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Trial record **1 of 2** for: CAIN457C2301

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Safety and Efficacy of AIN457 in Patients With Quiescent Non-infectious Uveitis (ENDURE)

This study has been terminated.

(Results of a planned interim analysis did not show significant effects for any of the 3 AIN dose regimens versus placebo on any primary or secondary endpoint)

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT01032915

First received: December 14, 2009
Last updated: October 8, 2015
Last verified: October 2015
History of Changes

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Results First Received: February 12, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Non-infectious Uveitis
Interventions:	Biological: AIN457 Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Between February 2010 and March 2011, 125 patients were randomized from 51 centers in 9 countries (United States, Germany, Switzerland, India, Spain, United Kingdom, Israel, Brazil and Italy). Recruitment did not reach the target of 340 patients due to early termination of the study.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c weekly for 3 weeks, then every 2 weeks
AIN457 300mg s.c Every 4 Weeks	AIN457 300mg s.c at baseline and Week 2, then every 4 weeks
AIN457 150mg s.c Every 4 Weeks	AIN457 150mg s.c at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c weekly for 3 weeks, then every 2 weeks

Participant Flow: Overall Study

	AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c Every 4 Weeks	AIN457 150mg s.c Every 4 Weeks	Placebo s.c Every 2 Weeks
STARTED	**29**	**31**	**31**	**34**
COMPLETED	**21**	**20**	**24**	**27**
NOT COMPLETED	**8**	**11**	**7**	**7**
Adverse Event	**2**	**2**	**1**	**1**
Abnormal test procedure result	**0**	**0**	**1**	**0**
Withdrawal by Subject	**0**	**3**	**1**	**1**

Administrative reasons	**5**	**6**	**4**	**4**
Protocol Violation	**1**	**0**	**0**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Randomized Set: This set included all randomized patients

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c weekly for 3 weeks, then every 2 weeks
AIN457 300mg s.c Every 4 Weeks	AIN457 300mg s.c at baseline and Week 2, then every 4 weeks
AIN457 150mg s.c Every 4 Weeks	AIN457 150mg s.c at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c weekly for 3 weeks, then every 2 weeks
Total	Total of all reporting groups

Baseline Measures

	AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c Every 4 Weeks	AIN457 150mg s.c Every 4 Weeks	Placebo s.c Every 2 Weeks	Total
Number of Participants [units: participants]	**29**	**31**	**31**	**34**	**125**
Age [units: Years] Mean (Standard	**46.2 (14.29)**	**49.2 (11.14)**	**47.7 (13.5)**	**47.3 (15.46)**	**47.6 (13.6)**

Deviation)					
Gender [units: Participants]					
Female	**17**	**16**	**20**	**18**	**71**
Male	**12**	**15**	**11**	**16**	**54**

Outcome Measures

Hide All Outcome Measures

1. Primary: Time to First Recurrence in Any Eye of Active Intermediate, Posterior, or Panuveitis From Baseline [Time Frame: Baseline to 24 weeks]

Measure Type	Primary
Measure Title	Time to First Recurrence in Any Eye of Active Intermediate, Posterior, or Panuveitis From Baseline
Measure Description	Kaplan-Meier estimates for the time to the first recurrence in any eye of active intermediate, posterior, or panuveitis from baselineRecurrence of active intermediate, posterior, or panuveitis defined by either: ≥ 2 step increase in vitreous haze with or without an increase in anterior chamber cell grade or decrease in best corrected visual acuity of ≥ 10 ETDRS letters
Time Frame	Baseline to 24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): all randomized patients who received at least one dose of study drug and have at least one post-baseline assessment for the primary efficacy parameter or any of its components. Following the intent-to-treat principle, patients were analyzed according to the treatment they are assigned to at randomization.

