27) | -3.8 (-6.69 to -1.00) | | | |
| Week 198 (n=23) | -3.2 (-5.99 to -0.35) | | | |
| Week 210 (n=13) | -5.2 (-10.23 to -0.17) | | | |
| Week 222 (n=10) | -4.6 (-11.17 to 1.93) | | | |
| Week 234 (n=8) | -3.6 (-13.06 to 5.77) | | | |
| Week 246 (n=6) | -3.4 (-14.83 to 7.93) | | | |

Notes:

[31] - All participants in the ITT analysis set with evaluable data at each timepoint.

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percent Change in Right Eye in Central Retinal Thickness (1 mm Subfield) From Baseline to Each Study Time Point Relative to Baseline for Participants Who Had Inactive Uveitis at Study Entry Over Time

| | |
|---|---|
| End point title | Percent Change in Right Eye in Central Retinal Thickness (1 mm Subfield) From Baseline to Each Study Time Point Relative to Baseline for Participants Who Had Inactive Uveitis at Study Entry Over Time |

End point description:

Central retinal thickness was measured using optical coherence tomography (OCT) and assessed by a

central reader. Percent change in right eye from baseline (Week 0) to each study time point relative to baseline for participants who had inactive uveitis at study entry is presented. n=the number of participants at given time point.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Baseline (Week 0) and Weeks 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 109[32] | | | |
| Units: Percent Change from Baseline | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 2 (n=109) | -0.2 (-1.92 to 1.45) | | | |
| Week 4 (n=99) | -0.8 (-2.99 to 1.39) | | | |
| Week 8 (n=104) | -1.5 (-3.19 to 0.25) | | | |
| Week 12 (n=103) | -1.0 (-2.76 to 0.66) | | | |
| Week 18 (n=103) | -0.4 (-2.73 to 1.84) | | | |
| Week 30 (n=102) | -2.8 (-4.78 to -0.86) | | | |
| Week 42 (n=101) | -2.2 (-4.31 to -0.15) | | | |
| Week 54 (n=99) | -3.7 (-6.00 to -1.44) | | | |
| Week 66 (n=94) | -3.3 (-5.66 to -0.97) | | | |
| Week 78 (n=86) | -3.9 (-6.36 to -1.38) | | | |
| Week 90 (n=83) | -3.8 (-6.47 to -1.08) | | | |
| Week 102 (n=80) | -5.3 (-7.99 to -2.67) | | | |
| Week 114 (n=73) | -5.6 (-8.65 to -2.53) | | | |
| Week 126 (n=65) | -5.4 (-8.57 to -2.21) | | | |
| Week 138 (n=56) | -4.7 (-7.75 to -1.72) | | | |
| Week 150 (n=51) | -2.1 (-9.07 to 4.90) | | | |
| Week 162 (n=32) | -2.9 (-6.06 to 0.36) | | | |
| Week 174 (n=29) | -2.7 (-5.88 to 0.56) | | | |
| Week 186 (n=27) | -2.0 (-5.49 to 1.46) | | | |
| Week 198 (n=23) | -1.2 (-5.91 to 3.48) | | | |
| Week 210 (n=13) | -2.3 (-6.35 to 1.66) | | | |

| | | | | |
|---|---|---|---|---|
| Week 222 (n=10) | -1.7 (-4.76 to 1.44) | | | |
| Week 234 (n=8) | -1.3 (-6.32 to 3.78) | | | |
| Week 246 (n=6) | 1.6 (-0.78 to 3.93) | | | |

Notes:

[32] - All participants in the ITT analysis set with evaluable data at each timepoint.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percent Change in Left Eye of Central Retinal Thickness (1 mm Subfield) at Each Study Time Point Relative to Week 8 for Participants Who Had Active Uveitis at Study Entry Over Time

| | |
|---|---|
| End point title | Percent Change in Left Eye of Central Retinal Thickness (1 mm Subfield) at Each Study Time Point Relative to Week 8 for Participants Who Had Active Uveitis at Study Entry Over Time |

End point description:

Central retinal thickness was measured using OCT and assessed by a central reader. Percent change in left eye at each study time point relative to Week 8 (baseline) for participants who had active uveitis at study entry is presented. n=the number of participants at given time point.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

Baseline (Week 8) and Weeks 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 206[33] | | | |
| Units: Percent Change from Baseline | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 12 (n=206) | 1.0 (-0.50 to 2.42) | | | |
| Week 18 (n=201) | -0.3 (-2.36 to 1.71) | | | |
| Week 30 (n=194) | -2.4 (-4.24 to -0.55) | | | |
| Week 42 (n=183) | -2.8 (-4.62 to -1.00) | | | |
| Week 54 (n=177) | -3.2 (-5.52 to -0.90) | | | |
| Week 66 (n=166) | -2.3 (-4.52 to 0.01) | | | |
| Week 78 (n=161) | -3.5 (-5.99 to -1.02) | | | |
| Week 90 (n=150) | -4.8 (-7.19 to -2.42) | | | |
| Week 102 (n=142) | -5.3 (-7.41 to -3.10) | | | |
| Week 114 (n=126) | -6.6 (-9.15 to -3.95) | | | |

| | | | | |
|---|---|---|---|---|
| Week 126 (n=124) | -5.3 (-8.66 to -1.92) | | | |
| Week 138 (n=118) | -7.0 (-9.96 to -3.99) | | | |
| Week 150 (n=109) | -7.3 (-10.22 to -4.48) | | | |
| Week 162 (n=104) | -7.5 (-11.31 to -3.72) | | | |
| Week 174 (n=92) | -9.5 (-13.20 to -5.81) | | | |
| Week 186 (n=83) | -7.6 (-10.21 to -4.93) | | | |
| Week 198 (n=74) | -8.4 (-11.84 to -4.99) | | | |
| Week 210 (n=67) | -6.6 (-10.40 to -2.74) | | | |
| Week 222 (n=53) | -9.3 (-13.42 to -5.17) | | | |
| Week 234 (n=39) | -8.2 (-11.85 to -4.46) | | | |
| Week 246 (n=32) | -9.1 (-13.41 to -4.82) | | | |

Notes:

[33] - All participants in the ITT analysis set with evaluable data at each timepoint.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percent Change in Right Eye of Central Retinal Thickness (1 mm Subfield) at Each Study Time Point Relative to Week 8 for Participants Who Had Active Uveitis at Study Entry Over Time

| | |
|---|---|
| End point title | Percent Change in Right Eye of Central Retinal Thickness (1 mm Subfield) at Each Study Time Point Relative to Week 8 for Participants Who Had Active Uveitis at Study Entry Over Time |

