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Trial record **1 of 2** for: CAIN457C2303

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38 Week Extension Study to CAIN457C2303 (SHIELD)

This study has been terminated.

(Core 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:
NCT01093846

First received: March 24, 2010
Last updated: January 22, 2016
Last verified: January 2016
History of Changes

Results First Received: February 12, 2015

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

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
No text entered.

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 300 mg Every 2 Weeks	300 mg every two weeks
AIN457 300 mg Monthly	300 mg monthly
AIN457 Placebo	No text entered.

Participant Flow: Overall Study

	AIN457 300 mg Every 2 Weeks	AIN457 300 mg Monthly	AIN457 Placebo
STARTED	**19**	**18**	**22**
COMPLETED	**0**	**0**	**1**
NOT COMPLETED	**19**	**18**	**21**
Adverse Event	**0**	**0**	**1**
Lack of Efficacy	**0**	**0**	**4**
Condition no longer required study drug	**1**	**1**	**1**
Administrative Problems	**18**	**17**	**15**

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 300 mg Every 2 Weeks	300 mg every two weeks
AIN457 300 mg Monthly	300 mg monthly
AIN457 Placebo	No text entered.
Total	Total of all reporting groups

Baseline Measures

	AIN457 300 mg Every 2 Weeks	**AIN457 300 mg Monthly**	**AIN457 Placebo**	**Total**
Number of Participants [units: participants]	**19**	**18**	**22**	**59**
Age [units: years] Mean (Standard Deviation)	**36.5 (10.01)**	**36.8 (13.07)**	**34.9 (11.20)**	**36.0 (11.29)**
Gender [units: Participants]				
Female	**6**	**5**	**11**	**22**
Male	**13**	**13**	**11**	**37**

Outcome Measures

Hide All Outcome Measures

1. Primary: The Effect of Continuous Treatment With Subcutaneous AIN457 Compared to Placebo in Reducing the Rate of Recurrent Ocular Exacerbations in Behçet's Patients With Intermediate Uveitis, Posterior Uveitis or Panuveitis in Group 1. [Time Frame: 62 weeks]

Measure Type	Primary
Measure Title	The Effect of Continuous Treatment With Subcutaneous AIN457 Compared to Placebo in Reducing the Rate of Recurrent Ocular Exacerbations in Behçet's Patients With Intermediate Uveitis, Posterior Uveitis or Panuveitis in Group 1.
Measure Description	The primary objective of the study was to determine the effect of continuous treatment with subcutaneous AIN457 compared to placebo in reducing the rate of recurrent ocular exacerbations in Behçet's patients with intermediate uveitis, posterior uveitis or panuveitis in patients who completed the core study and continued treatment in the extension study (Group 1).Due to early termination of the study AIN457C2303E1, the analysis of extension period was changed. No efficacy analyses were completed, the safety analyses are available in the summary of AEs which occurred during the extension and safety follow-up periods and are shown in the safety section .
Time Frame	62 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
Early Termination	No text entered.

Measured Values

	Early Termination
Number of Participants Analyzed **[units: participants]**	**0**

The Effect of Continuous Treatment With Subcutaneous AIN457 Compared to Placebo in Reducing the Rate of Recurrent Ocular Exacerbations in Behçet's Patients With Intermediate Uveitis, Posterior Uveitis or Panuveitis in Group 1.	

No statistical analysis provided for The Effect of Continuous Treatment With Subcutaneous AIN457 Compared to Placebo in Reducing the Rate of Recurrent Ocular Exacerbations in Behçet's Patients With Intermediate Uveitis, Posterior Uveitis or Panuveitis in Group 1.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300mg every 2 weeks. Safety is provided over the entire treatment period. This includes the core and extension period.
AIN457 300mg Monthly	AIN457 300mg monthly Safety is provided over the entire treatment period. This includes the core and extension period.
Placebo	Placebo Safety is provided over the entire treatment period. This includes the core and extension period.

Serious Adverse Events

	AIN457 300mg Every 2 Weeks	AIN457 300mg Monthly	Placebo
Total, serious adverse events			
# participants affected / at risk	**7/39 (17.95%)**	**8/39 (20.51%)**	**5/39 (12.82%)**
Cardiac disorders			
Supraventricular tachycardia †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Ear and labyrinth disorders			

