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Trial record **1 of 1** for: CAIN457A2220

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A Dose Ranging Study of AIN457 in Patients With Moderate to Severe Chronic Plaque-type Psoriasis

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01071252

First received: February 18, 2010
Last updated: February 12, 2015
Last verified: February 2015
History of Changes

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Results First Received: January 28, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Plaque-type Psoriasis
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
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 1x25mg	AIN457 25mg Subcutaneously as a single dose
AIN457 3x25mg	AIN457 25mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x75mg	AIN457 75mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x150mg	AIN457 150mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
Placebo	Placebo subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)

Participant Flow: Overall Study

	AIN457 1x25mg	AIN457 3x25mg	AIN457 3x75mg	AIN457 3x150mg	Placebo
STARTED	29	26	21	27	22
COMPLETED	14	16	17	20	11
NOT COMPLETED	15	10	4	7	11
unsatisfactory therapeutic effect	4	6	2	0	6
Withdrawal by Subject	8	2	1	2	3
administrative problems	1	1	0	2	1
Lost to Follow-up	1	0	1	2	0
Adverse Event	1	1	0	1	0
Death	0	0	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.
No text entered.

Reporting Groups

	Description
AIN457 1x25mg	AIN457 25mg Subcutaneously as a single dose
AIN457 3x25mg	AIN457 25mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x75mg	AIN457 75mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x150mg	AIN457 150mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
Placebo	Placebo subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
Total	Total of all reporting groups

Baseline Measures

	AIN457 1x25mg	AIN457 3x25mg	AIN457 3x75mg	AIN457 3x150mg	Placebo	Total
Number of Participants [units: participants]	29	26	21	27	22	125
Age [units: years] Mean (Standard Deviation)	46.1 (12.65)	46.3 (13.43)	45.8 (12.36)	45.4 (11.64)	45.9 (10.88)	45.9 (12.07)
Gender [units: participants]						
Female	9	4	7	6	8	34
Male	20	22	14	21	14	91

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants of Reponders of Psoriasis Area and Severity Index (PASI) 75 Achievement at Week 13 [Time Frame: week 13]

Measure Type	Primary
Measure Title	Percentage of Participants of Reponders of Psoriasis Area and Severity Index (PASI) 75 Achievement at Week 13
Measure Description	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4).
Time Frame	week 13
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 full analysis set (FAS), identical to the randomized set, also consisted of all randomized patients.

Reporting Groups

	Description
AIN457 1x25mg	AIN457 25mg Subcutaneously as a single dose
AIN457 3x25mg	AIN457 25mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x75mg	AIN457 75mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x150mg	AIN457 150mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
Placebo	Placebo subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)

Measured Values

	AIN457 1x25mg	**AIN457 3x25mg**	**AIN457 3x75mg**	**AIN457 3x150mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**29**	**26**	**21**	**27**	**22**
Percentage of Participants of Reponders of Psoriasis Area and Severity Index (PASI) 75 Achievement at Week 13 [units: percentage of participants]	**3.4**	**19.2**	**57.1**	**81.5**	**9.1**

No statistical analysis provided for Percentage of Participants of Reponders of Psoriasis Area and Severity Index (PASI) 75 Achievement at Week 13

2. Secondary: Percentage of Participants With Investigator's Global Assessment (IGA) Response [Time Frame: Week 2, 3, 5, 9, 13, 17, 21, 25, 29, 33, 37]

Measure Type	Secondary
Measure Title	Percentage of Participants With Investigator's Global Assessment (IGA) Response
Measure Description	IGA treatment response is defined as achievement of IGA 0 (clear) or 1 (almost clear) and improvement of at least 2 points on the IGA scale compare with baseline.
Time Frame	Week 2, 3, 5, 9, 13, 17, 21, 25, 29, 33, 37
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 full analysis set (FAS), identical to the randomized set, also consisted of all randomized patients.

