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Trial record **1 of 1** for: CACZ885H2255

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Targeted Dose Finding of Canakinumab (ACZ885) for Management of Acute Flare in Refractory or Contraindicated Gout Patients

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00798369

First received: November 25, 2008
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History of Changes

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Results First Received: January 20, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Acute Gout
Interventions:	Drug: Canakinumab Drug: Triamcinolone acetonide

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
Canakinumab 10 mg	Canakinumab 10 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 25 mg	Canakinumab 25 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 50 mg	Canakinumab 50 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or

	thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 90 mg	Canakinumab 90 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 150 mg	Canakinumab 150 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Triamcinolone Acetonide 40 mg	Triamcinolone acetonide 40 mg intramuscularly (i.m) once. The i.m. injection was recommended to be administered deeply into the gluteal muscle. Randomized patients received triamcinolone acetonide 40 mg i.m. once or canakinumab matching placebo once, on Day 1.

Participant Flow: Overall Study

	Canakinumab 10 mg	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 90 mg	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
STARTED	28	29	29	29	28	57
COMPLETED	27	28	27	28	27	54
NOT COMPLETED	1	1	2	1	1	3
Subject withdrew consent	0	0	1	1	0	2
Lost to Follow-up	1	1	1	0	1	0
Adminstrative problems	0	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
Canakinumab 10 mg	Canakinumab 10 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 25 mg	Canakinumab 25 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 50 mg	Canakinumab 50 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 90 mg	Canakinumab 90 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching

	triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 150 mg	Canakinumab 150 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Triamcinolone Acetonide 40 mg	Triamcinolone acetonide 40 mg intramuscularly (i.m) once. The i.m. injection was recommended to be administered deeply into the gluteal muscle. Randomized patients received triamcinolone acetonide 40 mg i.m. once or canakinumab matching placebo once, on Day 1.
Total	Total of all reporting groups

Baseline Measures

	Canakinumab 10 mg	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 90 mg	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg	Total
Number of Participants [units: participants]	**28**	**29**	**29**	**29**	**28**	**57**	**200**
Age, Customized [units: participants]							
≥18 years - 40 years	**6**	**4**	**3**	**5**	**8**	**7**	**33**
≥ 41 - 64 years	**21**	**21**	**19**	**20**	**15**	**39**	**135**
≥ 65 - 74 years	**0**	**3**	**6**	**2**	**3**	**10**	**24**
≥ 75 years	**1**	**1**	**1**	**2**	**2**	**1**	**8**
Gender [units: participants]							
Female	**2**	**3**	**2**	**5**	**0**	**2**	**14**
Male	**26**	**26**	**27**	**24**	**28**	**55**	**186**

Outcome Measures

Hide All Outcome Measures

1. Primary: The Dose of Canakinumab for Treatment of Acute Flares in Gout Patients That Leads to the Same Efficacy as Triamcinolone Acetonide With Respect to Pain Intensity on a 0-100 mm Visual Analog Scale (VAS) [Time Frame: at 24,48 and 72 hours post-baseline]

Measure Type	Primary
Measure Title	The Dose of Canakinumab for Treatment of Acute Flares in Gout Patients That Leads to the Same Efficacy as Triamcinolone Acetonide With Respect to Pain Intensity on a 0-100 mm Visual Analog Scale (VAS)
Measure Description	Mean target dose at 24, 48 and 72 hours. Four models: Emax, Logistic, Linear in log-dose, Linear were selected to describe the potential dose-response curve and hence estimate the target dose of canakinumab using baseline Visual Analog Scale (VAS) and Body Mass Index (BMI) as covariates. Target dose was defined as the dose for which the efficacy is equivalent to the efficacy of triamcinolone acetonide 40 mg and was identified by assessing the dose response relationship with regards to the pain intensity in the target joint measured on a 0- 100 mm VAS (0= no pain and 100= unbearable pain).
Time Frame	at 24,48 and 72 hours post-baseline
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) consisted of all participants as randomized that had at least one post baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, participants were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Linear Model	The linear model was the best-fitting model out of the 4 selected models (Emax, Logistic, Linear in Log-dose, Linear)with lowest Akaike Information Criterion (AIC).

