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Trial record **2 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.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01090310

First received: March 18, 2010
Last updated: December 8, 2015
Last verified: December 2015
History of Changes

Full Text View | Tabular View | **Study Results** | Disclaimer | How to Read a Study Record

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:	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
Between August 2010 and March 2011, 70 patients were enrolled from 51 centers in 9 countries (United States, Germany, Switzerland, India, Spain, United Kingdom, Israel, Brazil, Italy). Recruitment was stopped due to study termination, therefore 16 out of 86 patients signed informed consent while being in core study were not enrolled into extension

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
In total, 125 patients were randomized to the core study with 1 patient misrandomized. Of these 124 patients 70 patients entered the extension period of the study. Core study NCT01032915

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300 mg s.c. every 2 weeks
AIN457 300 mg Every 4 Weeks	AIN457 300 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
AIN457 150 mg Every 4 Weeks	AIN457 150 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
Placebo	Placebo s.c. every 2 weeks

Participant Flow for 2 periods

Period 1: Core Study

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

Administrative reasons	5	6	4	4
Protocol deviation	1	0	0	1

Period 2: Extension Study

	AIN457 300mg Every 2 Weeks	AIN457 300 mg Every 4 Weeks	AIN457 150 mg Every 4 Weeks	Placebo
STARTED	17	16	16	21
COMPLETED	3	0	1	1
NOT COMPLETED	14	16	15	20
Aministrative problems	13	15	14	18
Adverse Event	0	0	0	1
Unsatisfactory therapeutic effect	1	0	1	1
Subject withdrew consent	0	1	0	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 Every 2 Weeks	AIN457 300 mg s.c. every 2 weeks

AIN457 300 mg Every 4 Weeks	AIN457 300 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
AIN457 150 mg Every 4 Weeks	AIN457 150 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
Placebo	Placebo s.c. every 2 weeks
Total	Total of all reporting groups

Baseline Measures

	AIN457 300mg Every 2 Weeks	AIN457 300 mg Every 4 Weeks	AIN457 150 mg Every 4 Weeks	Placebo	Total
Number of Participants [units: participants]	**29**	**31**	**31**	**34**	**125**
Age [units: Years] Mean (Standard Deviation)	**46.2 (14.29)**	**49.2 (11.14)**	**47.7 (13.50)**	**47.3 (15.46)**	**47.6 (13.60)**
Gender [units: Participants]					
Female	**17**	**16**	**20**	**18**	**71**
Male	**12**	**15**	**11**	**16**	**54**

Outcome Measures

Hide All Outcome Measures

1. Primary: The Time to the First Recurrence in Any Eye of Active Intermediate, Posterior, or Panuveitis From Baseline [Time Frame: Baseline to 52 weeks]

Measure Type	Primary
Measure Title	The Time to the 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 baseline 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, core and extension
Time Frame	Baseline to 52 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 in the core study and had 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 were assigned to at randomization

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300 mg s.c. every 2 weeks
AIN457 300 mg Every 4 Weeks	AIN457 300 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
AIN457 150 mg Every 4 Weeks	AIN457 150 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
Placebo	Placebo s.c. every 2 weeks

Measured Values

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

[1] Not estimable due to low number of events

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

2. Secondary: Change in Vitreous Haze Score for the Study Eye From Baseline to the Highest Post-baseline Value [Time Frame: Baseline to 52 weeks]

Measure Type	Secondary
Measure Title	Change in Vitreous Haze Score for the Study Eye From Baseline to the Highest Post-baseline Value
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 52 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 in the core study and had 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 were assigned to at randomization

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300 mg s.c. every 2 weeks
AIN457 300 mg Every 4 Weeks	AIN457 300 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
AIN457 150 mg Every 4 Weeks	AIN457 150 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly

Placebo	Placebo s.c. every 2 weeks

Measured Values

	AIN457 300mg Every 2 Weeks	AIN457 300 mg Every 4 Weeks	AIN457 150 mg Every 4 Weeks	Placebo
Number of Participants Analyzed [units: participants]	**29**	**31**	**31**	**33**
Change in Vitreous Haze Score for the Study Eye From Baseline to the Highest Post-baseline Value [units: Number of participants]				
2 or more steps increase	**4**	**2**	**1**	**2**
1 step increase	**4**	**8**	**7**	**11**
No changes	**21**	**21**	**23**	**20**
1 step decrease	**0**	**0**	**0**	**0**
2 or more steps decrease	**0**	**0**	**0**	**0**

No statistical analysis provided for Change in Vitreous Haze Score for the Study Eye From Baseline to the Highest Post-baseline Value

3. Secondary: Mean Change in Best Corrected Visual Acuity From Baseline, Core and Extension [Time Frame: Baseline to 52 weeks]

Measure Type	Secondary
Measure Title	Mean Change in Best Corrected Visual Acuity From Baseline, Core and Extension
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 52 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 in the core study and had 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 were assigned to at randomization

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300 mg s.c. every 2 weeks
AIN457 300 mg Every 4 Weeks	AIN457 300 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
AIN457 150 mg Every 4 Weeks	AIN457 150 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
Placebo	Placebo s.c. every 2 weeks

Measured Values

	AIN457 300mg Every 2 Weeks	**AIN457 300 mg Every 4 Weeks**	**AIN457 150 mg Every 4 Weeks**	**Placebo**
Number of Participants Analyzed **[units: participants]**	**3**	**0**	**1**	**1**
Mean Change in Best Corrected Visual Acuity From Baseline, Core and Extension **[units: Letters]** **Mean (Standard Deviation)**	**9 (4.36)**		**16** [1]	**5** [1]

[1] No results due to no or low numbers completing this time point

No statistical analysis provided for Mean Change in Best Corrected Visual Acuity From Baseline, Core and Extension

4. Secondary: Number of Participants With First Recurrence in in Any Eye of Active Intermediate, Posterior, or Panuveitis From Baseline During the Core and Extension Studies [Time Frame: Baseline to 52 weeks]

Measure Type	Secondary
Measure Title	Number of Participants With First Recurrence in in Any Eye of Active Intermediate, Posterior, or Panuveitis From Baseline During the Core and Extension Studies
Measure Description	Evaluation of recurrence until resolution is ascertained, based on the first criteria (a >2 step increase in vitreous haze with or without an increase in anterior chamber cell grade in either eye). A 2 step increase is defined as any of the following changes: 0-2, 0.5-2, 1-3, 2-4
Time Frame	Baseline to 52 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 in the core study and had 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 were assigned to at randomization

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300 mg s.c. every 2 weeks
AIN457 300 mg Every 4 Weeks	AIN457 300 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
AIN457 150 mg Every 4 Weeks	AIN457 150 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
Placebo	Placebo s.c. every 2 weeks

Measured Values

	AIN457 300mg Every 2 Weeks	**AIN457 300 mg Every 4 Weeks**	**AIN457 150 mg Every 4 Weeks**	**Placebo**

Number of Participants Analyzed **[units: participants]**	**29**	**31**	**31**	**33**
Number of Participants With First Recurrence in in Any Eye of Active Intermediate, Posterior, or Panuveitis From Baseline During the Core and Extension Studies **[units: Number of participants]**				
Patients with recurrence	**8**	**11**	**10**	**11**
Patients with only vitreous haze criterion	**2**	**3**	**4**	**2**
Patients with only visual acuity criterion	**5**	**8**	**6**	**9**
Both criteria at the same time	**1**	**0**	**0**	**0**

No statistical analysis provided for Number of Participants With First Recurrence in in Any Eye of Active Intermediate, Posterior, or Panuveitis From Baseline During the Core and Extension Studies

5. Secondary: Composite Immunosuppressive Medication Score From Baseline to Week 52, Core and Extension [Time Frame: Baseline to 52 weeks]