Reporting Groups

	Description

AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c weekly for 3 weeks, then every 2 weeks
AIN457 300mg s.c Every 4 Weeks	AIN457 300mg s.c at baseline and Week 2, then every 4 weeks
AIN457 150mg s.c Every 4 Weeks	AIN457 150mg s.c at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c weekly for 3 weeks, then every 2 weeks

Measured Values

	AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c Every 4 Weeks	AIN457 150mg s.c Every 4 Weeks	Placebo s.c Every 2 Weeks
Number of Participants Analyzed **[units: participants]**	**29**	**31**	**31**	**33**
Time to First Recurrence in Any Eye of Active Intermediate, Posterior, or Panuveitis From Baseline **[units: Days]** **Median (95% Confidence Interval)**	**NA** [1]	**NA** [1]	**178** [1]	**NA** [1]

[1] Not estimable due to low number of events

No statistical analysis provided for Time to First Recurrence in Any Eye of Active Intermediate, Posterior, or Panuveitis From Baseline

2. Secondary: Change (Reduction) From Baseline in Composite Immunosuppressive Medication Score (IMS) From Baseline to 24 Weeks [Time Frame: Baseline to 24 weeks]

Measure Type	Secondary
Measure Title	Change (Reduction) From Baseline in Composite Immunosuppressive Medication Score (IMS) From Baseline to 24 Weeks
Measure Description	Participants could have received up to 5 immunosuppresive agents (prednisone, cyclosporine, azathioprine, methotrexate, mycophenolate). Immunosuppressive Medication Score (IMS) is a combined, single numeric score derived on basis of total daily dose of specific immunosuppressive agents / unit body weight, ranged on a scale from 0-9 for the total daily dose in mg per kg. Patients receiving multiple medications, the sum of the grading scores for each drug was used to calculate a total immunosuppression score at each visit. The total IMS is the sum of scores derived from the agents included into the score, and ranged from 0 to 55. Treatment groups compared using analysis of covariance with treatment & baseline IMS as covariate, where the lower IMS (or its reduction from baseline) showed better clinical outcome

Time Frame	Baseline to 24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): all randomized patients who received at least one dose of study drug and have at least one post-baseline assessment for the primary efficacy parameter or any of its components. Following the intent-to-treat principle, patients were analyzed according to the treatment they are assigned to at randomization.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c weekly for 3 weeks, then every 2 weeks
AIN457 300mg s.c Every 4 Weeks	AIN457 300mg s.c at baseline and Week 2, then every 4 weeks
AIN457 150mg s.c Every 4 Weeks	AIN457 150mg s.c at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c weekly for 3 weeks, then every 2 weeks

Measured Values

	AIN457 300mg s.c Every 2 Weeks	**AIN457 300mg s.c Every 4 Weeks**	**AIN457 150mg s.c Every 4 Weeks**	**Placebo s.c Every 2 Weeks**
Number of Participants Analyzed **[units: participants]**	**29**	**31**	**31**	**33**
Change (Reduction) From Baseline in Composite Immunosuppressive Medication Score (IMS) From Baseline to 24 Weeks **[units: Score]** **Mean (Standard Deviation)**	**-2.55 (3.22)**	**-2.81 (2.847)**	**-2.92 (2.874)**	**-2.13 (3.049)**

No statistical analysis provided for Change (Reduction) From Baseline in Composite Immunosuppressive Medication Score (IMS) From Baseline to 24 Weeks

3. Secondary: Mean Change in Best Corrected Visual Acuity From Baseline [Time Frame: Baseline to 24 weeks]

Measure Type	Secondary
Measure Title	Mean Change in Best Corrected Visual Acuity From Baseline
Measure Description	The Best Corrected Visual Acuity (BCVA) is tested using the Early Treatment Diabetic Retinopathy Study (ETDRS) Visual Acuity (VA) testing protocol. VA measurements are taken in a sitting position at an initial test distance of 4 meters using ETDRS charts. The overall BCVA score is calculated using the BCVA worksheet 0-100 letter score.
Time Frame	Baseline to 24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): all randomized patients who received at least one dose of study drug and have at least one post-baseline assessment for the primary efficacy parameter or any of its components. Following the intent-to-treat principle, patients were analyzed according to the treatment they are assigned to at randomization.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c weekly for 3 weeks, then every 2 weeks
AIN457 300mg s.c Every 4 Weeks	AIN457 300mg s.c at baseline and Week 2, then every 4 weeks
AIN457 150mg s.c Every 4 Weeks	AIN457 150mg s.c at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c weekly for 3 weeks, then every 2 weeks