Measured Values

	Linear Model
Number of Participants Analyzed **[units: participants]**	**197**
The Dose of Canakinumab for Treatment of Acute Flares in Gout Patients That Leads to the Same Efficacy as Triamcinolone Acetonide With Respect to Pain Intensity on a 0-100 mm Visual Analog Scale (VAS) **[units: mg]** **Number (95% Confidence Interval)**	
Target dose at 24 hrs post-baseline	**37** **(5.94 to 103.37)**
Target dose at 48 hrs post-baseline	**23** **(2.87 to 96.31)**
Target dose at 72 hrs post-baseline	**NA** **[1]**

[1] A target dose for canakinumab to be comparable to triamcinolone acetonide 40 mg could not be estimated at 72 hours as it lies below the range of all doses of canakinumab tested in this trial

No statistical analysis provided for The Dose of Canakinumab for Treatment of Acute Flares in Gout Patients That Leads to the Same Efficacy as Triamcinolone Acetonide With Respect to Pain Intensity on a 0-100 mm Visual Analog Scale (VAS)

2. Secondary: The Change in Pain Intensity in the Target Joint Following Canakinumab Administration Compared to Triamcinolone Acetonide [Time Frame: Baseline,at 72 hrs post-dose and 7 days post-dose]

Measure Type	Secondary
Measure Title	The Change in Pain Intensity in the Target Joint Following Canakinumab Administration Compared to Triamcinolone Acetonide
Measure Description	The change in pain intensity from baseline to 72 hours and 7 days post dose as measured on a 0-100 mm Visual Analog Scale(VAS): 0= no pain and 100= severe pain. Analysis of Covariance (ANCOVA) with treatment group, VAS at baseline and Body mass Index (BMI) at baseline as covariates. Change from baseline = (post-baseline measurement – baseline).
Time Frame	Baseline,at 72 hrs post-dose and 7 days post-dose
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 consisting of all participants with data for baseline and the given time point for each arm/group. Assessments up to Day 8, with 1 missing pain intensity value had it imputed. LOCF method was applied to impute post-dose measurements. Missing baseline values were replaced by the median baseline assessment

Reporting Groups

	Description
Canakinumab 10 mg	Canakinumab 10 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 25 mg	Canakinumab 25 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 50 mg	Canakinumab 50 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 90 mg	Canakinumab 90 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 150 mg	Canakinumab 150 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Triamcinolone Acetonide 40 mg	Triamcinolone acetonide 40 mg intramuscularly (i.m) once. The i.m. injection was recommended to be administered deeply into the gluteal muscle. Randomized patients received triamcinolone acetonide 40 mg i.m. once or canakinumab matching placebo once, on Day 1.

Measured Values

	Canakinumab 10 mg	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 90 mg	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**28**	**29**	**28**	**29**	**27**	**56**
The Change in Pain Intensity in the Target Joint Following Canakinumab Administration Compared to Triamcinolone Acetonide [units: Units on a scale] Least Squares Mean (Standard Error)						
72 hrs post-dose (n= 28, 28, 26, 28, 27, 53)	**-48.6 (4.36)**	**-46.6 (4.39)**	**-48.6 (4.56)**	**-52.7 (4.35)**	**-62.5 (4.58)**	**-43.3 (3.16)**
7 days post-dose (n= 26, 28, 27, 27, 26, 51)	**-57.6 (4.06)**	**-53.9 (3.93)**	**-63.4 (4.00)**	**-61.2 (3.96)**	**-66.4 (4.19)**	**-56.0 (2.88)**

