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Trial record **1 of 2** for: CAIN457C2302

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Safety and Efficacy of AIN457 in Patients With Active Non-infectious Uveitis (INSURE)

This study has been terminated.

(Terminated: Study in Behcet's disease with mostly active uveitis did not meet its primary endpoint.)

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01095250

First received: March 25, 2010
Last updated: October 5, 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; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Uveitis
Interventions:	Drug: 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
Disposition of the 31 randomized patients is summarized in the table below. As a consequence of the early termination, few patients (N=31) were randomized into this study. Of these, 30 patients were discontinued due to administrative reasons (30 patients due to study termination and also one due to misrandomization). One patient withdrew consent.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
As a consequence of the early termination, few patients (N=31) were randomized into this study. Of these, 30 patients were discontinued due to administrative reasons (30 patients due to study termination, including one due to misrandomization. One patient withdrew consent.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300 mg subcutaneously at baseline, Week 1 and Week 2, then every 2 weeks
AIN457 300mg s.c. Every 4 Weeks	AIN457 300 mg subcutaneously at baseline and Week 2, then every 4 weeks.
AIN457 150mg s.c Every 4 Weeks	AIN457 150 mg subcutaneously at baseline and Week 2, then every 4 weeks.
Placebo s.c Every 2 Weeks	Placebo s.c at baseline, Week 1 and Week 2, 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	**8**	**10**	**8**	**5**
COMPLETED	**0**	**0**	**0**	**0**
NOT COMPLETED	**8**	**10**	**8**	**5**
administrative reasons	**8**	**10**	**7**	**5**

Withdrawal by Subject	**0**	**0**	**1**	**0**

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.
No text entered.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300 mg subcutaneously at baseline, Week 1 and Week 2, then every 2 weeks
AIN457 300mg s.c. Every 4 Weeks	AIN457 300 mg subcutaneously at baseline and Week 2, then every 4 weeks.
AIN457 150mg s.c Every 4 Weeks	AIN457 150 mg s.c. at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c at baseline, Week 1 and Week 2, 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]	**8**	**10**	**8**	**5**	**31**
Age [units: Years] Mean (Standard Deviation)	**47.5 (21.13)**	**46.9 (12.80)**	**44.6 (15.99)**	**50.6 (12.99)**	**47.1 (15.47)**

Gender [units: Participants]					
Female	**4**	**6**	**2**	**3**	**15**
Male	**4**	**4**	**6**	**2**	**16**
Region of Enrollment [units: Participants]					
Canada	**0**	**2**	**1**	**1**	**4**
Switzerland	**0**	**1**	**0**	**0**	**1**
Germany	**0**	**0**	**0**	**1**	**1**
France	**0**	**0**	**1**	**0**	**1**
Hungary	**1**	**1**	**0**	**0**	**2**
Israel	**0**	**2**	**1**	**0**	**3**
Japan	**4**	**3**	**4**	**2**	**13**
Singapore	**1**	**0**	**0**	**0**	**1**
United States	**2**	**1**	**1**	**1**	**5**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Change in Vitreous Haze Grade in the Study Eye From Baseline to 28 Weeks or at Time of Rescue, if Earlier. [Time Frame: baseline to 28 weeks]

Measure Type	Primary
Measure Title	Mean Change in Vitreous Haze Grade in the Study Eye From Baseline to 28 Weeks or at Time of Rescue, if Earlier.
Measure Description	No patients of Study CAIN457C2303 achieved the milestone of the primary endpoint in non-infectious uveitis patients with Behçet's disease. Study CAIN457C2302 (active uveitis study) was terminated to avoid continuing patients on a study with a low

	probability of success.Since patients did not reach the endpoint of analysis there can be no meaningful interpretation of data and data will be not provided.
Time Frame	baseline to 28 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.
The results of Study CAIN457C2303 did not meet the primary endpoint in non-infectious uveitis patients with Behçet's disease. Study CAIN457C2302 (active uveitis study) was terminated to avoid continuing patients on a study with a low probability of success.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300 mg subcutaneously at baseline, Week 1 and Week 2, then every 2 weeks
AIN457 300mg s.c. Every 4 Weeks	AIN457 300 mg subcutaneously at baseline and Week 2, then every 4 weeks.
AIN457 150mg s.c Every 4 Weeks	AIN457 150 mg s.c. at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c at baseline, Week 1 and Week 2, 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]	**0**	**0**	**0**	**0**
Mean Change in Vitreous Haze Grade in the Study Eye From Baseline to 28 Weeks or at Time of Rescue, if Earlier.				