Reporting Groups

	Description
AIN457 1x25mg	AIN457 25mg Subcutaneously as a single dose
AIN457 3x25mg	AIN457 25mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x75mg	AIN457 75mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x150mg	AIN457 150mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
Placebo	Placebo subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)

Measured Values

	AIN457 1x25mg	**AIN457 3x25mg**	**AIN457 3x75mg**	**AIN457 3x150mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**29**	**26**	**21**	**27**	**22**
Percentage of Participants With Investigator's Global Assessment (IGA) Response [units: percentage of participants]					
Week 2	**0**	**0**	**0**	**3.7**	**0**
Week 3	**0**	**0**	**0**	**3.7**	**0**
Week 5	**0**	**3.8**	**4.8**	**7.4**	**0**
Week 9	**0**	**7.7**	**28.6**	**37**	**9.1**
Week 13	**0**	**11.5**	**33.3**	**48.1**	**9.1**
Week 17	**3.4**	**19.2**	**28.6**	**51.9**	**9.1**
Week 21	**0**	**19.2**	**38.1**	**40.7**	**13.6**
Week 25	**0**	**15.4**	**33.3**	**37**	**18.2**
Week 29	**0**	**11.5**	**19.0**	**40.7**	**13.6**
Week 33	**0**	**15.4**	**19.0**	**29.6**	**0**
Week 37	**0**	**15.4**	**9.5**	**25.9**	**0**

No statistical analysis provided for Percentage of Participants With Investigator's Global Assessment (IGA) Response

3. Secondary: Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI 50, PASI 75 or PASI 90) [Time Frame: Week 2, 3, 5, 9, 13, 17, 21, 25, 29, 33, 37]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI 50, PASI 75 or PASI 90)
Measure Description	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4).
Time Frame	Week 2, 3, 5, 9, 13, 17, 21, 25, 29, 33, 37

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 full analysis set (FAS), identical to the randomized set, also consisted of all randomized patients.

Reporting Groups

	Description
AIN457 1x25mg	AIN457 25mg Subcutaneously as a single dose
AIN457 3x25mg	AIN457 25mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x75mg	AIN457 75mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x150mg	AIN457 150mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
Placebo	Placebo subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)

Measured Values

	AIN457 1x25mg	AIN457 3x25mg	AIN457 3x75mg	AIN457 3x150mg	Placebo
Number of Participants Analyzed [units: participants]	**29**	**26**	**21**	**27**	**22**
Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI 50, PASI 75 or PASI 90) [units: Percentage of Participants]					
Week 2 PASI 50	**3.4**	**7.7**	**4.8**	**11.1**	**0**
Week 2 PASI 75	**0**	**0**	**0**	**0**	**0**
Week 2 PASI 90	**0**	**0**	**0**	**0**	**0**
Week 3 PASI 50	**3.4**	**7.7**	**23.8**	**18.5**	**4.5**
Week 3 PASI 75	**0**	**0**	**0**	**0**	**0**
Week 3 PASI 90	**0**	**0**	**0**	**0**	**0**
Week 5 PASI 50	**10.3**	**15.4**	**28.6**	**48.1**	**4.5**
Week 5 PASI 75	**0**	**7.7**	**4.8**	**14.8**	**4.5**
Week 5 PASI 90	**0**	**0**	**0**	**3.7**	**0**
Week 9 PASI 50	**10.3**	**38.5**	**52.4**	**85.2**	**13.6**
Week 9 PASI 75	**3.4**	**11.5**	**33.3**	**66.7**	**9.1**
Week 9 PASI 90	**0**	**3.8**	**9.5**	**14.8**	**0**
Week 13 PASI 50	**17.2**	**57.7**	**81.0**	**85.2**	**18.2**
Week 13 PASI 75	**3.4**	**19.2**	**57.1**	**81.5**	**9.1**
Week 13 PASI 90	**0**	**7.7**	**19.0**	**51.9**	**4.5**
Week 17 PASI 50	**20.7**	**53.8**	**76.2**	**85.2**	**27.3**
Week 17 PASI 75	**6.9**	**26.9**	**42.9**	**81.5**	**13.6**
Week 17 PASI 90	**0**	**15.4**	**9.5**	**44.4**	**0**
Week 21 PASI 50	**13.8**	**50.0**	**57.1**	**85.2**	**31.8**
Week 21 PASI 75	**0**	**23.1**	**38.1**	**77.8**	**13.6**
Week 21 PASI 90	**0**	**15.4**	**9.5**	**37.0**	**4.5**