No statistical analysis provided for The Change in Pain Intensity in the Target Joint Following Canakinumab Administration Compared to Triamcinolone Acetonide

3. Secondary: Percentage of Participants With an Excellent or Good Response With Regards to the Patient's Global Assessment of Response to Treatment [Time Frame: at 72 hours post-baseline]

Measure Type	Secondary

Measure Title	Percentage of Participants With an Excellent or Good Response With Regards to the Patient's Global Assessment of Response to Treatment
Measure Description	Participants scored their global assessment of response to treatment using a 5-point Likert scale: Excellent, Good, Acceptable, Slight and Poor.
Time Frame	at 72 hours post-baseline
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) consisted of all participants as randomized that had at least one post-baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, participants were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 10 mg	Canakinumab 10 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 25 mg	Canakinumab 25 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 50 mg	Canakinumab 50 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 90 mg	Canakinumab 90 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 150 mg	Canakinumab 150 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Triamcinolone Acetonide 40 mg	Triamcinolone acetonide 40 mg intramuscularly (i.m) once. The i.m. injection was recommended to be administered deeply into the gluteal muscle. Randomized patients received triamcinolone acetonide 40 mg i.m. once or canakinumab matching placebo once, on Day 1.

Measured Values

	Canakinumab 10 mg	**Canakinumab 25 mg**	**Canakinumab 50 mg**	**Canakinumab 90 mg**	**Canakinumab 150 mg**	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**28**	**29**	**28**	**29**	**27**	**56**
Percentage of Participants With an Excellent or Good Response With Regards to the Patient's Global Assessment of Response to Treatment [units: Percentage of Participants]	**64**	**62**	**71**	**66**	**89**	**54**

No statistical analysis provided for Percentage of Participants With an Excellent or Good Response With Regards to the Patient's Global Assessment of Response to Treatment

4. Secondary: The Time to 50% Reduction of Baseline Pain Intensity in the Target Joint [Time Frame: Baseline, within 7 days after randomization]

Measure Type	Secondary
Measure Title	The Time to 50% Reduction of Baseline Pain Intensity in the Target Joint
Measure Description	The median time in days to at least 50% reduction in Pain intensity from baseline as measured by Visual Analog Scale (VAS) for each treatment group. Participants scored their pain intensity in the target joint on a 0-100 mm VAS, ranging from no pain (0) to unbearable pain (100).
Time Frame	Baseline, within 7 days after randomization
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) consisted of all participants as randomized that had at least one post baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, participants were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 10 mg	Canakinumab 10 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 25 mg	Canakinumab 25 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 50 mg	Canakinumab 50 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 90 mg	Canakinumab 90 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 150 mg	Canakinumab 150 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Triamcinolone Acetonide 40 mg	Triamcinolone acetonide 40 mg intramuscularly (i.m) once. The i.m. injection was recommended to be administered deeply into the gluteal muscle. Randomized patients received triamcinolone acetonide 40 mg i.m. once or canakinumab matching placebo once, on Day 1.

Measured Values

	Canakinumab 10 mg	**Canakinumab 25 mg**	**Canakinumab 50 mg**	**Canakinumab 90 mg**	**Canakinumab 150 mg**	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**28**	**29**	**28**	**29**	**27**	**56**
The Time to 50% Reduction of Baseline Pain Intensity in the Target Joint	**2.9**	**2.9**	**1.0**	**1.0**	**1.0**	**2.0**

[units: Days] Median (95% Confidence Interval)	**(1.0 to 4.0)**	**(2.0 to 3.0)**	**(1.0 to 2.9)**	**(1.0 to 2.0)**	**(0.5 to 2.0)**	**(1.0 to 3.6)**

No statistical analysis provided for The Time to 50% Reduction of Baseline Pain Intensity in the Target Joint