Measure Type	Secondary
Measure Title	Composite Immunosuppressive Medication Score From Baseline to Week 52, Core and Extension
Measure Description	IMS is a combined, single numeric score derived on the basis of the total daily dose of specific immunosuppressive agents per unit body weight, ranged on a scale from 0 to 9 for the total daily dose in milligrams per kilogram. The total IMS is the sum of the scores derived for the agents included into the score. The treatment groups will be compared using an analysis of covariance with treatment, region, and baseline IMS as covariate. 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 showed better clinical outcome.
Time Frame	Baseline to 52 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 in the core study and had 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 were assigned to at randomization

Reporting Groups

	Description
AIN457 300mg Every 2 Weeks	AIN457 300 mg s.c. every 2 weeks
AIN457 300 mg Every 4 Weeks	AIN457 300 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
AIN457 150 mg Every 4 Weeks	AIN457 150 mg s.c. monthly, alternating with placebo s.c. at Weeks 1 and 4 and then monthly
Placebo	Placebo s.c. every 2 weeks

Measured Values

	AIN457 300mg Every 2 Weeks	AIN457 300 mg Every 4 Weeks	AIN457 150 mg Every 4 Weeks	Placebo
Number of Participants Analyzed **[units: participants]**	**3**	**0**	**1**	**1**
Composite Immunosuppressive Medication Score From Baseline to Week 52, Core and Extension **[units: Units on a scale]** **Mean (Standard Deviation)**	**-5.67 (4.163)**		**-1** [1]	**-1** [1]

[1] No results due to no or low numbers completing this time point

No statistical analysis provided for Composite Immunosuppressive Medication Score From Baseline to Week 52, Core and Extension

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
AIN457 300mg Every 4 Weeks	AIN457 300mg every 4 weeks
AIN457 150mg Every 4 Weeks	AIN457 150mg every 4 weeks
Placebo Every 2 Weeks	Placebo 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	**4/29 (13.79%)**	**1/31 (3.23%)**	**1/31 (3.23%)**	**2/33 (6.06%)**
Eye disorders				
Uveitis (Fellow eye) †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**1/31 (3.23%)**	**0/33 (0.00%)**
Uveitis (Study eye) †1				
# participants affected / at risk	**1/29 (3.45%)**	**0/31 (0.00%)**	**1/31 (3.23%)**	**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%)**
Injury, poisoning and procedural complications				
Joint dislocation †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%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Bowen's disease †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**0/31 (0.00%)**	**1/33 (3.03%)**
Breast cancer †1				
# participants affected / at risk	**1/29 (3.45%)**	**0/31 (0.00%)**	**0/31 (0.00%)**	**0/33 (0.00%)**
Seborrhoeic keratosis †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%)**
Skin and subcutaneous tissue disorders				
Dermal cyst †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**0/31 (0.00%)**	**1/33 (3.03%)**
Lentigo †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**0/31 (0.00%)**	**1/33 (3.03%)**

† 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
AIN457 300mg Every 4 Weeks	AIN457 300mg every 4 weeks
AIN457 150mg Every 4 Weeks	AIN457 150mg every 4 weeks
Placebo Every 2 Weeks	Placebo 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	**20/29 (68.97%)**	**19/31 (61.29%)**	**22/31 (70.97%)**	**22/33 (66.67%)**
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%)**
Cystoid macular oedema (Study eye) †1				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**0/31 (0.00%)**	**0/33 (0.00%)**
Dry eye (Fellow eye) †1				
# participants affected / at risk	**1/29 (3.45%)**	**2/31 (6.45%)**	**1/31 (3.23%)**	**0/33 (0.00%)**
Dry eye (Study eye) †1				