Week 25 PASI 50	**13.8**	**50.0**	**57.1**	**85.2**	**31.8**
Week 25 PASI 75	**0**	**19.2**	**33.3**	**70.4**	**9.1**
Week 25 PASI 90	**0**	**11.5**	**19.0**	**29.6**	**4.5**
Week 29 PASI 50	**17.2**	**46.2**	**52.4**	**85.2**	**27.3**
Week 29 PASI 75	**0**	**15.4**	**23.8**	**59.3**	**13.6**
Week 29 PASI 90	**0**	**7.7**	**14.3**	**22.2**	**9.1**
Week 33 PASI 50	**10.3**	**34.6**	**47.6**	**77.8**	**22.7**
Week 33 PASI 75	**3.4**	**19.2**	**23.8**	**55.6**	**4.5**
Week 33 PASI 90	**0**	**0**	**9.5**	**18.5**	**4.5**
Week 37 PASI 50	**17.2**	**30.8**	**47.6**	**63.0**	**22.7**
Week 37 PASI 75	**3.4**	**19.2**	**19.0**	**25.9**	**4.5**
Week 37 PASI 90	**0**	**3.8**	**9.5**	**11.1**	**4.5**

No statistical analysis provided for Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI 50, PASI 75 or PASI 90)

4. Secondary: To Assess the Time to Relapse [Time Frame: 37 weeks]

Measure Type	Secondary
Measure Title	To Assess the Time to Relapse
Measure Description	Relapse is defined as the loss of at least 50% of the maximum PASI change from baseline achieved at any time before that visit and analyzed only for the active treatment groups.
Time Frame	37 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 full analysis set (FAS), identical to the randomized set, also consisted of all randomized patients.

Reporting Groups

	Description
AIN457 1x25mg	AIN457 25mg Subcutaneously as a single dose
AIN457 3x25mg	AIN457 25mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x75mg	AIN457 75mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x150mg	AIN457 150mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)

Measured Values

	AIN457 1x25mg	**AIN457 3x25mg**	**AIN457 3x75mg**	**AIN457 3x150mg**
Number of Participants Analyzed [units: participants]	**1**	**5**	**12**	**22**
To Assess the Time to Relapse [units: days] Median (95% Confidence Interval)	**NA** [1]	**NA** [1]	**NA** [2]	**203** [2]

[1] Not Estimable because no relapses occured
[2] Not Estimable because very low relapses occured

No statistical analysis provided for To Assess the Time to Relapse

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
AIN457 1x25mg	AIN457 25mg Subcutaneously as a single dose
AIN457 3x25mg	AIN457 25mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x75mg	AIN457 75mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x150mg	AIN457 150mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
Placebo	Placebo subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)

Serious Adverse Events

	AIN457 1x25mg	AIN457 3x25mg	AIN457 3x75mg	AIN457 3x150mg	Placebo
Total, serious adverse events					
# participants affected / at risk	**0/29 (0.00%)**	**2/26 (7.69%)**	**1/21 (4.76%)**	**0/27 (0.00%)**	**2/22 (9.09%)**
Cardiac disorders					
Acute myocardial infarction † 1					
# participants affected / at risk	**0/29 (0.00%)**	**0/26 (0.00%)**	**0/21 (0.00%)**	**0/27 (0.00%)**	**1/22 (4.55%)**
Atrial fibrillation † 1					
# participants affected / at risk	**0/29 (0.00%)**	**1/26 (3.85%)**	**0/21 (0.00%)**	**0/27 (0.00%)**	**0/22 (0.00%)**
Cardiomyopathy † 1					
# participants affected / at risk	**0/29 (0.00%)**	**1/26 (3.85%)**	**0/21 (0.00%)**	**0/27 (0.00%)**	**0/22 (0.00%)**
Myocardial infarction † 1					
# participants affected / at risk	**0/29 (0.00%)**	**0/26 (0.00%)**	**0/21 (0.00%)**	**0/27 (0.00%)**	**1/22 (4.55%)**
Wolff-Parkinson-White syndrome † 1					
# participants affected / at risk	**0/29 (0.00%)**	**0/26 (0.00%)**	**1/21 (4.76%)**	**0/27 (0.00%)**	**0/22 (0.00%)**
Infections and infestations					
Gastroenteritis viral † 1					
# participants affected / at risk	**0/29 (0.00%)**	**1/26 (3.85%)**	**0/21 (0.00%)**	**0/27 (0.00%)**	**0/22 (0.00%)**
Musculoskeletal and connective tissue disorders					
Psoriatic arthropathy † 1					
# participants affected / at risk	**0/29 (0.00%)**	**1/26 (3.85%)**	**0/21 (0.00%)**	**0/27 (0.00%)**	**0/22 (0.00%)**
Nervous system disorders					
Transient ischaemic attack † 1					
# participants affected / at risk	**0/29 (0.00%)**	**1/26 (3.85%)**	**0/21 (0.00%)**	**0/27 (0.00%)**	**0/22 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