Vertigo [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	0/39 (0.00%)
Eye disorders			
Cataract cortical (Fellow eye) [†1]			
# participants affected / at risk	0/39 (0.00%)	0/39 (0.00%)	1/39 (2.56%)
Cataract nuclear (Fellow eye) [†1]			
# participants affected / at risk	0/39 (0.00%)	0/39 (0.00%)	1/39 (2.56%)
Cataract subcapsular (Fellow eye) [†1]			
# participants affected / at risk	0/39 (0.00%)	0/39 (0.00%)	1/39 (2.56%)
Choroiditis (Fellow eye) [†1]			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	0/39 (0.00%)
Glaucoma (Fellow eye) [†1]			
# participants affected / at risk	0/39 (0.00%)	0/39 (0.00%)	1/39 (2.56%)
Retinal infiltrates (Fellow eye) [†1]			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	0/39 (0.00%)
Retinal infiltrates (Study eye) [†1]			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	0/39 (0.00%)
Uveitis (Fellow eye) [†1]			
# participants affected / at risk	1/39 (2.56%)	1/39 (2.56%)	0/39 (0.00%)
Uveitis (Study eye) [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	1/39 (2.56%)
Gastrointestinal disorders			
Abdominal pain [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	0/39 (0.00%)
Aphthous stomatitis [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	0/39 (0.00%)
Diarrhoea [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	0/39 (0.00%)

Diarrhoea haemorrhagic [†1]			
# participants affected / at risk	0/39 (0.00%)	0/39 (0.00%)	1/39 (2.56%)
Enteritis [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	0/39 (0.00%)
Haematemesis [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	0/39 (0.00%)
Lower gastrointestinal haemorrhage [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	0/39 (0.00%)
General disorders			
Fatigue [†1]			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	0/39 (0.00%)
Immune system disorders			
Behcet's syndrome [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	0/39 (0.00%)
Behcet's syndrome (Fellow eye) [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	0/39 (0.00%)
Behcet's syndrome (Study eye) [†1]			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	0/39 (0.00%)
Infections and infestations			
Folliculitis [†1]			
# participants affected / at risk	2/39 (5.13%)	0/39 (0.00%)	0/39 (0.00%)
Hypopyon (Fellow eye) [†1]			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	0/39 (0.00%)
Urinary tract infection [†1]			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	0/39 (0.00%)
Injury, poisoning and procedural complications			
Fall [†1]			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	0/39 (0.00%)

Foot fracture †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Investigations			
Intraocular pressure increased (Fellow eye) †1			
# participants affected / at risk	**0/39 (0.00%)**	**0/39 (0.00%)**	**1/39 (2.56%)**
Weight decreased †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Metabolism and nutrition disorders			
Diabetes mellitus †1			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Musculoskeletal and connective tissue disorders			
Bone pain †1			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Renal and urinary disorders			
Nephrolithiasis †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**0/39 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism †1			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Skin and subcutaneous tissue disorders			
Skin lesion †1			
# participants affected / at risk	**0/39 (0.00%)**	**1/39 (2.56%)**	**0/39 (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	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300mg every 2 weeks. Safety is provided over the entire treatment period. This includes the core and extension period.
AIN457 300mg Monthly	AIN457 300mg monthly Safety is provided over the entire treatment period. This includes the core and extension period.
Placebo	Placebo Safety is provided over the entire treatment period. This includes the core and extension period.

Other Adverse Events

	AIN457 300mg Every 2 Weeks	AIN457 300mg Monthly	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**28/39 (71.79%)**	**27/39 (69.23%)**	**25/39 (64.10%)**
Eye disorders			
Cataract subcapsular (Fellow eye) †1			
# participants affected / at risk	**4/39 (10.26%)**	**1/39 (2.56%)**	**0/39 (0.00%)**
Cataract subcapsular (Study eye) †1			
# participants affected / at risk	**4/39 (10.26%)**	**1/39 (2.56%)**	**1/39 (2.56%)**
Eye pain (Study eye) †1			
# participants affected / at risk	**1/39 (2.56%)**	**2/39 (5.13%)**	**2/39 (5.13%)**
Retinal vasculitis (Study eye) †1			
# participants affected / at risk	**2/39 (5.13%)**	**0/39 (0.00%)**	**1/39 (2.56%)**
Vision blurred (Fellow eye) †1			

# participants affected / at risk	0/39 (0.00%)	6/39 (15.38%)	1/39 (2.56%)
Vision blurred (Study eye) †1			
# participants affected / at risk	0/39 (0.00%)	2/39 (5.13%)	3/39 (7.69%)
Visual acuity reduced (Study eye) †1			
# participants affected / at risk	4/39 (10.26%)	2/39 (5.13%)	1/39 (2.56%)
Vitreous floaters (Study eye) †1			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	2/39 (5.13%)
Gastrointestinal disorders			
Abdominal pain †1			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	2/39 (5.13%)
Abdominal pain upper †1			
# participants affected / at risk	3/39 (7.69%)	3/39 (7.69%)	1/39 (2.56%)
Aphthous stomatitis †1			
# participants affected / at risk	3/39 (7.69%)	2/39 (5.13%)	2/39 (5.13%)
Diarrhoea †1			
# participants affected / at risk	2/39 (5.13%)	3/39 (7.69%)	2/39 (5.13%)
Mouth ulceration †1			
# participants affected / at risk	0/39 (0.00%)	0/39 (0.00%)	2/39 (5.13%)
Nausea †1			
# participants affected / at risk	4/39 (10.26%)	3/39 (7.69%)	2/39 (5.13%)
Toothache †1			
# participants affected / at risk	2/39 (5.13%)	1/39 (2.56%)	0/39 (0.00%)
Vomiting †1			
# participants affected / at risk	2/39 (5.13%)	0/39 (0.00%)	3/39 (7.69%)
General disorders			
Fatigue †1			
# participants affected / at risk	2/39 (5.13%)	2/39 (5.13%)	4/39 (10.26%)
Non-cardiac chest pain †1			