5. Secondary: High Sensitivity C-reactive Protein (hsCRP) at 72 Hours, 7days, 4 Weeks and 8 Weeks Post Dose for Each Treatment Group [Time Frame: at 72 hours and 7 days, 4 and 8 weeks post-dose]

Measure Type	Secondary
Measure Title	High Sensitivity C-reactive Protein (hsCRP) at 72 Hours, 7days, 4 Weeks and 8 Weeks Post Dose for Each Treatment Group
Measure Description	High sensitivity C-reactive protein (hsCRP) was determined in serum at all visits (Visits 1-5) in order to identify the presence of inflammation, to determine its severity, and to monitor response to treatment. ANCOVA with treatment group, protein level at baseline and BMI at baseline as covariates.
Time Frame	at 72 hours and 7 days, 4 and 8 weeks post-dose
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) consisted of all participants as randomized that had at least one post baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, participants were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 10 mg	Canakinumab 10 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 25 mg	Canakinumab 25 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 50 mg	Canakinumab 50 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 90 mg	Canakinumab 90 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 150 mg	Canakinumab 150 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Triamcinolone Acetonide 40 mg	Triamcinolone acetonide 40 mg intramuscularly (i.m) once. The i.m. injection was recommended to be administered deeply into the gluteal muscle. Randomized patients received triamcinolone acetonide 40 mg i.m. once or canakinumab matching placebo once, on Day 1.

Measured Values

						Triamcinolone

	Canakinumab 10 mg	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 90 mg	Canakinumab 150 mg	Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**28**	**29**	**28**	**29**	**27**	**56**
High Sensitivity C-reactive Protein (hsCRP) at 72 Hours, 7days, 4 Weeks and 8 Weeks Post Dose for Each Treatment Group [units: mg/L] Least Squares Mean (Standard Error)						
72 hrs post-dose (n= 27, 28, 26, 28, 25, 53)	**16.7 (3.41)**	**7.9 (3.34)**	**11.7 (3.49)**	**13.4 (3.34)**	**9.2 (3.53)**	**13.4 (2.43)**
7 days post-dose (n= 28, 29, 28, 28, 27, 55)	**8.0 (3.30)**	**2.5 (3.23)**	**4.3 (3.31)**	**6.3 (3.29)**	**3.7 (3.36)**	**13.7 (2.35)**
4 week post-dose (n= 27, 28, 27, 28, 27, 55)	**3.0 (3.13)**	**2.9 (3.08)**	**2.9 (3.14)**	**4.8 (3.08)**	**4.8 (3.13)**	**9.2 (2.20)**
8 weeks post-dose (n= 26, 28, 27, 28, 27, 54)	**3.8 (1.79)**	**2.0 (1.72)**	**2.6 (1.75)**	**5.2 (1.72)**	**2.9 (1.75)**	**8.6 (1.24)**

No statistical analysis provided for High Sensitivity C-reactive Protein (hsCRP) at 72 Hours, 7days, 4 Weeks and 8 Weeks Post Dose for Each Treatment Group

6. Secondary: Serum Amyloid Protein (SAA) Levels at 72 Hours, 7days, 4 Weeks and 8 Weeks Post Dose for Each Treatment Group [Time Frame: at 72 hours and 7 days, 4 and 8 weeks post-dose]

Measure Type	Secondary
Measure Title	Serum Amyloid Protein (SAA) Levels at 72 Hours, 7days, 4 Weeks and 8 Weeks Post Dose for Each Treatment Group
Measure Description	Serum amyloid A (SAA) were determined in serum at all visits (Visits 1-5) in order to identify the presence of inflammation, to determine its severity, and to monitor response to treatment. ANCOVA with treatment group, protein level at baseline and BMI at baseline as covariates.
Time Frame	at 72 hours and 7 days, 4 and 8 weeks post-dose
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) consisted of all patients as randomized that had at least one post-baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 10 mg	Canakinumab 10 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 25 mg	Canakinumab 25 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 50 mg	Canakinumab 50 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching

	triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 90 mg	Canakinumab 90 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 150 mg	Canakinumab 150 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Triamcinolone Acetonide 40 mg	Triamcinolone acetonide 40 mg intramuscularly (i.m) once. The i.m. injection was recommended to be administered deeply into the gluteal muscle. Randomized patients received triamcinolone acetonide 40 mg i.m. once or canakinumab matching placebo once, on Day 1.