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 1x25mg	AIN457 25mg Subcutaneously as a single dose
AIN457 3x25mg	AIN457 25mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x75mg	AIN457 75mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
AIN457 3x150mg	AIN457 150mg subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)
Placebo	Placebo subcutaneous monthly dosing, 3 times (weeks 1, 5, and 9)

Other Adverse Events

	AIN457 1x25mg	AIN457 3x25mg	AIN457 3x75mg	AIN457 3x150mg	Placebo
Total, other (not including serious) adverse events					
# participants affected / at risk	**14/29 (48.28%)**	**11/26 (42.31%)**	**10/21 (47.62%)**	**16/27 (59.26%)**	**8/22 (36.36%)**
General disorders					
Fatigue † 1					
# participants affected / at risk	**0/29 (0.00%)**	**0/26 (0.00%)**	**0/21 (0.00%)**	**3/27 (11.11%)**	**1/22 (4.55%)**
Oedema peripheral † 1					
# participants affected / at risk	**0/29 (0.00%)**	**0/26 (0.00%)**	**0/21 (0.00%)**	**2/27 (7.41%)**	**1/22 (4.55%)**
Infections and infestations					
Nasopharyngitis † 1					
# participants affected / at risk	**1/29 (3.45%)**	**4/26 (15.38%)**	**4/21 (19.05%)**	**4/27 (14.81%)**	**2/22 (9.09%)**
Pharyngitis † 1					
# participants affected / at risk	**0/29 (0.00%)**	**1/26 (3.85%)**	**0/21 (0.00%)**	**2/27 (7.41%)**	**0/22 (0.00%)**
Respiratory tract infection viral † 1					
# participants affected / at risk	**1/29 (3.45%)**	**1/26 (3.85%)**	**1/21 (4.76%)**	**0/27 (0.00%)**	**2/22 (9.09%)**
Upper respiratory tract infection † 1					
# participants affected / at risk	**3/29 (10.34%)**	**2/26 (7.69%)**	**1/21 (4.76%)**	**2/27 (7.41%)**	**0/22 (0.00%)**
Injury, poisoning and procedural complications					
Muscle strain † 1					
# participants affected / at risk	**1/29 (3.45%)**	**0/26 (0.00%)**	**0/21 (0.00%)**	**2/27 (7.41%)**	**0/22 (0.00%)**

Musculoskeletal and connective tissue disorders					
Back pain † 1					
# participants affected / at risk	**0/29 (0.00%)**	**1/26 (3.85%)**	**2/21 (9.52%)**	**1/27 (3.70%)**	**0/22 (0.00%)**
Myalgia † 1					
# participants affected / at risk	**2/29 (6.90%)**	**0/26 (0.00%)**	**0/21 (0.00%)**	**0/27 (0.00%)**	**1/22 (4.55%)**
Nervous system disorders					
Headache † 1					
# participants affected / at risk	**1/29 (3.45%)**	**2/26 (7.69%)**	**1/21 (4.76%)**	**1/27 (3.70%)**	**0/22 (0.00%)**
Skin and subcutaneous tissue disorders					
Pruritus † 1					
# participants affected / at risk	**1/29 (3.45%)**	**0/26 (0.00%)**	**0/21 (0.00%)**	**1/27 (3.70%)**	**3/22 (13.64%)**
Psoriasis † 1					
# participants affected / at risk	**8/29 (27.59%)**	**4/26 (15.38%)**	**4/21 (19.05%)**	**3/27 (11.11%)**	**2/22 (9.09%)**
Vascular disorders					
Hypertension † 1					
# participants affected / at risk	**1/29 (3.45%)**	**1/26 (3.85%)**	**0/21 (0.00%)**	**2/27 (7.41%)**	**0/22 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

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 Pharmaceuticals
phone: 862-778-8300

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01071252 History of Changes
Other Study ID Numbers:	**CAIN457A2220** 2009-016807-42
Study First Received:	February 18, 2010
Results First Received:	January 28, 2015
Last Updated:	February 12, 2015
Health Authority:	United States: Food and Drug Administration Canada: Health Canada Iceland: Icelandic Medicines Control Agency Estonia: The State Agency of Medicine Latvia: Agency of Medicines Japan: Pharmaceuticals and Medical Devices Agency