# participants affected / at risk	1/29 (3.45%)	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%)	3/33 (9.09%)
Macular oedema (Study eye) †1				
# participants affected / at risk	1/29 (3.45%)	1/31 (3.23%)	0/31 (0.00%)	2/33 (6.06%)
Vision blurred (Fellow eye) †1				
# participants affected / at risk	2/29 (6.90%)	1/31 (3.23%)	1/31 (3.23%)	2/33 (6.06%)
Vision blurred (Study eye) †1				
# participants affected / at risk	2/29 (6.90%)	0/31 (0.00%)	1/31 (3.23%)	2/33 (6.06%)
Visual acuity reduced (Fellow eye) †1				
# participants affected / at risk	2/29 (6.90%)	1/31 (3.23%)	1/31 (3.23%)	0/33 (0.00%)
Visual impairment (Study eye) †1				
# participants affected / at risk	0/29 (0.00%)	0/31 (0.00%)	0/31 (0.00%)	2/33 (6.06%)
Vitreous floaters (Fellow eye) †1				
# participants affected / at risk	1/29 (3.45%)	1/31 (3.23%)	1/31 (3.23%)	2/33 (6.06%)
Vitreous floaters (Study eye) †1				
# participants affected / at risk	0/29 (0.00%)	2/31 (6.45%)	1/31 (3.23%)	2/33 (6.06%)
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%)
Abdominal pain upper †1				
# participants affected / at risk	0/29 (0.00%)	0/31 (0.00%)	1/31 (3.23%)	2/33 (6.06%)
Diarrhoea †1				
# participants affected / at risk	2/29 (6.90%)	2/31 (6.45%)	1/31 (3.23%)	1/33 (3.03%)
Dyspepsia †1				
# participants affected / at risk	0/29 (0.00%)	1/31 (3.23%)	0/31 (0.00%)	2/33 (6.06%)
Nausea †1				
# participants affected / at risk	0/29 (0.00%)	2/31 (6.45%)	2/31 (6.45%)	4/33 (12.12%)
General disorders				

Asthenia †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**2/31 (6.45%)**	**1/33 (3.03%)**
Malaise †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**2/31 (6.45%)**	**0/33 (0.00%)**
Infections and infestations				
Ear infection †1				
# participants affected / at risk	**2/29 (6.90%)**	**2/31 (6.45%)**	**1/31 (3.23%)**	**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	**3/29 (10.34%)**	**3/31 (9.68%)**	**2/31 (6.45%)**	**0/33 (0.00%)**
Nasopharyngitis †1				
# participants affected / at risk	**6/29 (20.69%)**	**4/31 (12.90%)**	**4/31 (12.90%)**	**5/33 (15.15%)**
Oral herpes †1				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**0/31 (0.00%)**	**0/33 (0.00%)**
Sinusitis †1				
# participants affected / at risk	**0/29 (0.00%)**	**1/31 (3.23%)**	**2/31 (6.45%)**	**1/33 (3.03%)**
Upper respiratory tract infection †1				
# participants affected / at risk	**2/29 (6.90%)**	**1/31 (3.23%)**	**1/31 (3.23%)**	**0/33 (0.00%)**
Urinary tract infection †1				
# participants affected / at risk	**1/29 (3.45%)**	**2/31 (6.45%)**	**1/31 (3.23%)**	**1/33 (3.03%)**
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%)**
Investigations				
Intraocular pressure increased (Fellow eye) †1				

# participants affected / at risk	2/29 (6.90%)	0/31 (0.00%)	1/31 (3.23%)	0/33 (0.00%)
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 pain †1				
# participants affected / at risk	0/29 (0.00%)	0/31 (0.00%)	0/31 (0.00%)	2/33 (6.06%)
Musculoskeletal stiffness †1				
# participants affected / at risk	0/29 (0.00%)	2/31 (6.45%)	0/31 (0.00%)	0/33 (0.00%)
Myalgia †1				
# participants affected / at risk	1/29 (3.45%)	2/31 (6.45%)	0/31 (0.00%)	1/33 (3.03%)
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%)	3/31 (9.68%)	1/31 (3.23%)	4/33 (12.12%)
Headache †1				
# participants affected / at risk	6/29 (20.69%)	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%)**	**3/31 (9.68%)**	**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%)**
Rash †1				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**2/31 (6.45%)**	**0/33 (0.00%)**
Rash erythematous †1				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**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.
- [x] 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

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01090310 History of Changes
Other Study ID Numbers:	**CAIN457C2301**E1 2009-015508-24
Study First Received:	March 18, 2010
Results First Received:	February 12, 2015
Last Updated:	December 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