# participants affected / at risk	2/39 (5.13%)	0/39 (0.00%)	1/39 (2.56%)
Oedema peripheral †1			
# participants affected / at risk	3/39 (7.69%)	2/39 (5.13%)	0/39 (0.00%)
Pyrexia †1			
# participants affected / at risk	6/39 (15.38%)	3/39 (7.69%)	4/39 (10.26%)
Infections and infestations			
Conjunctivitis infective (Study eye) †1			
# participants affected / at risk	1/39 (2.56%)	2/39 (5.13%)	1/39 (2.56%)
Influenza †1			
# participants affected / at risk	2/39 (5.13%)	4/39 (10.26%)	1/39 (2.56%)
Nasopharyngitis †1			
# participants affected / at risk	2/39 (5.13%)	2/39 (5.13%)	1/39 (2.56%)
Oral herpes †1			
# participants affected / at risk	0/39 (0.00%)	0/39 (0.00%)	2/39 (5.13%)
Rash pustular †1			
# participants affected / at risk	2/39 (5.13%)	0/39 (0.00%)	1/39 (2.56%)
Sinusitis †1			
# participants affected / at risk	0/39 (0.00%)	2/39 (5.13%)	1/39 (2.56%)
Upper respiratory tract infection †1			
# participants affected / at risk	3/39 (7.69%)	5/39 (12.82%)	1/39 (2.56%)
Urinary tract infection †1			
# participants affected / at risk	1/39 (2.56%)	1/39 (2.56%)	2/39 (5.13%)
Investigations			
Alanine aminotransferase increased †1			
# participants affected / at risk	0/39 (0.00%)	0/39 (0.00%)	2/39 (5.13%)
Blood glucose increased †1			
# participants affected / at risk	0/39 (0.00%)	2/39 (5.13%)	0/39 (0.00%)
Intraocular pressure increased (Study eye) †1			

# participants affected / at risk	2/39 (5.13%)	3/39 (7.69%)	0/39 (0.00%)
Musculoskeletal and connective tissue disorders			
Arthralgia †1			
# participants affected / at risk	4/39 (10.26%)	3/39 (7.69%)	3/39 (7.69%)
Pain in extremity †1			
# participants affected / at risk	3/39 (7.69%)	1/39 (2.56%)	2/39 (5.13%)
Nervous system disorders			
Dizziness †1			
# participants affected / at risk	0/39 (0.00%)	3/39 (7.69%)	0/39 (0.00%)
Headache †1			
# participants affected / at risk	9/39 (23.08%)	7/39 (17.95%)	10/39 (25.64%)
Psychiatric disorders			
Anxiety †1			
# participants affected / at risk	0/39 (0.00%)	3/39 (7.69%)	0/39 (0.00%)
Respiratory, thoracic and mediastinal disorders			
Dyspnoea †1			
# participants affected / at risk	2/39 (5.13%)	0/39 (0.00%)	0/39 (0.00%)
Oropharyngeal pain †1			
# participants affected / at risk	0/39 (0.00%)	2/39 (5.13%)	2/39 (5.13%)
Rhinorrhoea †1			
# participants affected / at risk	0/39 (0.00%)	1/39 (2.56%)	2/39 (5.13%)
Skin and subcutaneous tissue disorders			
Acne †1			
# participants affected / at risk	1/39 (2.56%)	0/39 (0.00%)	2/39 (5.13%)
Erythema †1			
# participants affected / at risk	1/39 (2.56%)	1/39 (2.56%)	2/39 (5.13%)
Hirsutism †1			
# participants affected / at risk	2/39 (5.13%)	0/39 (0.00%)	1/39 (2.56%)

Skin lesion †1			
# participants affected / at risk	**1/39 (2.56%)**	**0/39 (0.00%)**	**2/39 (5.13%)**
Vascular disorders			
Hypertension †1			
# participants affected / at risk	**1/39 (2.56%)**	**2/39 (5.13%)**	**1/39 (2.56%)**

† 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
Due to early termination of the study AIN457C2303E1, the analysis of extension period was changed. No efficacy analyses were completed, the safety analyses were reduced to summary of AEs occurred during the extension and safety follow-up periods.

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

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01093846 History of Changes
Other Study ID Numbers:	**CAIN457C2303**E1 2009-013901-33
Study First Received:	March 24, 2010
Results First Received:	February 12, 2015
Last Updated:	January 22, 2016
Health Authority:	United States: Food and Drug Administration