End point description:

Central retinal thickness was measured using OCT and assessed by a central reader. Percent change in right eye at each study time point relative to Week 8 (baseline) for participants who had active uveitis at study entry is presented. n=the number of participants at given time point.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

Baseline (Week 8) and Weeks 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 205[34] | | | |
| Units: Percent Change from Baseline | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 12 (n=205) | 0.4 (-1.58 to 2.47) | | | |
| Week 18 (n=202) | -0.7 (-2.71 to 1.30) | | | |

| | | | | |
|---|---|---|---|---|
| Week 30 (n=194) | -0.7 (-3.36 to 1.90) | | | |
| Week 42 (n=183) | -2.4 (-4.85 to 0.05) | | | |
| Week 54 (n=176) | -2.4 (-5.25 to 0.36) | | | |
| Week 66 (n=167) | -1.3 (-4.81 to 2.27) | | | |
| Week 78 (n=160) | -2.1 (-5.61 to 1.50) | | | |
| Week 90 (n=149) | -3.6 (-6.44 to -0.76) | | | |
| Week 102 (n=142) | -3.4 (-6.98 to 0.13) | | | |
| Week 114 (n=125) | -2.2 (-6.18 to 1.81) | | | |
| Week 126 (n=124) | -3.5 (-7.43 to 0.47) | | | |
| Week 138 (n=118) | -4.6 (-8.22 to -0.92) | | | |
| Week 150 (n=109) | -6.5 (-9.81 to -3.15) | | | |
| Week 162 (n=104) | -4.8 (-8.91 to -0.75) | | | |
| Week 174 (n=93) | -5.4 (-9.46 to -1.27) | | | |
| Week 186 (n=83) | -7.9 (-12.74 to -3.03) | | | |
| Week 198 (n=75) | -8.2 (-12.30 to -4.13) | | | |
| Week 210 (n=67) | -6.6 (-10.76 to -2.43) | | | |
| Week 222 (n=52) | -9.7 (-13.24 to -6.19) | | | |
| Week 234 (n=39) | -9.7 (-14.24 to -5.07) | | | |
| Week 246 (n=32) | -9.9 (-15.43 to -4.35) | | | |

Notes:

[34] - All participants in the ITT analysis set with evaluable data at each timepoint.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Participants With Grade ≤0.5+ in Anterior Chamber (AC) Cells in Both Eyes on Slit Lamp Exam According to Standardization of Uveitis Nomenclature (SUN) Criteria Over Time

| | |
|---|---|
| End point title | Percentage of Participants With Grade ≤0.5+ in Anterior Chamber (AC) Cells in Both Eyes on Slit Lamp Exam According to Standardization of Uveitis Nomenclature (SUN) Criteria Over Time |

End point description:

Slit lamp examinations were conducted at each visit to assess AC cell count. The number of AC cells observed within a 1 mm * 1 mm slit beam was used to determine the grade according to the Standardization of Uveitis Nomenclature (SUN) criteria: Grade 0:  1 cell; Grade 0.5+: 1 - 5 cells; Grade 1+: 6 - 15 cells; Grade 2+: 16 - 25 cells; Grade 3+: 26 - 50 cells; and Grade 4+: ≥ 50 cells. n=the number of participants at given time point.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 364[35] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 0 (n=364) | 65.4 (60.3 to 70.3) | | | |
| Week 2 (n=348) | 85.9 (81.8 to 89.4) | | | |
| Week 4 (n=323) | 90.4 (86.7 to 93.4) | | | |
| Week 8 (n=343) | 91.5 (88.1 to 94.3) | | | |
| Week 12 (n=333) | 91.3 (87.7 to 94.1) | | | |
| Week 18 (n=330) | 90.9 (87.3 to 93.8) | | | |
| Week 30 (n=319) | 94.7 (91.6 to 96.9) | | | |
| Week 42 (n=310) | 92.3 (88.7 to 95.0) | | | |
| Week 54 (n=296) | 92.9 (89.4 to 95.6) | | | |
| Week 66 (n=284) | 95.1 (91.9 to 97.3) | | | |
| Week 78 (n=272) | 93.0 (89.3 to 95.7) | | | |
| Week 90 (n=261) | 94.4 (90.7 to 96.7) | | | |
| Week 102 (n=245) | 93.5 (89.6 to 96.2) | | | |
| Week 114 (n=231) | 93.5 (89.5 to 96.3) | | | |
| Week 126 (n=217) | 94.0 (90.0 to 96.8) | | | |
| Week 138 (n=197) | 93.4 (89.0 to 96.4) | | | |
| Week 150 (n=181) | 94.5 (90.1 to 97.3) | | | |
| Week 162 (n=154) | 95.5 (90.9 to 98.2) | | | |
| Week 174 (n=142) | 94.4 (89.2 to 97.5) | | | |
| Week 186 (n=128) | 96.1 (91.1 to 98.7) | | | |
| Week 198 (n=113) | 94.7 (88.8 to 98.0) | | | |
| Week 210 (n=89) | 96.6 (90.5 to 99.3) | | | |
| Week 222 (n=71) | 98.6 (92.4 to 100) | | | |
| Week 234 (n=51) | 100 (93.0 to 100) | | | |

| | | | | |
|---|---|---|---|---|
| Week 246 (n=42) | 95.2 (83.8 to 99.4) | | | |

Notes:

[35] - All participants in the ITT analysis set with evaluable data at each timepoint.