No statistical analysis provided for Mean Change in Vitreous Haze Grade in the Study Eye From Baseline to 28 Weeks or at Time of Rescue, if Earlier.

2. Secondary: Proportion of Responders With no Recurrence of Active Intermediate, Posterior, or Panuveitis in the Study Eye at 28 Weeks [Time Frame: baseline to 28 weeks]

Measure Type	Secondary
Measure Title	Proportion of Responders With no Recurrence of Active Intermediate, Posterior, or Panuveitis in the Study Eye at 28 Weeks
Measure Description	No patients of Study CAIN457C2303 achieved the milestone of the primary endpoint in non-infectious uveitis patients with Behçet's disease. Study CAIN457C2302 (active uveitis study) was terminated to avoid continuing patients on a study with a low probability of success.Since patients did not reach the endpoint of analysis there can be no meaningful interpretation of data and data will be not provided.
Time Frame	baseline to 28 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.
No text entered.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300 mg subcutaneously at baseline, Week 1 and Week 2, then every 2 weeks
AIN457 300mg s.c. Every 4 Weeks	AIN457 300 mg subcutaneously at baseline and Week 2, then every 4 weeks.
AIN457 150mg s.c Every 4 Weeks	AIN457 150 mg s.c. at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c at baseline, Week 1 and Week 2, 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]	**0**	**0**	**0**	**0**
Proportion of Responders With no Recurrence of Active Intermediate, Posterior, or Panuveitis in the Study Eye at 28 Weeks				

No statistical analysis provided for Proportion of Responders With no Recurrence of Active Intermediate, Posterior, or Panuveitis in the Study Eye at 28 Weeks

3. Secondary: Mean Change in Best Corrected Visual Acuity From Baseline to 28 Weeks [Time Frame: baseline to 28 weeks]

Measure Type	Secondary
Measure Title	Mean Change in Best Corrected Visual Acuity From Baseline to 28 Weeks
Measure Description	No patients of Study CAIN457C2303 achieved the milestone of the primary endpoint in non-infectious uveitis patients with Behçet's disease. Study CAIN457C2302 (active uveitis study) was terminated to avoid continuing patients on a study with a low probability of success.Since patients did not reach the endpoint of analysis there can be no meaningful interpretation of data and data will be not provided.
Time Frame	baseline to 28 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.
No text entered.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300 mg subcutaneously at baseline, Week 1 and Week 2, then every 2 weeks
AIN457 300mg s.c. Every 4 Weeks	AIN457 300 mg subcutaneously at baseline and Week 2, then every 4 weeks.
AIN457 150mg s.c Every 4 Weeks	AIN457 150 mg s.c. at baseline and Week 2, then every 4 weeks

Placebo s.c Every 2 Weeks	Placebo s.c at baseline, Week 1 and Week 2, 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]	**0**	**0**	**0**	**0**
Mean Change in Best Corrected Visual Acuity From Baseline to 28 Weeks				

No statistical analysis provided for Mean Change in Best Corrected Visual Acuity From Baseline to 28 Weeks

4. Secondary: Change From Baseline in Quality of Life/Patient Reported Outcome Assessments [Time Frame: baseline to 28 weeks]