Measured Values

	Canakinumab 10 mg	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 90 mg	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**28**	**29**	**28**	**29**	**27**	**56**
Serum Amyloid Protein (SAA) Levels at 72 Hours, 7days, 4 Weeks and 8 Weeks Post Dose for Each Treatment Group [units: mg/L] Least Squares Mean (Standard Error)						
72 hrs post-dose (n= 26, 28, 28, 28, 27, 50)	**50.1 (20.05)**	**27.6 (19.32)**	**70.7 (19.37)**	**29.4 (19.28)**	**26.9 (19.69)**	**52.5 (14.48)**
7 days post-dose (n= 28, 28, 28, 28, 26, 49)	**10.6 (10.92)**	**5.4 (10.91)**	**11.9 (10.94)**	**10.5 (10.89)**	**10.3 (11.33)**	**39.4 (8.26)**
4 week post-dose (n= 27, 28, 27, 28, 27, 50)	**4.4 (3.53)**	**4.2 (3.46)**	**4.9 (3.53)**	**14.3 (3.45)**	**6.2 (3.53)**	**12.9 (2.59)**
8 weeks post-dose (n= 26, 26, 26, 27, 27, 48)	**5.5 (3.64)**	**4.6 (3.64)**	**5.7 (3.64)**	**8.2 (3.56)**	**4.1 (3.57)**	**18.0 (2.68)**

No statistical analysis provided for Serum Amyloid Protein (SAA) Levels at 72 Hours, 7days, 4 Weeks and 8 Weeks Post Dose for Each Treatment Group

7. Secondary: Amount of Rescue Medication Taken for Each Treatment Group [Time Frame: 7 days after study drug administration]

Measure Type	Secondary
Measure Title	Amount of Rescue Medication Taken for Each Treatment Group
Measure Description	Participants who had difficulty in tolerating their pain after the 6-hour post-dose pain assessments and during the first 7 study days were allowed to take a maximum of 30 mg prednisolone (or equivalent dose of prednisone [30 mg]) orally once a day for a maximum of 5 days. In addition, participants could use 500 mg acetaminophen (paracetamol) and/or 30 mg codeine as needed during the first 7 study days. A maximum of 1 g/dose or 3 g/day of acetaminophen and 30 mg/dose or 180 mg/day of codeine was allowed during the first 7 days of the study.
Time Frame	7 days after study drug administration
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) consisted of all participants as randomized that had at least one post baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, participants were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 10 mg	Canakinumab 10 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 25 mg	Canakinumab 25 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 50 mg	Canakinumab 50 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 90 mg	Canakinumab 90 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 150 mg	Canakinumab 150 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Triamcinolone Acetonide 40 mg	Triamcinolone acetonide 40 mg intramuscularly (i.m) once. The i.m. injection was recommended to be administered deeply into the gluteal muscle. Randomized patients received triamcinolone acetonide 40 mg i.m. once or canakinumab matching placebo once, on Day 1.

Measured Values

	Canakinumab 10 mg	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 90 mg	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**28**	**29**	**28**	**29**	**27**	**56**
Amount of Rescue Medication Taken for Each Treatment Group [units: mg] Mean (Standard Deviation)						
Acetaminophen	**1414.3 (2628.58)**	**1656.9 (4437.26)**	**2178.6 (2925.67)**	**1646.6 (3161.20)**	**607.4 (2250.12)**	**1614.3 (2958.51)**
Codeine	**42.9 (138.19)**	**78.6 (164.20)**	**49.3 (139.57)**	**27.9 (87.07)**	**4.4 (23.09)**	**52.0 (158.28)**
Prednisolone/Prednisone	**13.4 (36.82)**	**23.8 (44.03)**	**24.1 (59.36)**	**13.1 (35.37)**	**6.2 (24.54)**	**13.3 (26.13)**

No statistical analysis provided for Amount of Rescue Medication Taken for Each Treatment Group

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	End of study (8 weeks)

Additional Description	No text entered.