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Participants Achieving a ≥50% Reduction in Immunosuppression Load Relative to Baseline Over Time Among Participants With Inactive Uveitis at Study Entry

| | |
|---|---|
| End point title | Percentage of Participants Achieving a ≥50% Reduction in Immunosuppression Load Relative to Baseline Over Time Among Participants With Inactive Uveitis at Study Entry |

End point description:

Immunosuppression load was assessed using a weighted semiquantitative scale, applying grades ranging from 0 to 9 for each immunosuppressive agent on a scale for the total daily dose in milligrams per kilogram per day or per week if dosed weekly. A higher score indicating a higher immunosuppression load and a lower or decreased score indicated improvement or less need for immunosuppressive therapy. The grading scheme was used to accommodate the simultaneous use of multiple agents and provided a combined, single numeric score for the total immunosuppression load per unit body weight per day at each visit. For participants receiving multiple medications, the sum of the grading scores for each drug was used to calculate a total immunosuppression score at each visit. Data not presented after Week 234 as no participants remained on study as of Week 234. n=the number of participants at given time point.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

Weeks 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, and 234

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 55[36] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 (n=55) | 3.6 (0.4 to 12.5) | | | |
| Week 4 (n=55) | 9.1 (3.0 to 20.0) | | | |
| Week 8 (n=52) | 17.3 (8.2 to 30.3) | | | |
| Week 12 (n=52) | 17.3 (8.2 to 30.3) | | | |
| Week 18 (n=51) | 21.6 (11.3 to 35.3) | | | |
| Week 30 (n=49) | 24.5 (13.3 to 38.9) | | | |
| Week 42 (n=48) | 22.9 (12.0 to 37.3) | | | |
| Week 54 (n=45) | 17.8 (8.0 to 32.1) | | | |
| Week 66 (n=40) | 15.0 (5.7 to 29.8) | | | |

| | | | | |
|---|---|---|---|---|
| Week 78 (n=40) | 15.0 (5.7 to 29.8) | | | |
| Week 90 (n=37) | 13.5 (4.5 to 28.8) | | | |
| Week 102 (n=34) | 14.7 (5.0 to 31.1) | | | |
| Week 114 (n=32) | 25.0 (11.5 to 43.4) | | | |
| Week 126 (n=28) | 25.0 (10.7 to 44.9) | | | |
| Week 138 (n=24) | 25.0 (9.8 to 46.7) | | | |
| Week 150 (n=21) | 23.8 (8.2 to 47.2) | | | |
| Week 162 (n=16) | 18.8 (4.0 to 45.6) | | | |
| Week 174 (n=16) | 12.5 (1.6 to 38.3) | | | |
| Week 186 (n=16) | 12.5 (1.6 to 38.3) | | | |
| Week 198 (n=10) | 0 (0 to 0) | | | |
| Week 210 (n=8) | 12.5 (0.3 to 52.7) | | | |
| Week 222 (n=4) | 25.0 (0.6 to 80.6) | | | |
| Week 234 (n=4) | 50.0 (6.8 to 93.2) | | | |

Notes:

[36] - ITT set with immunosuppression load 0 at baseline (Week 0) with evaluable data at each timepoint

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Participants Achieving a ≥50% Reduction in Immunosuppression Load Relative to Week 8 Over Time Among Participants With Active Uveitis at Study Entry

| | |
|---|---|
| End point title | Percentage of Participants Achieving a ≥50% Reduction in Immunosuppression Load Relative to Week 8 Over Time Among Participants With Active Uveitis at Study Entry |

End point description:

Immunosuppression load was assessed using a weighted semiquantitative scale, applying grades ranging from 0 to 9 for each immunosuppressive agent on a scale for the total daily dose in milligrams per kilogram per day or per week if dosed weekly. A higher score indicating a higher immunosuppression load and a lower or decreased score indicated improvement or less need for immunosuppressive therapy. The grading scheme was used to accommodate the simultaneous use of multiple agents and provided a combined, single numeric score for the total immunosuppression load per unit body weight per day at each visit. For participants receiving multiple medications, the sum of the grading scores for each drug was used to calculate a total immunosuppression score at each visit. n=the number of participants at given time point.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

Weeks 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 140[37] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 12 (n=140) | 17.1 (11.3 to 24.4) | | | |
| Week 18 (n=136) | 27.2 (19.9 to 35.5) | | | |
| Week 30 (n=128) | 33.6 (25.5 to 42.5) | | | |
| Week 42 (n=125) | 41.6 (32.9 to 50.8) | | | |
| Week 54 (n=119) | 44.5 (35.4 to 53.9) | | | |
| Week 66 (n=113) | 48.7 (39.2 to 58.3) | | | |
| Week 78 (n=109) | 48.6 (38.9 to 58.4) | | | |
| Week 90 (n=106) | 53.8 (43.8 to 63.5) | | | |
| Week 102 (n=98) | 54.1 (43.7 to 64.2) | | | |
| Week 114 (n=90) | 51.1 (40.3 to 61.8) | | | |
| Week 126 (n=87) | 52.9 (41.9 to 63.7) | | | |
| Week 138 (n=80) | 52.5 (41.0 to 63.8) | | | |
| Week 150 (n=76) | 53.9 (42.1 to 65.5) | | | |
| Week 162 (n=71) | 53.5 (41.3 to 65.5) | | | |
| Week 174 (n=63) | 55.6 (42.5 to 68.1) | | | |
| Week 186 (n=59) | 55.9 (42.4 to 68.8) | | | |
| Week 198 (n=50) | 52.0 (37.4 to 66.3) | | | |
| Week 210 (n=41) | 51.2 (35.1 to 67.1) | | | |
| Week 222 (n=31) | 54.8 (36.0 to 72.7) | | | |
| Week 234 (n=23) | 56.5 (34.5 to 76.8) | | | |
| Week 246 (n=19) | 63.2 (38.4 to 83.7) | | | |

Notes:

[37] - ITT set with immunosuppression load 0 at baseline (Week 8) with evaluable data at each timepoint

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Participants With No New Active, Inflammatory Chorioretinal or Inflammatory Retinal Vascular Lesion in Both Eyes Relative to Baseline Over Time Among Participants With Inactive Uveitis at Study Entry

| End point title | Percentage of Participants With No New Active, Inflammatory |
|---|---|

| | Chorioretinal or Inflammatory Retinal Vascular Lesion in Both Eyes Relative to Baseline Over Time Among Participants With Inactive Uveitis at Study Entry |
|---|---|

End point description:

Percentage of participants at each study time point with no new active, inflammatory chorioretinal or inflammatory retinal vascular lesion in both eyes relative to Baseline for participants who had inactive uveitis when they entered the study. n=the number of participants at given time point.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Weeks 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 124[38] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 (n=118) | 100 (96.9 to 100) | | | |
| Week 4 (n=107) | 99.1 (94.9 to 100) | | | |
| Week 8 (n=113) | 100 (96.8 to 100) | | | |
| Week 12 (n=112) | 100 (96.8 to 100) | | | |
| Week 18 (n=112) | 98.2 (93.7 to 99.8) | | | |
| Week 30 (n=112) | 100 (96.8 to 100) | | | |
| Week 42 (n=112) | 98.2 (93.7 to 99.8) | | | |
| Week 54 (n=107) | 99.1 (94.9 to 100) | | | |
| Week 66 (n=103) | 100 (96.5 to 100) | | | |
| Week 78 (n=99) | 100 (96.3 to 100) | | | |
| Week 90 (n=95) | 98.9 (94.3 to 100) | | | |
| Week 102 (n=89) | 98.9 (93.9 to 100) | | | |
| Week 114 (n=84) | 100 (95.7 to 100) | | | |
| Week 126 (n=75) | 100 (95.2 to 100) | | | |
| Week 138 (n=64) | 98.4 (91.6 to 100) | | | |
| Week 150 (n=57) | 96.5 (87.9 to 99.6) | | | |
| Week 162 (n=39) | 97.4 (86.5 to 99.9) | | | |
| Week 174 (n=34) | 100 (89.7 to 100) | | | |
| Week 186 (n=31) | 100 (88.8 to 100) | | | |
| Week 198 (n=26) | 100 (86.8 to 100) | | | |

| | | | | |
|---|---|---|---|---|
| Week 210 (n=16) | 100 (79.4 to 100) | | | |
| Week 222 (n=12) | 100 (73.5 to 100) | | | |
| Week 234 (n=9) | 100 (66.4 to 100) | | | |
| Week 246 (n=7) | 100 (59.0 to 100) | | | |

Notes:

[38] - All participants in the ITT analysis set that had evaluable data at each timepoint.

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Participants With No New Active, Inflammatory Chorioretinal or Inflammatory Retinal Vascular Lesion in Both Eyes Relative to Week 8 Over Time Among Participants With Active Uveitis at Study Entry

| | |
|---|---|
| End point title | Percentage of Participants With No New Active, Inflammatory Chorioretinal or Inflammatory Retinal Vascular Lesion in Both Eyes Relative to Week 8 Over Time Among Participants With Active Uveitis at Study Entry |

End point description:

Percentage of participants at each study time point with no new active, inflammatory chorioretinal or inflammatory retinal vascular lesion in both eyes relative to Week 8 for participants who had active uveitis when they entered the study. n=the number of participants at given time point.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

Weeks 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 225[39] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 12 (n=221) | 97.7 (94.8 to 99.3) | | | |
| Week 18 (n=218) | 99.1 (96.7 to 99.9) | | | |
| Week 30 (n=207) | 97.1 (93.8 to 98.9) | | | |
| Week 42 (n=198) | 99.0 (96.4 to 99.9) | | | |
| Week 54 (n=188) | 98.9 (96.2 to 99.9) | | | |
| Week 66 (n=181) | 98.3 (95.2 to 99.7) | | | |
| Week 78 (n=173) | 97.7 (94.2 to 99.4) | | | |
| Week 90 (n=166) | 97.6 (93.9 to 99.3) | | | |
| Week102 (n=156) | 99.4 (96.5 to 100) | | | |

| | | | | |
|---|---|---|---|---|
| Week 114 (n=147) | 97.3 (93.2 to 99.3) | | | |
| Week 126 (n=140) | 99.3 (96.1 to 100) | | | |
| Week 138 (n=132) | 100 (97.2 to 100) | | | |
| Week 150 (n=123) | 96.7 (91.9 to 99.1) | | | |
| Week 162 (n=115) | 97.4 (92.6 to 99.5) | | | |
| Week 174 (n=108) | 100 (96.6 to 100) | | | |
| Week 186 (n=97) | 99.0 (94.4 to 100) | | | |
| Week 198 (n=87) | 100 (95.8 to 100) | | | |
| Week 210 (n=73) | 100 (95.1 to 100) | | | |
| Week 222 (n=59) | 100 (93.9 to 100) | | | |
| Week 234 (n=42) | 100 (91.6 to 100) | | | |
| Week 246 (n=35) | 100 (90.0 to 100) | | | |

Notes:

[39] - All participants in the ITT analysis set with evaluable data at each timepoint

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Participants With Grade ≤0.5+ in VH in Both Eyes on Indirect Ophthalmoscopy According to NEI/SUN Criteria Over Time

| | |
|---|---|
| End point title | Percentage of Participants With Grade ≤0.5+ in VH in Both Eyes on Indirect Ophthalmoscopy According to NEI/SUN Criteria Over Time |

End point description:

Vitreous haze was measured using dilated indirect ophthalmoscopy (DIO) and assessed by the Investigator according to NEI and SUN criteria: Grade 0: No evident vitreous haze; Grade 0.5+: Slight blurring of the optic disc margin because of the haze; normal striations and reflex of the nerve fiber layer cannot be visualized; Grade 1+: Permits a better definition of both the optic nerve head and the retinal vessels (compared to higher grades); Grade 2+: Permits better visualization of the retinal vessels (compared to higher grades); Grade 3+: Permits the observer to see the optic nerve head, but the borders are quite blurry; Grade 4+: Optic nerve head is obscured. n=the number of participants at given time point.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

Weeks 0, 2, 4, 8, 12, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| End point values | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 364[40] | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Week 0 (n=364) | 58.0 (52.7 to 63.1) | | | |
| Week 2 (n=348) | 75.6 (70.7 to 80.0) | | | |
| Week 4 (n=323) | 77.7 (72.8 to 82.1) | | | |
| Week 8 (n=342) | 84.2 (79.9 to 87.9) | | | |
| Week 12 (n=333) | 84.4 (80.0 to 88.1) | | | |
| Week 18 (n=330) | 87.3 (83.2 to 90.7) | | | |
| Week 30 (n=319) | 87.1 (83.0 to 90.6) | | | |
| Week 42 (n=310) | 90.3 (86.5 to 93.4) | | | |
| Week 54 (n=295) | 89.5 (85.4 to 92.7) | | | |
| Week 66 (n=283) | 92.2 (88.5 to 95.1) | | | |
| Week 78 (n=270) | 93.3 (89.7 to 96.0) | | | |
| Week 90 (n=261) | 93.5 (89.8 to 96.2) | | | |
| Week 102 (n=245) | 93.9 (90.1 to 96.5) | | | |
| Week 114 (n=231) | 93.1 (89.0 to 96.0) | | | |
| Week 126 (n=215) | 94.9 (91.0 to 97.4) | | | |
| Week 138 (n=196) | 95.4 (91.5 to 97.9) | | | |
| Week 150 (n=180) | 92.2 (87.3 to 95.7) | | | |
| Week 162 (n=154) | 91.6 (86.0 to 95.4) | | | |
| Week 174 (n=142) | 92.3 (86.6 to 96.1) | | | |
| Week 186 (n=128) | 96.1 (91.1 to 98.7) | | | |
| Week 198 (n=113) | 93.8 (87.7 to 97.5) | | | |
| Week 210 (n=88) | 92.0 (84.3 to 96.7) | | | |
| Week 222 (n=70) | 95.7 (88.0 to 99.1) | | | |
| Week 234 (n=51) | 96.1 (86.5 to 99.5) | | | |
| Week 246 (n=42) | 97.6 (87.4 to 99.9) | | | |