Measured Values

	AIN457 300mg s.c Every 2 Weeks	**AIN457 300mg s.c Every 4 Weeks**	**AIN457 150mg s.c Every 4 Weeks**	**Placebo s.c Every 2 Weeks**

Number of Participants Analyzed [units: participants]	**29**	**31**	**31**	**33**
Mean Change in Best Corrected Visual Acuity From Baseline [units: Letters] Mean (Standard Deviation)	**2.9 (4.86)**	**1.8 (6.12)**	**1.9 (4.46)**	**1.4 (9.42)**

No statistical analysis provided for Mean Change in Best Corrected Visual Acuity From Baseline

4. Secondary: Mean Change in Vitreous Haze Grade From Baseline to 24 Weeks [Time Frame: Baseline to 24 weeks]

Measure Type	Secondary
Measure Title	Mean Change in Vitreous Haze Grade From Baseline to 24 Weeks
Measure Description	The changes in steps (0, 1, or >= 2) from previous visit for vitreous haze, where the score is evaluated based on NEI Vitreous Haze Grading Scale (0 -4). Vitreous haze was recorded as 0-clear; to 4+ as dense opacity obscuring the optic nerve head. A 1 step increase is defined as any of the following changes: 0-1, 0.5-1, 1-2, 2-3, 3-4. A 2 step increase is defined as any of the following changes: 0-2, 0.5-2, 1-3, 2-4. A recurrent episode of active intermediate, posterior or panuveitis was considered to be resolved, if the eye returns and maintains in a quiescent state (<1+ anterior chamber cell grade and <1+ vitreous haze) for at least 2 weeks
Time Frame	Baseline to 24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): all randomized patients who received at least one dose of study drug and have at least one post-baseline assessment for the primary efficacy parameter or any of its components. Following the intent-to-treat principle, patients were analyzed according to the treatment they are assigned to at randomization.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c weekly for 3 weeks, then every 2 weeks
AIN457 300mg s.c Every 4 Weeks	AIN457 300mg s.c at baseline and Week 2, then every 4 weeks
AIN457 150mg s.c Every 4 Weeks	AIN457 150mg s.c at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c weekly for 3 weeks, then every 2 weeks

Measured Values

	AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c Every 4 Weeks	AIN457 150mg s.c Every 4 Weeks	Placebo s.c Every 2 Weeks
Number of Participants Analyzed **[units: participants]**	**29**	**31**	**31**	**33**
Mean Change in Vitreous Haze Grade From Baseline to 24 Weeks **[units: Score]** **Mean (Standard Deviation)**	**0.02 (0.295)**	**0.03 (0.197)**	**0.02 (0.232)**	**0.2 (0.465)**

No statistical analysis provided for Mean Change in Vitreous Haze Grade From Baseline to 24 Weeks

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety Analysis Set: The safety set consists of all patients who received at least one dose of study drug and have at least one post-baseline safety assessment. Patients were analyzed according to the treatment they actually received, regardless of study drug relationship, by system preferred term

Reporting Groups

	Description

AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c weekly for 3 weeks, then every 2 weeks
AIN457 300mg s.c Every 4 Weeks	AIN457 300mg s.c at baseline and Week 2, then every 4 weeks
AIN457 150mg s.c Every 4 Weeks	AIN457 150mg s.c at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c weekly for 3 weeks, then every 2 weeks