Reporting Groups

	Description
Canakinumab 10 mg	Canakinumab 10 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 25 mg	Canakinumab 25 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 50 mg	Canakinumab 50 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 90 mg	Canakinumab 90 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 150 mg	Canakinumab 150 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Triamcinolone Acetonide 40 mg	Triamcinolone acetonide 40 mg intramuscularly (i.m) once. The i.m. injection was recommended to be administered deeply into the gluteal muscle. Randomized patients received triamcinolone acetonide 40 mg i.m. once or canakinumab matching placebo once, on Day 1.

Serious Adverse Events

	Canakinumab 10 mg	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 90 mg	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Total, serious adverse events						
# participants affected / at risk	**0/28 (0.00%)**	**2/29 (6.90%)**	**2/29 (6.90%)**	**0/29 (0.00%)**	**0/28 (0.00%)**	**1/57 (1.75%)**
Infections and infestations						
Appendicitis † 1						
# participants affected / at risk	**0/28 (0.00%)**	**1/29 (3.45%)**	**1/29 (3.45%)**	**0/29 (0.00%)**	**0/28 (0.00%)**	**0/57 (0.00%)**
Bronchitis † 1						
# participants affected / at risk	**0/28 (0.00%)**	**1/29 (3.45%)**	**0/29 (0.00%)**	**0/29 (0.00%)**	**0/28 (0.00%)**	**0/57 (0.00%)**
Nervous system disorders						
Carotid artery stenosis † 1						
# participants affected / at risk	**0/28 (0.00%)**	**0/29 (0.00%)**	**1/29 (3.45%)**	**0/29 (0.00%)**	**0/28 (0.00%)**	**0/57 (0.00%)**
Cerebrovascular disorder † 1						
# participants affected / at risk	**0/28 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**	**0/28 (0.00%)**	**1/57 (1.75%)**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	End of study (8 weeks)
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Canakinumab 10 mg	Canakinumab 10 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 25 mg	Canakinumab 25 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 50 mg	Canakinumab 50 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 90 mg	Canakinumab 90 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Canakinumab 150 mg	Canakinumab 150 mg subcutaneous (s.c) once. The s.c. injection could be administered into the arm or thigh. Randomized patients received one s.c. injection of canakinumab and placebo matching triamcinolone acetonide (0.9% sodium chloride) intramuscularly (i.m.) once,on Day 1. The i.m. injection was recommended to be administered deeply into the gluteal muscle.
Triamcinolone Acetonide 40 mg	Triamcinolone acetonide 40 mg intramuscularly (i.m) once. The i.m. injection was recommended to be administered deeply into the gluteal muscle. Randomized patients received triamcinolone acetonide 40 mg i.m. once or canakinumab matching placebo once, on Day 1.

Other Adverse Events

	Canakinumab 10 mg	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 90 mg	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Total, other (not including serious) adverse events						
# participants affected / at risk	**2/28 (7.14%)**	**7/29 (24.14%)**	**5/29 (17.24%)**	**8/29 (27.59%)**	**5/28 (17.86%)**	**8/57 (14.04%)**
Infections and infestations						
Nasopharyngitis † 1						
# participants affected / at risk	**1/28 (3.57%)**	**1/29 (3.45%)**	**2/29 (6.90%)**	**0/29 (0.00%)**	**1/28 (3.57%)**	**2/57 (3.51%)**
Urinary tract infection † 1						

# participants affected / at risk	**0/28 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**	**1/29 (3.45%)**	**0/28 (0.00%)**	**3/57 (5.26%)**
Investigations						
Alanine aminotransferase increased † 1						
# participants affected / at risk	**0/28 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**	**2/29 (6.90%)**	**0/28 (0.00%)**	**0/57 (0.00%)**
Aspartate aminotransferase increased † 1						
# participants affected / at risk	**0/28 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**	**2/29 (6.90%)**	**1/28 (3.57%)**	**0/57 (0.00%)**
Blood uric acid increased † 1						
# participants affected / at risk	**0/28 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**	**2/29 (6.90%)**	**1/28 (3.57%)**	**0/57 (0.00%)**
Musculoskeletal and connective tissue disorders						
Bone pain † 1						
# participants affected / at risk	**0/28 (0.00%)**	**0/29 (0.00%)**	**2/29 (6.90%)**	**0/29 (0.00%)**	**0/28 (0.00%)**	**0/57 (0.00%)**
Pain in extremity † 1						
# participants affected / at risk	**0/28 (0.00%)**	**1/29 (3.45%)**	**1/29 (3.45%)**	**0/29 (0.00%)**	**0/28 (0.00%)**	**3/57 (5.26%)**
Nervous system disorders						
Headache † 1						
# participants affected / at risk	**1/28 (3.57%)**	**3/29 (10.34%)**	**1/29 (3.45%)**	**2/29 (6.90%)**	**1/28 (3.57%)**	**4/57 (7.02%)**
Respiratory, thoracic and mediastinal disorders						
Oropharyngeal pain † 1						
# participants affected / at risk	**0/28 (0.00%)**	**0/29 (0.00%)**	**0/29 (0.00%)**	**2/29 (6.90%)**	**1/28 (3.57%)**	**0/57 (0.00%)**
Skin and subcutaneous tissue disorders						
Hyperhidrosis † 1						
# participants affected / at risk	**0/28 (0.00%)**	**2/29 (6.90%)**	**0/29 (0.00%)**	**0/29 (0.00%)**	**0/28 (0.00%)**	**0/57 (0.00%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

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:

Chakraborty A, Van LM, Skerjanec A, Floch D, Klein UR, Krammer G, Sunkara G, Howard D. Pharmacokinetic and pharmacodynamic properties of canakinumab in patients with gouty arthritis. J Clin Pharmacol. 2013 Dec;53(12):1240-51. doi: 10.1002/jcph.162. Epub 2013 Sep 30.

Schlesinger N, De Meulemeester M, Pikhlak A, Yücel AE, Richard D, Murphy V, Arulmani U, Sallstig P, So A. Canakinumab relieves symptoms of acute flares and improves health-related quality of life in patients with difficult-to-treat Gouty Arthritis by suppressing inflammation: results of a randomized, dose-ranging study. Arthritis Res Ther. 2011 Mar 25;13(2):R53. doi: 10.1186/ar3297.

So A, De Meulemeester M, Pikhlak A, Yücel AE, Richard D, Murphy V, Arulmani U, Sallstig P, Schlesinger N. Canakinumab for the treatment of acute flares in difficult-to-treat gouty arthritis: Results of a multicenter, phase II, dose-ranging study. Arthritis Rheum. 2010 Oct;62(10):3064-76. doi: 10.1002/art.27600.

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00798369 History of Changes
Other Study ID Numbers:	**CACZ885H2255** EudraCT 2008-004666-61
Study First Received:	November 25, 2008
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Health Authority:	Argentina: Ministry of Health Belgium: Federal Agency for Medicinal Products and Health Products Canada: Health Canada France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Russia: Pharmacological Committee, Ministry of Health Switzerland: Federal Office of Public Health Turkey: Ministry of Health United Kingdom: Medicines and Healthcare Products Regulatory Agency United States: Food and Drug Administration