Measure Type	Secondary
Measure Title	Change From Baseline in Quality of Life/Patient Reported Outcome Assessments
Measure Description	No patients of Study CAIN457C2303 achieved the milestone of the primary endpoint in non-infectious uveitis patients with Behçet's disease. Study CAIN457C2302 (active uveitis study) was terminated to avoid continuing patients on a study with a low probability of success.Since patients did not reach the endpoint of analysis there can be no meaningful interpretation of data and data will be not provided.
Time Frame	baseline to 28 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.
No text entered.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300 mg subcutaneously at baseline, Week 1 and Week 2, then every 2 weeks
AIN457 300mg s.c. Every 4 Weeks	AIN457 300 mg subcutaneously at baseline and Week 2, then every 4 weeks.
AIN457 150mg s.c Every 4 Weeks	AIN457 150 mg s.c. at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c at baseline, Week 1 and Week 2, 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]	**0**	**0**	**0**	**0**
Change From Baseline in Quality of Life/Patient Reported Outcome Assessments				

No statistical analysis provided for Change From Baseline in Quality of Life/Patient Reported Outcome Assessments

5. Secondary: Mean Change in Vitreous Haze Grade and Anterior Chamber Cell Grade From Baseline to 28 Weeks [Time Frame: baseline to 28 weeks]

Measure Type	Secondary
Measure Title	Mean Change in Vitreous Haze Grade and Anterior Chamber Cell Grade From Baseline to 28 Weeks
Measure Description	No patients of Study CAIN457C2303 achieved the milestone of the primary endpoint in non-infectious uveitis patients with Behçet's disease. Study CAIN457C2302 (active uveitis study) was terminated to avoid continuing patients on a study with a low probability of success.Since patients did not reach the endpoint of analysis there can be no meaningful interpretation of data and data will be not provided.
Time Frame	baseline to 28 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.
No text entered.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300 mg subcutaneously at baseline, Week 1 and Week 2, then every 2 weeks
AIN457 300mg s.c. Every 4 Weeks	AIN457 300 mg subcutaneously at baseline and Week 2, then every 4 weeks.
AIN457 150mg s.c Every 4 Weeks	AIN457 150 mg s.c. at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c at baseline, Week 1 and Week 2, 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]	**0**	**0**	**0**	**0**
Mean Change in Vitreous Haze Grade and Anterior Chamber Cell Grade From Baseline to 28 Weeks				

No statistical analysis provided for Mean Change in Vitreous Haze Grade and Anterior Chamber Cell Grade From Baseline to 28 Weeks

6. Secondary: Change in Immunosuppressive Medication Score From Baseline to Week 28 [Time Frame: baseline to 28 weeks]

Measure Type	Secondary
Measure Title	Change in Immunosuppressive Medication Score From Baseline to Week 28
Measure Description	No patients of Study CAIN457C2303 achieved the milestone of the primary endpoint in non-infectious uveitis patients with Behçet's disease. Study CAIN457C2302 (active uveitis study) was terminated to avoid continuing patients on a study with a low probability of success.Since patients did not reach the endpoint of analysis there can be no meaningful interpretation of data and

	data will be not provided.
Time Frame	baseline to 28 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.
No text entered.

Reporting Groups

	Description
AIN457 300mg s.c Every 2 Weeks	AIN457 300 mg subcutaneously at baseline, Week 1 and Week 2, then every 2 weeks
AIN457 300mg s.c. Every 4 Weeks	AIN457 300 mg subcutaneously at baseline and Week 2, then every 4 weeks.
AIN457 150mg s.c Every 4 Weeks	AIN457 150 mg s.c. at baseline and Week 2, then every 4 weeks
Placebo s.c Every 2 Weeks	Placebo s.c at baseline, Week 1 and Week 2, 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]	**0**	**0**	**0**	**0**
Change in Immunosuppressive Medication Score From Baseline to Week 28				

No statistical analysis provided for Change in Immunosuppressive Medication Score From Baseline to Week 28

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	One patient in the placebo arm was a misrandomized patient and did not receive any treatment and is not included in the adverse events section.