Notes:

[40] - All participants in the ITT analysis set with evaluable data at each timepoint

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Change in National Eye Institute (NEI) Visual Functioning Questionnaire (VFQ-25) Score at Each Study Time Point Relative to Baseline for Participants Who Had Inactive Uveitis at Study Entry Over Time

| End point title | Change in National Eye Institute (NEI) Visual Functioning Questionnaire (VFQ-25) Score at Each Study Time Point Relative to Baseline for Participants Who Had Inactive Uveitis at Study Entry Over Time |
|---|---|

End point description:

The National Eye Institute (NEI) Visual Functioning Questionnaire (VFQ-25) is an ocular disease-specific survey that measures the influence of visual disability and visual symptoms on generic health domains such as emotional well-being and social functioning, in addition to task-oriented domains related to daily visual functioning. The VFQ-25 consists of a base set of 25 vision-targeted questions plus an additional single-item general health rating question. The overall composite score ranges from 0 to 100, where higher scores or increases in score indicate better vision-related functioning. Baseline was defined as Week 0 for participants with inactive uveitis. n=the number of participants at given time point.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Weeks 0, 8, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 122[41] | | | |
| Units: Score on a Scale | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 0 (n=122) | 84.77 (81.93 to 87.62) | | | |
| Week 8 (n=111) | 84.37 (81.37 to 87.37) | | | |
| Week 18 (n=112) | 85.21 (82.30 to 88.13) | | | |
| Week 30 (n=111) | 84.75 (81.91 to 87.59) | | | |
| Week 42 (n=111) | 84.41 (81.29 to 87.53) | | | |
| Week 54 (n=105) | 84.47 (81.82 to 87.91) | | | |
| Week 66 (n=103) | 84.09 (80.97 to 87.21) | | | |
| Week 78 (n=99) | 83.59 (80.33 to 86.85) | | | |
| Week 90 (n=95) | 83.66 (80.18 to 87.15) | | | |
| Week 102 (n=89) | 84.19 (80.62 to 87.76) | | | |
| Week 114 (n=83) | 84.09 (80.40 to 87.78) | | | |
| Week 126 (n=76) | 84.44 (80.59 to 88.28) | | | |
| Week 138 (n=64) | 84.85 (80.56 to 89.14) | | | |
| Week 150 (n=57) | 83.90 (78.95 to 88.85) | | | |

| | | | | |
|---|---|---|---|---|
| Week 162 (n=39) | 86.60 (81.31 to 91.90) | | | |
| Week 174 (n=34) | 87.25 (81.51 to 92.99) | | | |
| Week 186 (n=31) | 87.25 (81.43 to 93.06) | | | |
| Week 198 (n=26) | 85.30 (78.35 to 92.26) | | | |
| Week 210 (n=16) | 85.71 (76.61 to 94.82) | | | |
| Week 222 (n=12) | 85.67 (74.60 to 96.74) | | | |
| Week 234 (n=9) | 82.90 (68.16 to 97.63) | | | |
| Week 246 (n=7) | 79.83 (61.00 to 98.66) | | | |

Notes:

[41] - All participants in the ITT analysis set with evaluable data at each timepoint

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Change in NEI VFQ-25 Score at Each Study Time Point Relative to Week 8 for Participants Who Had Active Uveitis at Study Entry Over Time

| | |
|---|---|
| End point title | Change in NEI VFQ-25 Score at Each Study Time Point Relative to Week 8 for Participants Who Had Active Uveitis at Study Entry Over Time |

End point description:

The National Eye Institute (NEI) Visual Functioning Questionnaire (VFQ-25) is an ocular disease-specific survey that measures the influence of visual disability and visual symptoms on generic health domains such as emotional well-being and social functioning, in addition to task-oriented domains related to daily visual functioning. The VFQ-25 consists of a base set of 25 vision-targeted questions plus an additional single-item general health rating question. The overall composite score ranges from 0 to 100, where higher scores or increases in score indicate better vision-related functioning. Baseline was defined as Week 8 for participants with active uveitis. n=the number of participants at given time point.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

Weeks 0, 8, 18, 30, 42, 54, 66, 78, 90, 102, 114, 126, 138, 150, 162, 174, 186, 198, 210, 222, 234, and 246

| **End point values** | Adalimumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 240[42] | | | |
| Units: Score on a Scale | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| Week 0 (n=240) | 72.00 (69.52 to 74.48) | | | |
| Week 8 (n=226) | 75.77 (73.27 to 78.26) | | | |
| Week 18 (n=215) | 78.12 (75.65 to 80.58) | | | |
| Week 30 (n=206) | 78.98 (76.46 to 81.50) | | | |

| | | | | |
|---|---|---|---|---|
| Week 42 (n=197) | 79.77 (77.37 to 82.18) | | | |
| Week 54 (n=188) | 80.10 (77.69 to 82.50) | | | |
| Week 66 (n=180) | 80.42 (77.87 to 82.97) | | | |
| Week 78 (n=169) | 80.98 (78.39 to 83.58) | | | |
| Week 90 (n=163) | 81.85 (79.32 to 84.37) | | | |
| Week 102 (n=156) | 81.44 (78.74 to 84.14) | | | |
| Week 114 (n=146) | 81.76 (78.99 to 84.54) | | | |
| Week 126 (n=140) | 81.86 (79.11 to 84.61) | | | |
| Week 138 (n=133) | 81.76 (78.94 to 84.59) | | | |
| Week 150 (n=123) | 82.41 (79.51 to 85.31) | | | |
| Week 162 (n=115) | 81.87 (78.90 to 84.85) | | | |
| Week 174 (n=108) | 81.96 (78.78 to 85.14) | | | |
| Week 186 (n=97) | 81.27 (78.07 to 84.46) | | | |
| Week 198 (n=87) | 82.08 (78.82 to 85.34) | | | |
| Week 210 (n=72) | 80.75 (76.99 to 84.51) | | | |
| Week 222 (n=59) | 81.65 (77.24 to 86.05) | | | |
| Week 234 (n=42) | 81.86 (76.32 to 87.40) | | | |
| Week 246 (n=35) | 81.57 (75.44 to 87.70) | | | |

Notes:

[42] - All participants in the ITT analysis set with evaluable data at each timepoint

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) and serious adverse events (TESAEs) were collected from first dose of study drug until either 70 days after the last dose of study drug or until the first dose of commercially available drug (up to 370 weeks).