Serious Adverse Events

	AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c Every 4 Weeks	AIN457 150mg s.c Every 4 Weeks	Placebo s.c Every 2 Weeks
Total, serious adverse events				
# participants affected / at risk	**2/29 (6.90%)**	**1/31 (3.23%)**	**0/31 (0.00%)**	**1/33 (3.03%)**
Eye disorders				
Uveitis (Study eye) †1				
# participants affected / at risk	**1/29 (3.45%)**	**0/31 (0.00%)**	**0/31 (0.00%)**	**0/33 (0.00%)**
Immune system disorders				
Sarcoidosis †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**0/31 (0.00%)**	**1/33 (3.03%)**
Infections and infestations				
Lower respiratory tract infection †1				
# participants affected / at risk	**1/29 (3.45%)**	**0/31 (0.00%)**	**0/31 (0.00%)**	**0/33 (0.00%)**
Metabolism and nutrition disorders				
Diabetes mellitus †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**0/31 (0.00%)**	**1/33 (3.03%)**
Nervous system disorders				

Mononeuropathy multiplex † 1				
# participants affected / at risk	**0/29 (0.00%)**	**1/31 (3.23%)**	**0/31 (0.00%)**	**0/33 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Safety Analysis Set: The safety set consists of all patients who received at least one dose of study drug and have at least one post-baseline safety assessment. Patients were analyzed according to the treatment they actually received, regardless of study drug relationship, by system preferred term

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c weekly for 3 weeks, then every 2 weeks
AIN457 300mg s.c Every 4 Weeks	AIN457 300mg s.c at baseline and Week 2, then every 4 weeks
AIN457 150mg s.c Every 4 Weeks	AIN457 150mg s.c at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c weekly for 3 weeks, then every 2 weeks

Other Adverse Events

	AIN457 300mg s.c Every 2 Weeks	AIN457 300mg s.c Every 4 Weeks	AIN457 150mg s.c Every 4 Weeks	Placebo s.c Every 2 Weeks

Total, other (not including serious) adverse events				
# participants affected / at risk	**14/29 (48.28%)**	**17/31 (54.84%)**	**19/31 (61.29%)**	**14/33 (42.42%)**
Eye disorders				
Cataract subcapsular (Study eye) †1				
# participants affected / at risk	**1/29 (3.45%)**	**0/31 (0.00%)**	**2/31 (6.45%)**	**1/33 (3.03%)**
Conjunctivitis (Fellow eye) †1				
# participants affected / at risk	**0/29 (0.00%)**	**1/31 (3.23%)**	**2/31 (6.45%)**	**0/33 (0.00%)**
Dry eye (Fellow eye) †1				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**1/31 (3.23%)**	**0/33 (0.00%)**
Dry eye (Study eye) †1				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**1/31 (3.23%)**	**0/33 (0.00%)**
Macular oedema (Fellow eye) †1				
# participants affected / at risk	**1/29 (3.45%)**	**0/31 (0.00%)**	**1/31 (3.23%)**	**2/33 (6.06%)**
Vision blurred (Fellow eye) †1				
# participants affected / at risk	**2/29 (6.90%)**	**1/31 (3.23%)**	**0/31 (0.00%)**	**1/33 (3.03%)**
Vision blurred (Study eye) †1				
# participants affected / at risk	**2/29 (6.90%)**	**0/31 (0.00%)**	**1/31 (3.23%)**	**1/33 (3.03%)**
Gastrointestinal disorders				
Abdominal pain †1				
# participants affected / at risk	**2/29 (6.90%)**	**0/31 (0.00%)**	**0/31 (0.00%)**	**0/33 (0.00%)**
Diarrhoea †1				
# participants affected / at risk	**1/29 (3.45%)**	**2/31 (6.45%)**	**1/31 (3.23%)**	**0/33 (0.00%)**
Nausea †1				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**2/31 (6.45%)**	**2/33 (6.06%)**
General disorders				
Asthenia †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**2/31 (6.45%)**	**1/33 (3.03%)**