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300 mg s.c. at baseline, Week 1 and Week 2, then every 2 weeks
AIN457 300mg Every 4 Weeks	AIN457 300 mg subcutaneously at baseline and Week 2, then every 4 weeks.
AIN457 150mg Every 4 Weeks	AIN457 150 mg s.c. at baseline and Week 2, then every 4 weeks
Placebo Every 2 Weeks	Placebo s.c at baseline, Week 1 and Week 2, then every 2 weeks

Serious Adverse Events

	AIN457 300mg Every 2 Weeks	AIN457 300mg Every 4 Weeks	AIN457 150mg Every 4 Weeks	Placebo Every 2 Weeks
Total, serious adverse events				
# participants affected / at risk	**1/8 (12.50%)**	**1/10 (10.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**
Cardiac disorders				
Cardiac arrest †1				
# participants affected / at risk	**0/8 (0.00%)**	**1/10 (10.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**
Ventricular fibrillation †1				
# participants affected / at risk	**0/8 (0.00%)**	**1/10 (10.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**
Injury, poisoning and procedural complications				
Overdose †1				
# participants affected / at risk	**1/8 (12.50%)**	**0/10 (0.00%)**	**0/8 (0.00%)**	**0/4 (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	One patient in the placebo arm was a misrandomized patient and did not receive any treatment and is not included in the adverse events section.

Frequency Threshold

Threshold above which other adverse events are reported	0.0%

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300 mg s.c. at baseline, Week 1 and Week 2, then every 2 weeks
AIN457 300mg Every 4 Weeks	AIN457 300 mg subcutaneously at baseline and Week 2, then every 4 weeks.
AIN457 150mg Every 4 Weeks	AIN457 150 mg s.c. at baseline and Week 2, then every 4 weeks
Placebo Every 2 Weeks	Placebo s.c at baseline, Week 1 and Week 2, then every 2 weeks

Other Adverse Events

	AIN457 300mg Every 2 Weeks	AIN457 300mg Every 4 Weeks	AIN457 150mg Every 4 Weeks	Placebo Every 2 Weeks
Total, other (not including serious) adverse events				
# participants affected / at risk	**6/8 (75.00%)**	**4/10 (40.00%)**	**6/8 (75.00%)**	**4/4 (100.00%)**
Eye disorders				
Blepharitis (Fellow eye) [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**0/8 (0.00%)**	**1/4 (25.00%)**

Blepharitis (Study eye) [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**0/8 (0.00%)**	**1/4 (25.00%)**
Cataract (Fellow eye) [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**
Cataract nuclear (Fellow eye) [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**
Cataract nuclear (Study eye) [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**
Glaucoma (Fellow eye) [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**1/10 (10.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**
Lacrimation increased (Fellow eye) [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**0/8 (0.00%)**	**1/4 (25.00%)**
Lacrimation increased (Study eye) [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**0/8 (0.00%)**	**1/4 (25.00%)**
Ocular sarcoidosis (Fellow eye) [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**
Ocular sarcoidosis (Study eye) [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**
Gastrointestinal disorders				
Dental caries [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**0/8 (0.00%)**	**1/4 (25.00%)**
Diarrhoea [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**1/10 (10.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**
Nausea [†1]				
# participants affected / at risk	**1/8 (12.50%)**	**0/10 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**
General disorders				
Puncture site haemorrhage [†1]				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**

Pyrexia [†1]				
# participants affected / at risk	0/8 (0.00%)	0/10 (0.00%)	1/8 (12.50%)	0/4 (0.00%)
Immune system disorders				
Seasonal allergy [†1]				
# participants affected / at risk	1/8 (12.50%)	0/10 (0.00%)	0/8 (0.00%)	0/4 (0.00%)
Infections and infestations				
Gastroenteritis [†1]				
# participants affected / at risk	1/8 (12.50%)	0/10 (0.00%)	0/8 (0.00%)	0/4 (0.00%)
Influenza [†1]				
# participants affected / at risk	1/8 (12.50%)	1/10 (10.00%)	0/8 (0.00%)	0/4 (0.00%)
Nasopharyngitis [†1]				
# participants affected / at risk	1/8 (12.50%)	0/10 (0.00%)	0/8 (0.00%)	0/4 (0.00%)
Urinary tract infection [†1]				
# participants affected / at risk	1/8 (12.50%)	0/10 (0.00%)	0/8 (0.00%)	0/4 (0.00%)
Injury, poisoning and procedural complications				
Cataract traumatic (Fellow eye) [†1]				
# participants affected / at risk	0/8 (0.00%)	0/10 (0.00%)	1/8 (12.50%)	0/4 (0.00%)
Eye injury (Fellow eye) [†1]				
# participants affected / at risk	0/8 (0.00%)	0/10 (0.00%)	1/8 (12.50%)	0/4 (0.00%)
Investigations				
Gamma-glutamyltransferase increased [†1]				
# participants affected / at risk	0/8 (0.00%)	0/10 (0.00%)	0/8 (0.00%)	1/4 (25.00%)
Intraocular pressure increased (Fellow eye) [†1]				
# participants affected / at risk	0/8 (0.00%)	0/10 (0.00%)	0/8 (0.00%)	1/4 (25.00%)
Intraocular pressure increased (Study eye) [†1]				

# participants affected / at risk	0/8 (0.00%)	0/10 (0.00%)	0/8 (0.00%)	1/4 (25.00%)
Weight increased †1				
# participants affected / at risk	0/8 (0.00%)	1/10 (10.00%)	0/8 (0.00%)	0/4 (0.00%)
White blood cell count increased †1				
# participants affected / at risk	0/8 (0.00%)	0/10 (0.00%)	0/8 (0.00%)	1/4 (25.00%)
Metabolism and nutrition disorders				
Diabetes mellitus †1				
# participants affected / at risk	0/8 (0.00%)	0/10 (0.00%)	1/8 (12.50%)	0/4 (0.00%)
Musculoskeletal and connective tissue disorders				
Joint swelling †1				
# participants affected / at risk	0/8 (0.00%)	0/10 (0.00%)	0/8 (0.00%)	1/4 (25.00%)
Neck pain †1				
# participants affected / at risk	1/8 (12.50%)	0/10 (0.00%)	0/8 (0.00%)	0/4 (0.00%)
Pain in extremity †1				
# participants affected / at risk	0/8 (0.00%)	1/10 (10.00%)	0/8 (0.00%)	0/4 (0.00%)
Nervous system disorders				
Dementia Alzheimer's type †1				
# participants affected / at risk	1/8 (12.50%)	0/10 (0.00%)	0/8 (0.00%)	0/4 (0.00%)
Headache †1				
# participants affected / at risk	0/8 (0.00%)	0/10 (0.00%)	1/8 (12.50%)	0/4 (0.00%)
Psychiatric disorders				
Depression †1				
# participants affected / at risk	1/8 (12.50%)	0/10 (0.00%)	0/8 (0.00%)	0/4 (0.00%)
Intentional self-injury †1				
# participants affected / at risk	1/8 (12.50%)	0/10 (0.00%)	0/8 (0.00%)	0/4 (0.00%)
Respiratory, thoracic and mediastinal disorders				

Cough †1				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**
Epistaxis †1				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**0/8 (0.00%)**	**1/4 (25.00%)**
Skin and subcutaneous tissue disorders				
Erythema †1				
# participants affected / at risk	**0/8 (0.00%)**	**0/10 (0.00%)**	**1/8 (12.50%)**	**0/4 (0.00%)**
Rash †1				
# participants affected / at risk	**1/8 (12.50%)**	**0/10 (0.00%)**	**0/8 (0.00%)**	**0/4 (0.00%)**
Vascular disorders				
Hypertension †1				
# participants affected / at risk	**0/8 (0.00%)**	**1/10 (10.00%)**	**0/8 (0.00%)**	**0/4 (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
Study CAIN457C2302 was terminated to avoid continuing patients on a study with a low probability of success. Since patients did not reach the endpoint of analysis there can be no meaningful interpretation of data and data will be not provided.

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 (ie, data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
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)
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