Adverse event reporting additional description:

TEAEs/SAEs are defined as any AE or SAE with onset or worsening reported by a participant from the time first dose of adalimumab is administered in Study M11-327 until 5 half-lives (70 days) have elapsed following discontinuation of adalimumab or until first dose of commercially available adalimumab post regulatory and/or reimbursement approval.

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 19.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | ADALIMUMAB |

Reporting group description: -

| Serious adverse events | ADALIMUMAB | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 101 / 424 (23.82%) | | |
| number of deaths (all causes) | 4 | | |
| number of deaths resulting from adverse events | | | |
| Vascular disorders | | | |
| AORTIC DILATATION | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| BEHCET'S SYNDROME | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| HYPERTENSION | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |

| | | | |
|---|---|---|---|
| ADENOCARCINOMA OF COLON | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| B-CELL LYMPHOMA | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| BASAL CELL CARCINOMA | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| COLORECTAL CANCER | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| LOBULAR BREAST CARCINOMA IN SITU | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| PANCREATIC CARCINOMA METASTATIC | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| RECTAL ADENOCARCINOMA | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| SQUAMOUS CELL CARCINOMA OF SKIN | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|---|---|---|
| UTERINE LEIOMYOMA | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Immune system disorders | | | |
| SARCOIDOSIS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pregnancy, puerperium and perinatal conditions | | | |
| ECTOPIC PREGNANCY | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| HYPEREMESIS GRAVIDARUM | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| CHEST PAIN | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| DEATH | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| GENERALISED OEDEMA | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| CYSTOCELE | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |

| | | | | |
|---|---|---|---|---|
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| HYDROCELE FEMALE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| RECTOCELE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| VAGINAL HAEMORRHAGE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Injury, poisoning and procedural complications | | | | |
| COMMINUTED FRACTURE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CORNEAL ABRASION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ELSCHNIG'S BODIES | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| EPICONDYLITIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| FALL | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |

| | | | | |
|---|---|---|---|---|
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| FOREARM FRACTURE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| JOINT DISLOCATION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| LACERATION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| POST PROCEDURAL HAEMORRHAGE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SPINAL COMPRESSION FRACTURE | | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| STRESS FRACTURE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| TIBIA FRACTURE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| UPPER LIMB FRACTURE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |

| | | | |
|---|---|---|---|
| deaths causally related to treatment / all | 0 / 0 | | |
| Investigations | | | |
| CARDIAC MURMUR | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| HEPATIC ENZYME INCREASED | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| INTRAOCULAR PRESSURE INCREASED | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| MYCOBACTERIUM TUBERCULOSIS COMPLEX TEST POSITIVE | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| TUBERCULIN TEST POSITIVE | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| ACUTE MYOCARDIAL INFARCTION | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| AORTIC VALVE STENOSIS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| CARDIAC FAILURE ACUTE | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |

| | | | | |
|---|---|---|---|---|
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CORONARY ARTERY DISEASE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| MYOCARDIAL INFARCTION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital, familial and genetic disorders | | | | |
| BICUSPID AORTIC VALVE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory, thoracic and mediastinal disorders | | | | |
| ACUTE RESPIRATORY FAILURE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| NASAL POLYPS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PLEURAL EFFUSION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PNEUMOTHORAX | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PULMONARY FIBROSIS | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PULMONARY EMBOLISM | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SLEEP APNOEA SYNDROME | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Blood and lymphatic system disorders | | | | |
| PSEUDOLYMPHOMA | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nervous system disorders | | | | |
| ATAXIA | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DEMYELINATION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ENCEPHALITIS AUTOIMMUNE | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| MULTIPLE SCLEROSIS | | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | | |
| occurrences causally related to treatment / all | 1 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| TENSION HEADACHE | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| TRANSIENT ISCHAEMIC ATTACK | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| BLINDNESS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| CATARACT | | | |
| subjects affected / exposed | 7 / 424 (1.65%) | | |
| occurrences causally related to treatment / all | 0 / 11 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| CILIARY ZONULAR DEHISCENCE | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| CORNEAL OEDEMA | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| EYE INFLAMMATION | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| GLAUCOMA | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| MACULAR FIBROSIS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |

| | | | |
|---|---|---|---|
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| OCULAR HYPERTENSION | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| OPTIC NEUROPATHY | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| PAPILLOEDEMA | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| RETINAL DETACHMENT | | | |
| subjects affected / exposed | 3 / 424 (0.71%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| RETINAL VASCULITIS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| UVEITIS | | | |
| subjects affected / exposed | 5 / 424 (1.18%) | | |
| occurrences causally related to treatment / all | 0 / 5 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| VISUAL ACUITY REDUCED | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| VITREOUS FLOATERS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |

| | | | |
|---|---|---|---|
| deaths causally related to treatment / all | 0 / 0 | | |
| VITREOUS HAEMORRHAGE | | | |
| subjects affected / exposed | 3 / 424 (0.71%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| VITREOUS OPACITIES | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| COLITIS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| CROHN'S DISEASE | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| GASTRIC ULCER | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| GASTRITIS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| LARGE INTESTINE POLYP | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |

| | | | |
|---|---|---|---|
| deaths causally related to treatment / all | 0 / 0 | | |
| PANCREATITIS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| ACUTE KIDNEY INJURY | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| BLADDER DIVERTICULUM | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| NEPHROLITHIASIS | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| MICTURITION DISORDER | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| RENAL COLIC | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| URETEROLITHIASIS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| BILIARY COLIC | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |

| | | | |
|---|---|---|---|
| deaths causally related to treatment / all | 0 / 0 | | |
| CHOLELITHIASIS | | | |
| subjects affected / exposed | 3 / 424 (0.71%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Product issues | | | |
| DEVICE DISLOCATION | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| INGROWING NAIL | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| MUSCULOSKELETAL PAIN | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| MYOPATHY | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| OSTEOARTHRITIS | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| OSTEOLYSIS | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | |

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|---|---|---|---|---|
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PATELLOFEMORAL PAIN SYNDROME | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SYNOVITIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Metabolism and nutrition disorders | | | | |
| HYPOGLYCAEMIA | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| OBESITY | | | | |
| subjects affected / exposed | 3 / 424 (0.71%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infections and infestations | | | | |
| APPENDICITIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| APPENDICITIS PERFORATED | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ASPERGILLUS INFECTION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| BRAIN ABSCESS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |

| | | | | |
|---|---|---|---|---|
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| CELLULITIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CYTOMEGALOVIRUS CHORIORETINITIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CYTOMEGALOVIRUS INFECTION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DEVICE RELATED INFECTION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DIVERTICULITIS | | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ESCHERICHIA URINARY TRACT INFECTION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| GASTROENTERITIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| INFECTION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |

| | | | | |
|---|---|---|---|---|
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| LATENT TUBERCULOSIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| MENINGITIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| OPHTHALMIC HERPES ZOSTER | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PERITONSILLAR ABSCESS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PNEUMONIA | | | | |
| subjects affected / exposed | 3 / 424 (0.71%) | | | |
| occurrences causally related to treatment / all | 1 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PYELONEPHRITIS | | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PYONEPHROSIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SEPTIC SHOCK | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |

| | | | | |
|---|---|---|---|---|
| deaths causally related to treatment / all | 0 / 0 | | | |
| SINUSITIS | | | | |
| subjects affected / exposed | 2 / 424 (0.47%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SINUSITIS FUNGAL | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SOFT TISSUE INFECTION | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SUBCUTANEOUS ABSCESS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| TOOTH ABSCESS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| TUBERCULOSIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| URINARY TRACT INFECTION | | | | |
| subjects affected / exposed | 5 / 424 (1.18%) | | | |
| occurrences causally related to treatment / all | 1 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| UROSEPSIS | | | | |
| subjects affected / exposed | 1 / 424 (0.24%) | | | |
| 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** | ADALIMUMAB | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed | 332 / 424 (78.30%) | | |
| Vascular disorders<br>HYPERTENSION<br>subjects affected / exposed<br>occurrences (all) | 27 / 424 (6.37%)<br>28 | | |
| Investigations<br>INTRAOCULAR PRESSURE INCREASED<br>subjects affected / exposed<br>occurrences (all) | 23 / 424 (5.42%)<br>30 | | |
| Respiratory, thoracic and mediastinal disorders<br>OROPHARYNGEAL PAIN<br>subjects affected / exposed<br>occurrences (all)<br>COUGH<br>subjects affected / exposed<br>occurrences (all) | 32 / 424 (7.55%)<br>39<br>42 / 424 (9.91%)<br>45 | | |
| Nervous system disorders<br>HEADACHE<br>subjects affected / exposed<br>occurrences (all) | 63 / 424 (14.86%)<br>83 | | |
| Eye disorders<br>CATARACT<br>subjects affected / exposed<br>occurrences (all)<br>CYSTOID MACULAR OEDEMA<br>subjects affected / exposed<br>occurrences (all)<br>DRY EYE<br>subjects affected / exposed | 30 / 424 (7.08%)<br>38<br>43 / 424 (10.14%)<br>70<br>30 / 424 (7.08%) | | |

| | | | |
|---|---|---|---|
| occurrences (all) | 33 | | |
| EYE PAIN | | | |
| subjects affected / exposed | 25 / 424 (5.90%) | | |
| occurrences (all) | 27 | | |
| IRIDOCYCLITIS | | | |
| subjects affected / exposed | 22 / 424 (5.19%) | | |
| occurrences (all) | 29 | | |
| MACULAR OEDEMA | | | |
| subjects affected / exposed | 24 / 424 (5.66%) | | |
| occurrences (all) | 31 | | |
| VISUAL ACUITY REDUCED | | | |
| subjects affected / exposed | 30 / 424 (7.08%) | | |
| occurrences (all) | 36 | | |
| UVEITIS | | | |
| subjects affected / exposed | 123 / 424 (29.01%) | | |
| occurrences (all) | 217 | | |
| General disorders and administration site conditions | | | |
| FATIGUE | | | |
| subjects affected / exposed | 36 / 424 (8.49%) | | |
| occurrences (all) | 42 | | |
| PYREXIA | | | |
| subjects affected / exposed | 24 / 424 (5.66%) | | |
| occurrences (all) | 28 | | |
| Gastrointestinal disorders | | | |
| NAUSEA | | | |
| subjects affected / exposed | 32 / 424 (7.55%) | | |
| occurrences (all) | 45 | | |
| DIARRHOEA | | | |
| subjects affected / exposed | 28 / 424 (6.60%) | | |
| occurrences (all) | 33 | | |
| Skin and subcutaneous tissue disorders | | | |
| RASH | | | |
| subjects affected / exposed | 24 / 424 (5.66%) | | |
| occurrences (all) | 30 | | |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|---|---|---|
| ARTHRALGIA | | | |
| subjects affected / exposed | 72 / 424 (16.98%) | | |
| occurrences (all) | 94 | | |
| BACK PAIN | | | |
| subjects affected / exposed | 26 / 424 (6.13%) | | |
| occurrences (all) | 30 | | |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 24 / 424 (5.66%) | | |
| occurrences (all) | 25 | | |
| Infections and infestations | | | |
| INFLUENZA | | | |
| subjects affected / exposed | 36 / 424 (8.49%) | | |
| occurrences (all) | 44 | | |
| BRONCHITIS | | | |
| subjects affected / exposed | 38 / 424 (8.96%) | | |
| occurrences (all) | 50 | | |
| SINUSITIS | | | |
| subjects affected / exposed | 33 / 424 (7.78%) | | |
| occurrences (all) | 43 | | |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 105 / 424 (24.76%) | | |
| occurrences (all) | 214 | | |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 47 / 424 (11.08%) | | |
| occurrences (all) | 66 | | |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 43 / 424 (10.14%) | | |
| occurrences (all) | 65 | | |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 23 April 2010 | Revisions were made to exclusion criterion 11 for clarity: a separate sentence was created to specify that participants with chronic recurring infections or active tuberculosis should be excluded. The health resources questionnaire administration frequency was updated to be conducted at every visit to better meet protocol objectives. |
| 09 June 2010 | Revisions to the protocol were as follows: The order of eye exams was changed so that they are performed in the correct order to maximize the results of these procedures. For consistency of results, the comprehensive physical exams were to be performed by a qualified physician. Participants could use one periocular corticosteroid injection during the OLE study (these were prohibited in the parent studies). Anti-vascular endothelial growth factor therapy and intraocular or intravitreal injections were specified in prohibited medications. To satisfy local requirements in Japan, chest x-ray assessments and findings were adjusted. |
| 14 February 2011 | Revisions were made to remove exclusion criteria that were already exclusions for which participants were screened and tested for in parent studies. Exclusion criterion 5 was modified to exclude participants with macular edema due to diabetic retinopathy, as clinical manifestations of these comorbidities can interfere with evaluations in the study. Exclusion Criterion 13 clarified that participants with active systemic viral infection or any active viral infection were to be excluded as they are unsuitable candidates for the study.<br>Prohibited medications were modified to include dexamethasone implant to ensure proper participant population. Medical marijuana use was prohibited to ensure study participants were not at risk for aspergillus infection.<br>Requirements were added for pregnancy occurrence and testing by adding instructions for required action in the event of positive urine pregnancy test and adding the requirement for monthly pregnancy test per Austrian regulations.<br>Screening for tuberculosis (TB) using PPD or QuantiFERON-TB Gold and completing a chest x-ray in case of positive TB test was added.<br>Instructions to use consistent examination technique and instrument for indirect ophthalmoscopy throughout the study were added to support collection of consistent data.<br>Requirement for discontinuation of participants with dysplasia of the gastrointestinal tract, lupus like syndrome, multiple sclerosis or demyelinating disease, non-compliance with TB therapy was added. To ensure consistency of data, minimum documentation required for participants lost to follow-up and requirement for the principal investigator to review and sign chest x-ray were added. |
| 22 February 2011 | Instructions were added to document the participant’s initial anti-nuclear antibody status and allow for repeat testing as medically warranted during the study. |
| 21 March 2011 | The use of systemic carbonic anhydrase was prohibited, as it is a therapeutic option for macular edema and hence could impact study endpoints. Detailed instructions were added clarifying chest x-ray requirements if the tuberculosis test was positive. |