Infections and infestations				
Ear infection †1				
# participants affected / at risk	**1/29 (3.45%)**	**2/31 (6.45%)**	**0/31 (0.00%)**	**1/33 (3.03%)**
Hordeolum †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**2/31 (6.45%)**	**0/33 (0.00%)**
Influenza †1				
# participants affected / at risk	**2/29 (6.90%)**	**2/31 (6.45%)**	**1/31 (3.23%)**	**0/33 (0.00%)**
Nasopharyngitis †1				
# participants affected / at risk	**5/29 (17.24%)**	**2/31 (6.45%)**	**4/31 (12.90%)**	**3/33 (9.09%)**
Oral herpes †1				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**0/31 (0.00%)**	**0/33 (0.00%)**
Injury, poisoning and procedural complications				
Contusion †1				
# participants affected / at risk	**1/29 (3.45%)**	**2/31 (6.45%)**	**0/31 (0.00%)**	**1/33 (3.03%)**
Musculoskeletal and connective tissue disorders				
Arthralgia †1				
# participants affected / at risk	**0/29 (0.00%)**	**4/31 (12.90%)**	**3/31 (9.68%)**	**2/33 (6.06%)**
Back pain †1				
# participants affected / at risk	**2/29 (6.90%)**	**0/31 (0.00%)**	**0/31 (0.00%)**	**0/33 (0.00%)**
Musculoskeletal stiffness †1				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**0/31 (0.00%)**	**0/33 (0.00%)**
Pain in extremity †1				
# participants affected / at risk	**0/29 (0.00%)**	**1/31 (3.23%)**	**4/31 (12.90%)**	**0/33 (0.00%)**
Nervous system disorders				
Dizziness †1				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**1/31 (3.23%)**	**4/33 (12.12%)**

Headache †1				
# participants affected / at risk	**5/29 (17.24%)**	**4/31 (12.90%)**	**2/31 (6.45%)**	**0/33 (0.00%)**
Migraine †1				
# participants affected / at risk	**0/29 (0.00%)**	**1/31 (3.23%)**	**0/31 (0.00%)**	**2/33 (6.06%)**
Psychiatric disorders				
Anxiety †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**2/31 (6.45%)**	**0/33 (0.00%)**
Respiratory, thoracic and mediastinal disorders				
Cough †1				
# participants affected / at risk	**1/29 (3.45%)**	**0/31 (0.00%)**	**3/31 (9.68%)**	**2/33 (6.06%)**
Oropharyngeal pain †1				
# participants affected / at risk	**2/29 (6.90%)**	**2/31 (6.45%)**	**1/31 (3.23%)**	**2/33 (6.06%)**
Skin and subcutaneous tissue disorders				
Alopecia †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**1/31 (3.23%)**	**2/33 (6.06%)**
Pruritus †1				
# participants affected / at risk	**0/29 (0.00%)**	**3/31 (9.68%)**	**0/31 (0.00%)**	**0/33 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial or disclosure of trial results in their entirety

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis
phone: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Dick AD, Tugal-Tutkun I, Foster S, Zierhut M, Melissa Liew SH, Bezlyak V, Androudi S. Secukinumab in the treatment of noninfectious uveitis: results of three randomized, controlled clinical trials. Ophthalmology. 2013 Apr;120(4):777-87. doi: 10.1016/j.ophtha.2012.09.040. Epub 2013 Jan 3.

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01032915 History of Changes
Other Study ID Numbers:	**CAIN457C2301** 2009-014835-19 (EudraCT Number)
Study First Received:	December 14, 2009
Results First Received:	February 12, 2015
Last Updated:	October 8, 2015
Health Authority:	United States: Food and Drug Administration Switzerland: Swissmedic Germany: Paul-Ehrlich-Institut Spain: Spanish Agency of Medicines Italy: National Monitoring Centre for Clinical Trials - Ministry of Health Turkey: Ministry of Health United Kingdom: Medicines and Healthcare Products Regulatory Agency Brazil: National Health Surveillance Agency India: Ministry of Health Israel: Ministry of Health