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|---|---|
| 23 August 2011 | Revisions were made to exclude participants that may have an infection (specifically tuberculosis [TB]) as the origin of their uveitis and exclusion criterion 4 that participants with BCVA worse than 20/200 will be excluded was removed. Exclusion of participants with an infectious (TB) origin of uveitis was done to prevent unnecessary harm due to PPD skin test if this had been documented previously.<br>Concomitant medications were revised to allow participants one periocular corticosteroid injection per eye during the study. Prohibited therapies were revised so that any TB prophylaxis therapy and glucocorticosteroid implant were prohibited. Participants on TB-prophylaxis were to be discontinued beginning with this amendment<br>Urine pregnancy test requirements were changed so that they could be performed locally for all visits to ensure participants of childbearing potential are carefully screened throughout the study.<br>For study procedures, optical coherence tomography was clarified to ensure consistency throughout the study and instructions for dilated indirect ophthalmoscopy to record number, locations, sizes, and whether lesions are active or inactive were added.<br>Efficacy endpoint was changed to percent change in central retinal thickness.<br>Adverse event criteria were modified to include worsening severity to be reported as a new adverse event and hypotony was added to list of uveitis-related events.<br>TB testing was made consistent across regions by removing Japan-specific requirements. |
| 15 March 2012 | The number of sites and countries to be included was increased to accurately reflect the number of sites and countries and timely completion of enrollment. The study duration of 78 weeks was removed to allow for extension of treatment of responding subjects while waiting for approval. Visits every 12 weeks were added following week 66 through end of study to accommodate study extension. A termination clause for when study will end was added. Annual tuberculosis (TB) screening was added due to study extension. A clarification that 70 day call/visit should be noted in source and EDC9 was added. No new risks/benefits added, but language was clarified in the benefits and risks section. A number of changes were made for TB testing: Inclusion criterion 6 of negative TB result at baseline was removed (testing to still be done for TB), changes were made to TB screening to reflect new CDC guidelines, the same type of TB test should be done on study as was done at baseline for consistency, and instructions for TB screening were added. Timing of collecting adverse events and serious adverse events was updated. Uveitis-related event reporting language updated to match reporting for all adverse events and clarified that list of potential uveitis-events was not exhaustive. Tacrolimus was added as an acceptable concomitant immunosuppressant. An equivalent drug to mycophenolate mofetil as approved by medical monitor was added as an option as some regions do not have mycophenolate mofetil. Instructions were added that results of ketone and glucose testing should be interpreted in the context of additional clinical findings. |
| 28 December 2012 | Malignancy in participants who are 30 years old or younger and non-serious events of malignancy in participants 30 years old or younger reporting requirements were updated as AbbVie is participating in an FDA-requested, tumor necrosis factor inhibitor class wide exploration of these rare malignancies. The only other meaningful change was to periocular corticosteroid injection, which was changed to two injections per eye per year. |
| 26 June 2013 | Revisions included the following: The requirement for a 70-day follow up phone call was clarified. Ustekinumab and belimumab were added to prohibited therapies. The same tuberculosis test used in parent protocol was to be used in this study and text clarifying this was added for consistency. The early stopping rule for parent study was removed from this protocol, as was the language on pregnancy forms and registry. |

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|---|---|
| 04 June 2015 | Revisions included an update to Sponsor/Emergency Contact information throughout, including the information for serious adverse event reporting. The study end date was changed to March 2018 to allow for extension of treatment for participants that will complete the study prior to indication approval. As part of this extension, additional visits were added every 12 weeks following Week 280 to the end of study to ensure appropriate follow-up for participants continuing the extended treatment. The complaint and product complaint definitions were added to implement a standard collection process to comply with FDA regulation for reporting of post-marketing safety in clinical trials. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was planned for 78 weeks but extended until regulatory/reimbursement approval obtained locally. Data were collected through Week 366; efficacy data cut off was Week 246, as less than 10% of participants had visits beyond this timepoint.

Notes: