Trial record **1 of 3** for: CACZ885H2356
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Canakinumab in the Treatment of Acute Gout Flares and Prevention of New Flares in Patients Unable to Use Non-steroidal Anti-inflammatory Drugs (NSAIDs) and/or Colchicine Including a 12 Weeks Extension and an Open-label 48 Weeks Extension Study (β-RELIEVED)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01029652

First received: December 9, 2009
Last updated: December 24, 2013
Last verified: September 2012
History of Changes

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Results First Received: July 26, 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 150 mg Drug: Triamcinolone acetonide 40 mg Drug: Placebo to canakinumab Drug: Placebo to 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
Two patients randomized to canakinumab did not receive any study medication and were discontinued from the core study on the day of randomization, with the reason for discontinuation listed as Administrative Problems.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

	After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period. No patient received triamcinolone acetonide in second extension Study .

Participant Flow for 3 periods

Period 1: Core Study (0-12 Weeks)

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
STARTED	**115**	**115**
Full Analysis Set (FAS), Safety Set	**113**	**115**
COMPLETED	**109**	**105**
NOT COMPLETED	**6**	**10**
Unsatisfactory therapeutic effect	**0**	**4**
Patient Withdrew Consent	**1**	**3**
Lost to Follow-up	**3**	**1**
Administrative problems	**2**	**1**
Death	**0**	**1**

Period 2: Extension Study 1 (12-24 Weeks)

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
STARTED	**90**	**85**
COMPLETED	**87**	**80**
NOT COMPLETED	**3**	**5**
Unsatisfactory therapeutic effect	**0**	**1**
Lost to Follow-up	**2**	**3**
Protocol Deviation	**1**	**0**
Withdrawal by Subject	**0**	**1**

Period 3: Extension Study 2 (25-72 Weeks)

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
STARTED	**69**	**66**
Re-treated With or Switch to Canakinumab	**69** [1]	**39** [2]
COMPLETED	**68**	**63**
NOT COMPLETED	**1**	**3**
Death	**1**	**1**
Unsatisfactory therapeutic effect	**0**	**1**
Withdrawal by Subject	**0**	**1**

[1] Includes patients re-treated with canakinumab over 72 weeks study duration overall

[2] Includes patients switched to canakinumab from Week 25 - Week 72

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 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Total	Total of all reporting groups

Baseline Measures

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**	**Total**
Number of Participants [units: participants]	**113**	**115**	**228**
Age [1] [units: years] Mean (Standard Deviation)	**54 (11.18)**	**54.6 (10.71)**	**54.3 (10.93)**
Age, Customized [units: participants]			
< 65 years	**92**	**92**	**184**
≥ 65 - 74 years	**16**	**21**	**37**
≥ 75 years	**5**	**2**	**7**
Gender [units: participants]			
Female	**12**	**7**	**19**
Male	**101**	**108**	**209**

[1] Two patients randomized to canakinumab were not included in the data set (safety set) used to calculate demographic data as they did not receive any study medication and were discontinued from the study on the day of randomization.

Outcome Measures

Hide All Outcome Measures

1. Primary: Time to First New Flare [Time Frame: 12 weeks]

Measure Type	Primary
Measure Title	Time to First New Flare
Measure Description	Kaplan-Meier estimates of time to first new flare and confidence intervals were determined. For patients with event, time to event = (date of event – date of first dose of study drug + 1). Patients met definition of new flare if they had: • Flare in joint, not a previously affected joint (at baseline or during study) • Flare in joint previously affected (at baseline or during study) after previous flare in joint has resolved completely. Patients did not meet criterion of having new gout flare if: · Increasing/renewed gout pain in an affected joint before flare has resolved completely.
Time Frame	12 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) consisted of all patients as randomized in the core study who had taken at least one dose of study drug.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Time to First New Flare [units: Days] Median (95% Confidence Interval)	**NA** [1]	**NA** [1]

[1] The median time to first new flare could not be estimated because <50% of patients had a new flare during the time period.

No statistical analysis provided for Time to First New Flare

2. Primary: Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100mm VAS) [Time Frame: 72 hours post-dose (randomization)]

Measure Type	Primary
Measure Title	Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100mm VAS)
Measure Description	Patients scored their pain intensity in the joint most affected at baseline on a 0-100 mm VAS, ranging from no pain (0) to unbearable pain (100), at 72 hours post-dose. Scores on the 100 mm linear scale were measured to the nearest

	millimeter from the left. The ANCOVA analysis included treatment group, Baseline VAS score, and body mass index (BMI) at Baseline as covariates.
Time Frame	72 hours post-dose (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 patients as randomized in the core study who had taken at least one dose of study drug. Last Observation Carried Forward (LOCF) method was used to impute post dose measurement.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**111**
Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100mm VAS) [units: mm] Least Squares Mean (Standard Error)	**28.1 (2.42)**	**39.5 (2.44)**

No statistical analysis provided for Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100mm VAS)

3. Primary: Number of Participants With Adverse Events (AE), Death and Serious Adverse Events (24 Weeks Overall) [Time Frame: 24 weeks overall]

Measure Type	Primary
Measure Title	Number of Participants With Adverse Events (AE), Death and Serious Adverse Events (24 Weeks Overall)
Measure Description	This was the primary endpoint of both extension studies. Adverse event is defined as any unfavorable and unintended diagnosis, symptom, sign(including an abnormal laboratory finding),syndrome or disease which either occurs during the study, having been absent at baseline, or,if present at baseline, appears to worsen. Serious adverse event is defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.
Time Frame	24 weeks overall
Safety Issue	Yes

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.
Safety population consisted of all patients who received study drug in the core study and had at least one post-baseline safety assessment.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Number of Participants With Adverse Events (AE), Death and Serious Adverse Events (24 Weeks Overall) [units: Participants]		
Adverse Event	**71**	**56**
Death	**0**	**1**
Serious Adverse Event	**11**	**6**

No statistical analysis provided for Number of Participants With Adverse Events (AE), Death and Serious Adverse Events (24 Weeks Overall)

4. Primary: Number of Participants With Adverse Events (AE), Death and Serious Adverse Events (72 Weeks Overall) [Time Frame: 72 weeks overall]

Measure Type	Primary
Measure Title	Number of Participants With Adverse Events (AE), Death and Serious Adverse Events (72 Weeks Overall)
Measure Description	This was the primary endpoint of both extension studies. Adverse event is defined as any unfavorable and unintended diagnosis, symptom, sign(including an abnormal laboratory finding),syndrome or disease which either occurs during the study, having been absent at baseline, or,if present at baseline, appears to worsen. Serious adverse event is defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.
Time Frame	72 weeks overall
Safety Issue	Yes

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.

Safety population consisted of all patients who received study drug in the core study and had at least one post-baseline safety assessment.

Reporting Groups

	Description
All Randomized to Canakinumab	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study. After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study.
Randomized to Canakinumab :Before Re-treated With Canakinumab	All patients who were randomized to Canakinumab in core study period received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1 but experienced adverse events before re-treated with canakinumab
Randomized to Canakinumab :After Re-treated With Canakinumab	All patients who were randomized to Canakinumab in core study period received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1 but experienced adverse events after re-treated with canakinumab
Randomized to Triamcinolone Acetonide (Triam)	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period. AE/SAE were only assigned to this group before being switched to canakinumab
Randomized to Triam: Before Switched to Canakinumab	All patients who were randomized to triamcinolone acetonide (Triam) received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1, experienced adverse event before switched to canakinumab
Randomized to Triam: After Switched to Canakinumab	All patients who were randomized to triamcinolone acetonide (Triam) received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1, experienced adverse event after switched to canakinumab

Measured Values

	All Randomized to Canakinumab	Randomized to Canakinumab :Before Re-treated With Canakinumab	Randomized to Canakinumab :After Re-treated With Canakinumab	Randomized to Triamcinolone Acetonide (Triam)	Randomized to Triam: Before Switched to Canakinumab	Randomized to Triam: After Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**113**	**69**	**69**	**115**	**39**	**39**

Number of Participants With Adverse Events (AE), Death and Serious Adverse Events (72 Weeks Overall) [units: Participants]						
Adverse Event	76	41	38	60	20	19
Death	1	0	1	2	0	0
Serious Adverse Event	19	6	8	11	2	0

No statistical analysis provided for Number of Participants With Adverse Events (AE), Death and Serious Adverse Events (72 Weeks Overall)

5. Secondary: Time to at Least a 50% Reduction in Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100mm VAS) [Time Frame: From baseline to 7 days post dose (randomization)]

Measure Type	Secondary
Measure Title	Time to at Least a 50% Reduction in Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100mm VAS)
Measure Description	The Kaplan-Meier estimates of the time to at least a 50% reduction in self-assessed pain intensity in the joint most affected at baseline was determined along with the 95% confidence interval. Patients scored their pain intensity on a 0-100 mm VAS, ranging from no pain (0) to unbearable pain (100). Scores on the 100 mm linear scale were measured to the nearest millimeter from the left. Pain was scored at Baseline; at 6 and 12 hours post-dose; and at 1, 2, 3, 4, 5, 6, and 7 days post-dose.
Time Frame	From baseline to 7 days post dose (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 patients as randomized in the core study who had taken at least one dose of study drug. Last Observation Carried Forward (LOCF) method was used to impute post dose measurement.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**111**

Time to at Least a 50% Reduction in Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100mm VAS) [units: Hours] Median (95% Confidence Interval)	**48.0 (24.0 to 60.0)**	**72.0 (48.0 to 96.0)**

No statistical analysis provided for Time to at Least a 50% Reduction in Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100mm VAS)

6. Secondary: Time to Complete Resolution of Pain [Time Frame: 7 days post-dose (randomization)]

Measure Type	Secondary
Measure Title	Time to Complete Resolution of Pain
Measure Description	Patients scored their pain intensity on a 5-point Likert scale (none, mild, moderate, severe, extreme). Complete Resolution of Pain is defined as no pain (None) on the Likert Scale. Pain was scored at Baseline; at 6 and 12 hours post-dose; and at 1, 2, 3, 4, 5, 6, and 7 days post-dose. The Kaplan-Meier estimates of time to complete resolution of self-assessed pain intensity in the joint most affected and their confidence intervals were determined.
Time Frame	7 days post-dose (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 patients as randomized in the core study who had taken at least one dose of study drug.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Time to Complete Resolution of Pain [units: Hours] Median (95% Confidence Interval)	**NA** [1]	**NA** [1]

[1] The median time to complete resolution could not be estimated because <50% of patients had a complete resolution during the time period.

No statistical analysis provided for Time to Complete Resolution of Pain

7. Secondary: Percentage of Participants With Complete Resolution of Pain [Time Frame: 7 days post-dose (randomization)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Complete Resolution of Pain
Measure Description	Patients scored their pain intensity on a 5-point Likert scale (none, mild, moderate, severe, extreme). Pain was scored at Baseline; at 6 and 12 hours post-dose; and at 1, 2, 3, 4, 5, 6, and 7 days post-dose. Complete Resolution of Pain is defined as no pain (None) on the Likert Scale. The Kaplan-Meier estimates of cumulative event rate = percentage of participants with event up to the end of the time interval.
Time Frame	7 days post-dose (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 patients as randomized in the core study who had taken at least one dose of study drug.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Percentage of Participants With Complete Resolution of Pain [units: Percentage of participants] Number (95% Confidence Interval)	**34.5 (26.6 to 44.1)**	**31.3 (23.7 to 40.6)**

No statistical analysis provided for Percentage of Participants With Complete Resolution of Pain

8. Secondary: Percentage of Participants With at Least 1 New Gout Flare During the 12 Weeks [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Percentage of Participants With at Least 1 New Gout Flare During the 12 Weeks
Measure Description	Patients met definition of new flare if they had: • Flare in joint, not a previously affected joint (at baseline or during study) • Flare in joint previously affected (at baseline or during study) after previous flare in joint has resolved completely. Patients did not meet criterion of having new gout flare if: · Increasing/renewed gout pain in an affected joint before the flare has resolved completely.
Time Frame	12 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) consisted of all patients as randomized in the core study who had taken at least one dose of study drug.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Percentage of Participants With at Least 1 New Gout Flare During the 12 Weeks [units: Percentage of participants]	**18.6**	**34.8**

No statistical analysis provided for Percentage of Participants With at Least 1 New Gout Flare During the 12 Weeks

9. Secondary: Mean Number of New Gout Flares Per Patient [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Mean Number of New Gout Flares Per Patient
Measure Description	Patients met definition of new flare if they had: • Flare in joint, not a previously affected joint (at baseline or during study) • Flare in joint previously affected (at baseline or during study) after previous flare in joint has resolved completely. Patients did not meet criterion of having new gout flare if: · Increasing/renewed gout pain in an affected joint before the flare has resolved completely.
Time Frame	12 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) consisted of all patients as randomized in the core study who had taken at least one dose of study drug.

Reporting Groups

	Description

Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Mean Number of New Gout Flares Per Patient [units: New flares/patient/12 weeks] Mean (Standard Deviation)	**0.21 (0.472)**	**0.53 (0.892)**

No statistical analysis provided for Mean Number of New Gout Flares Per Patient

10. Secondary: SF36 Physical Function Score at Week 12 [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	SF36 Physical Function Score at Week 12
Measure Description	The SF-36 measures the impact of disease on overall quality of life (QoL). This 36-item survey has 8 subscales that can be aggregated into physical- and mental-component summary scores. Scores are standardized with the use of norm-based methods based on an assessment of the general U.S. population free of chronic conditions. Scores range from 1-100 with a mean=50 and a standard deviation=10. A higher score indicates less impact on QoL. A negative change score indicates improvement. An ANCOVA model was used with treatment group and baseline SF-36 physical function subscore as covariates.
Time Frame	Week 12
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 in the core study who had taken at least one dose of study drug. Participant observations at Week 12 were included in the analysis.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12

	weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**96**	**92**
SF36 Physical Function Score at Week 12 [units: Units on a scale] Least Squares Mean (Standard Error)	**71.76 (2.688)**	**71.48 (2.745)**

No statistical analysis provided for SF36 Physical Function Score at Week 12

11. Secondary: Time to First New Flare [Time Frame: 24 weeks]

Measure Type	Secondary
Measure Title	Time to First New Flare
Measure Description	Kaplan-Meier (KM) estimates of time to first new flare and confidence intervals were determined. Patients met definition of new flare if they had: • Flare in joint, not a previously affected joint (at baseline or during study) • Flare in joint previously affected (at baseline or during study) after previous flare in joint has resolved completely. Patients did not meet criterion of having new gout flare if: · Increasing/renewed gout pain in an affected joint before the flare has resolved completely.
Time Frame	24 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) consisted of all patients as randomized in the core study who had taken at least one dose of study drug.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**113**	**115**
	NA [1]	**119** [2]

Time to First New Flare [units: Days] Median (95% Confidence Interval)		

[1] The median time to first new flare could not be estimated because <50% of patients had a new flare during the time period.
[2] The upper limit was not estimable in the study as it is longer than the duration of the study (24 weeks).

No statistical analysis provided for Time to First New Flare

12. Secondary: Mean Number of New Gout Flares Per Patient During the 24 Weeks of the Study [Time Frame: 24 weeks]

Measure Type	Secondary
Measure Title	Mean Number of New Gout Flares Per Patient During the 24 Weeks of the Study
Measure Description	Patients met definition of new flare if they had: • Flare in joint, not a previously affected joint (at baseline or during study) • Flare in joint previously affected (at baseline or during study) after previous flare in joint has resolved completely. Patients did not meet criterion of having new gout flare if: · Increasing/renewed gout pain in an affected joint before the flare has resolved completely.
Time Frame	24 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) consisted of all patients as randomized in the core study who had taken at least one dose of study drug.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Mean Number of New Gout Flares Per Patient During the 24 Weeks of the Study [units: New flares/patient/24 weeks] Mean (Standard Deviation)	**0.40 (0.634)**	**0.87 (1.104)**

No statistical analysis provided for Mean Number of New Gout Flares Per Patient During the 24 Weeks of the Study

13. Secondary: Time to First Intake of Rescue Medication After the Last Post Baseline Flare. [Time Frame: 72 hours post-dose for the last post-baseline flare (during 24 weeks overall)]

Measure Type	Secondary
Measure Title	Time to First Intake of Rescue Medication After the Last Post Baseline Flare.
Measure Description	The Kaplan-Meier estimates of medians and 95% confidence intervals were used to calculate the endpoint.
Time Frame	72 hours post-dose for the last post-baseline flare (during 24 weeks overall)
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 in the core study who had taken at least one dose of study drug. Patients with observations 72 hours post-dose for the last post-baseline flare during 24 weeks were included in analysis.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**35**	**43**
Time to First Intake of Rescue Medication After the Last Post Baseline Flare. [units: Hours] Median (95% Confidence Interval)	**NA** [1]	**NA** [1]

[1] The data were not estimable as <50% patients took rescue medication.

No statistical analysis provided for Time to First Intake of Rescue Medication After the Last Post Baseline Flare.

14. Secondary: Patient's Assessment of Gout Pain Intensity in the Most Affected Joint on a Visual Analog Scale (VAS) in Extension [Time Frame: 72 hours post-dose for the last post-baseline flare (during 24 weeks overall)]

Measure Type	Secondary
Measure Title	Patient's Assessment of Gout Pain Intensity in the Most Affected Joint on a Visual Analog Scale (VAS) in Extension
Measure Description	Patients scored their pain intensity in the joint most affected at baseline on a 0-100 mm VAS, ranging from no pain (0) to unbearable pain (100). Scores on the 100 mm linear scale were measured to the nearest millimeter from the left. The ANCOVA analysis included treatment group, Baseline VAS score, and body mass index (BMI) at Baseline as covariates.

Time Frame	72 hours post-dose for the last post-baseline flare (during 24 weeks overall)
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 in the core study who had taken at least one dose of study drug. Last Observation Carried Forward (LOCF) method was applied to impute post dose measurements.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**35**	**41**
Patient's Assessment of Gout Pain Intensity in the Most Affected Joint on a Visual Analog Scale (VAS) in Extension [units: mm] Least Squares Mean (Standard Error)	**34.6 (4.35)**	**44.9 (4.01)**

No statistical analysis provided for Patient's Assessment of Gout Pain Intensity in the Most Affected Joint on a Visual Analog Scale (VAS) in Extension

15. Secondary: Percentage of Participants With Maximum Severity of Last Post-baseline Flare (5-point Likert Scale) [Time Frame: Last post-baseline flare (during 24 weeks overall)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Maximum Severity of Last Post-baseline Flare (5-point Likert Scale)
Measure Description	Maximum severity is the maximum Likert score recorded after the start of the flare. Participant scored their current pain intensity in the most affected joint of the gout flare on a 5-point Likert Scale (none, mild, moderate, severe, extreme). It participant had a new flare, they also scored the maximum amount of acute gout pain in the most affected joint since the onset of a new flare on 5 point Likert scale (none, mild, moderate, severe, extreme).
Time Frame	Last post-baseline flare (during 24 weeks overall)
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 in the core study who had taken at least one dose of study drug. Participants with baseline and last post-baseline observations were included in this analysis.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**35**	**43**
Percentage of Participants With Maximum Severity of Last Post-baseline Flare (5-point Likert Scale) [units: Percentage of participants]		
None	**0.0**	**0.0**
Mild	**0.0**	**2.3**
Moderate	**14.3**	**16.3**
Severe	**77.1**	**60.5**
Extreme	**8.6**	**20.9**

No statistical analysis provided for Percentage of Participants With Maximum Severity of Last Post-baseline Flare (5-point Likert Scale)

16. Secondary: Amount of Rescue Medication Taken [Time Frame: 7 days last post-baseline flare (during 24 weeks)]

Measure Type	Secondary
Measure Title	Amount of Rescue Medication Taken
Measure Description	Patients who had difficulty in tolerating their pain were allowed to take rescue medication after the 6-hour post-dose pain assessments as follows: • Acetaminophen (paracetamol) 500 mg and/ or codeine 30 mg as required. A maximum of 1 g/dose or 3 g/day of acetaminophen and 30 mg/ dose or 180 mg/day of codeine was allowed. • If they had insufficient pain relief, patients were allowed to take a maximum of 30 mg of oral prednisolon as required per day for 2 days followed by up to 20 mg of prednisolone as required subsequent days within 7 days of a gout flare.
Time Frame	7 days last post-baseline flare (during 24 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) consisted of all patients as randomized in the core study who had taken at least one dose of study drug. Patients with observations at 7 days last post-baseline flare were included in this analysis.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**35**	**43**
Amount of Rescue Medication Taken [units: mg] Mean (Standard Deviation)		
Acetaminophen	**1931.4 (3266.12)**	**2058.1 (3331.33)**
Codeine	**7.7 (25.56)**	**46.0 (118.26)**
Prednisolone/Prednisone	**4.1 (17.34)**	**21.6 (47.42)**

No statistical analysis provided for Amount of Rescue Medication Taken

17. Secondary: Percentage of Participants Who Took Rescue Medication [Time Frame: during 12 weeks core, 24 weeks overall]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Took Rescue Medication
Measure Description	Patients who had difficulty in tolerating their pain were allowed to take rescue medication after the 6-hour post-dose pain assessments. Permitted rescue medications included acetaminophen 500 mg and/ or codeine 30 mg as needed. If they had insufficient pain relief, patients were allowed to take a maximum of 30 mg of oral prednisolone as needed per day for 2 days followed by up to 20 mg of prednisolone as needed per day for 3 subsequent days within 7 days after randomization or after re-dose/injection administration.
Time Frame	during 12 weeks core, 24 weeks overall
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 in core study who had taken at least one dose of study drug. "12 weeks:Core" consisted of patients taking rescue medication during baseline flare of Core study and "24 weeks:Overall" consisted of patients who took rescue medication during last post-baseline flare during 24 weeks.

Reporting Groups

	Description

Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Percentage of Participants Who Took Rescue Medication [units: Percentage of participants]		
12 weeks :Core (N=113, 115)	**31.0**	**52.2**
24 weeks: Overall (N=35, 43)	**48.6**	**44.2**

No statistical analysis provided for Percentage of Participants Who Took Rescue Medication

18. Secondary: High-sensitivity C-reactive Protein (hsCRP) and Serum Amyloid A Protein (SAA) Levels for Core and 24 Weeks Overall [Time Frame: 72 hours post-dose (randomization), 72 hours post-dose for the last post-baseline flare (during 24 weeks overall)]

Measure Type	Secondary
Measure Title	High-sensitivity C-reactive Protein (hsCRP) and Serum Amyloid A Protein (SAA) Levels for Core and 24 Weeks Overall
Measure Description	High sensitivity C-reactive protein (hsCRP) and serum amyloid A (SAA) were determined in blood serum in order to identify the presence of inflammation, to determine its severity, and to monitor the response to treatment. Analytes were measured by a central laboratory. The analysis included treatment group, log-transformed protein level at baseline, and body mass index (BMI) at baseline as covariates.
Time Frame	72 hours post-dose (randomization), 72 hours post-dose for the last post-baseline flare (during 24 weeks overall)
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 in core study who had taken at least one dose of study drug. Patients with baseline flare and data at 72 hours post-dose in core and patients with a new flare and data at 72 hours post-dose for the last post-baseline flare (during 24 weeks overall) were included in this analysis.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand

	upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**113**	**115**
High-sensitivity C-reactive Protein (hsCRP) and Serum Amyloid A Protein (SAA) Levels for Core and 24 Weeks Overall [units: mg/L] Least Squares Mean (95% Confidence Interval)		
hsCRP : Core(n= 109, 107)	**4.50 (3.96 to 5.12)**	**7.08 (6.22 to 8.07)**
SAA protein : Core (n=105, 106)	**6.77 (5.57 to 8.21)**	**17.00 (14.01 to 20.62)**
hsCRP : 24 weeks(n= 31, 32)	**5.18 (3.79 to 7.09)**	**7.18 (5.27 to 9.77)**
SAA protein : 24 weeks (n=28, 33)	**11.43 (7.76 to 16.84)**	**21.11 (14.78 to 30.16)**

No statistical analysis provided for High-sensitivity C-reactive Protein (hsCRP) and Serum Amyloid A Protein (SAA) Levels for Core and 24 Weeks Overall

19. Secondary: Physician's Global Assessment of Response to Treatment [Time Frame: 72 hours post-dose (randomization), 72 hours post-dose for the last post-baseline flare (during 24 weeks overall)]

Measure Type	Secondary
Measure Title	Physician's Global Assessment of Response to Treatment
Measure Description	The study physician made a global assessment of the patient's response to treatment using a 5-point Likert scale: Very good, good, fair, poor, very poor. The percentage of patients in each category is reported. The physician completed the assessment without viewing any of the patient's assessments (pain intensity [Visual Analog Scale and Likert scale] and patient's global assessment of response to treatment).
Time Frame	72 hours post-dose (randomization), 72 hours post-dose for the last post-baseline flare (during 24 weeks overall)
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 in the core study who had taken at least one dose of study drug. 'N' in each category indicates participants with observations analyzed for this endpoint at specified time points.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

	After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**113**	**115**
Physician's Global Assessment of Response to Treatment [units: Percentage of participants]		
Very good (Core) [N=113,110]	**16.8**	**15.5**
Good (Core) [N=113, 110]	**47.8**	**30.0**
Fair (Core) [N= 113, 110]	**26.5**	**32.7**
Poor (Core) [N= 113, 110]	**7.1**	**14.5**
Very poor (Core) [N=113, 110]	**1.8**	**7.3**
Very Good (24 weeks) [N=87, 79]	**43.7**	**27.8**
Good (24 weeks) [N=87, 79]	**50.6**	**50.6**
Fair (24 weeks) [N=87, 79]	**5.7**	**17.7**
Poor (24 weeks) [N=87, 79]	**0.0**	**3.8**
Very Poor (24 weeks) [N=87, 79]	**0.0**	**0.0**

No statistical analysis provided for Physician's Global Assessment of Response to Treatment

20. Secondary: Patient's Global Assessment of Response to Treatment [Time Frame: 72 hours post-dose (randomization), 72 hours post-dose for the last post-baseline flare (during 24 weeks overall)]

Measure Type	Secondary
Measure Title	Patient's Global Assessment of Response to Treatment
Measure Description	Patients made a global assessment of response to treatment using a 5-point Likert scale: Excellent, good, acceptable, slight, poor. Percentage of participants in each category for both core and extension periods were measured.
Time Frame	72 hours post-dose (randomization), 72 hours post-dose for the last post-baseline flare (during 24 weeks overall)
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 in the core study who had taken at least one dose of study drug. 'N' in each category indicates participants with observations analyzed for this endpoint at specified time points.

Reporting Groups

	Description

Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**113**	**115**
Patient's Global Assessment of Response to Treatment [units: Percentage of participants]		
Excellent (Core) [N=113, 111]	**12.4**	**12.6**
Good (Core) [N=113, 111]	**38.9**	**28.8**
Acceptable (Core) [N=113, 111]	**37.2**	**30.6**
Slight (Core) [N=113, 111]	**8.8**	**12.6**
Poor (Core) [N=113, 111]	**2.7**	**15.3**
Excellent (24 weeks) [N=87, 78]	**31**	**17.9**
Good (24 weeks) [N=87, 78]	**46**	**44.9**
Acceptable (24 weeks) [N=87, 78]	**20.7**	**25.6**
Slight (24 weeks) [N=87, 78]	**1.1**	**9.0**
Poor (24 weeks) [N=87, 78]	**1.1**	**2.6**

No statistical analysis provided for Patient's Global Assessment of Response to Treatment

21. Secondary: Physician's Assessment of Tenderness, Swelling, and Erythema of the Most Affected Joint [Time Frame: 72 hours post-dose (randomization), 72 hours post-dose for the last post-baseline flare (during 24 weeks overall)]

Measure Type	Secondary
Measure Title	Physician's Assessment of Tenderness, Swelling, and Erythema of the Most Affected Joint
Measure Description	The study physician assessed the most affected joint for: Tenderness on a 0-3 point scale: No pain, patient states that "there is pain", patient states "there is pain and winces", and patient states "there is pain, winces, and withdraws" on palpation or passive movement of the affected study joint; Swelling on a 0-3 point scale: No swelling, palpable, visible, and bulging beyond the joint margins; and Erythema: Present or absent. The percentage of patients in each category is reported.
Time Frame	72 hours post-dose (randomization), 72 hours post-dose for the last post-baseline flare (during 24 weeks overall)
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 in the core study who had taken at least one dose of study drug. 'N' in each category indicates participants with observations analyzed for this endpoint at specified time points.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**113**	**115**
Physician's Assessment of Tenderness, Swelling, and Erythema of the Most Affected Joint [units: Percentage of participants]		
TENDERNESS - No pain (Core) [N=113, 110]	**33.6**	**26.4**
Pain (Core) [N=113, 110]	**56.6**	**51.8**
Pain and winces (Core) [N=113, 110]	**8.0**	**17.3**
Pain,winces,withdraws (Core) [N=113,110]	**1.8**	**4.5**
SWELLING - No swelling (Core) [N=113, 110]	**38.1**	**30.0**
Palpable (Core) [N=113, 110]	**38.9**	**35.5**
Visible (Core) [N=113, 110]	**21.2**	**29.1**
Bulging beyond joint margin (Core) [N=113, 110]	**1.8**	**5.5**
ERYTHEMA - Absent (Core) [N=112, 109]	**78.6**	**65.1**
Present (Core) [N=112, 109]	**21.4**	**34.9**
TENDERNESS - No pain (24 weeks) [N=87, 80]	**82.8**	**85.0**
Pain (24 weeks) [N=87, 80]	**17.2**	**13.8**
Pain and winces (24 weeks) [N=87, 80]	**0.0**	**1.3**
Pain,winces,withdraws (24 weeks) [N=87, 80]	**0.0**	**0.0**
SWELLING - No swelling (24 weeks) [N=87, 80]	**88.5**	**93.8**
Palpable (24 weeks) [N=87, 80]	**8.0**	**5.0**
Visible (24 weeks) [N=87, 80]	**3.4**	**1.3**
Bulging beyond joint margin (24 week)[N=87,80]	**0.0**	**0.0**
ERYTHEMA - Absent (24 weeks) [N=87, 80]	**98.9**	**100**
Present (24 weeks) [N=87, 80]	**1.1**	**0.0**

No statistical analysis provided for Physician's Assessment of Tenderness, Swelling, and Erythema of the Most Affected Joint

22. Secondary:

Physician's Assessment of Range of Motion of the Most Affected Joint [Time Frame: 72 hours post-dose (randomization), 72 hours post-dose for the last post-baseline flare (24 weeks overall)]

Measure Type	Secondary
Measure Title	Physician's Assessment of Range of Motion of the Most Affected Joint
Measure Description	The study physician assessed the range of motion of the most affected joint for range of motion on a 5-point Likert scale: Normal, mildly restricted, moderately restricted, severely restricted, immobilized. The percentage of patients in each category is reported.
Time Frame	72 hours post-dose (randomization), 72 hours post-dose for the last post-baseline flare (24 weeks overall)
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 patients that received study drug. 'N' in each category indicates participants with observations analyzed for this endpoint at specified time points.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Physician's Assessment of Range of Motion of the Most Affected Joint [units: Percentage of participants]		
Normal (Core) [N=113, 111]	**25.7**	**31.5**
Mildly restricted (Core) [N=113, 111]	**50.4**	**29.7**
Moderately restricted (Core) [N=113, 111]	**21.2**	**27.0**
Severely restricted (Core) [N=113, 111]	**2.7**	**8.1**
Immobilized (Core) [N=113, 111]	**0.0**	**3.6**
Normal (24 weeks) [N=87, 79]	**66.7**	**65.8**
Mildly restricted (24 weeks) [N=87, 79]	**31.0**	**29.1**
Moderately Restricted (24 weeks) [N=87, 79]	**2.3**	**3.8**
Severely Restricted (24 weeks) [N=87, 79]	**0.0**	**1.3**
Immobilized (24 weeks) [N=87, 79]	**0.0**	**0.0**

No statistical analysis provided for Physician's Assessment of Range of Motion of the Most Affected Joint

23. Secondary: Patient's Assessment of Gout Pain Intensity in the Most Affected Joint (Likert Scale) [Time Frame: 7 days post dose (randomization), 24 weeks post-dose]

Measure Type	Secondary
Measure Title	Patient's Assessment of Gout Pain Intensity in the Most Affected Joint (Likert Scale)
Measure Description	Participant scored their current pain intensity in the most affected joint of the gout flare on a 5-point Likert Scale (none, mild, moderate, severe, extreme). It participant had a new flare, they also scored the maximum amount of acute gout pain in the most affected joint since the onset of a new flare on 5 point Likert scale (none, mild, moderate, severe, extreme).
Time Frame	7 days post dose (randomization), 24 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.
Full Analysis Set includes all patients that received study drug. 'N' in each category indicates participants with observations analyzed for this endpoint at specified time points.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Patient's Assessment of Gout Pain Intensity in the Most Affected Joint (Likert Scale) [units: Percentage of participants]		
None (7 days post-dose) [N= 110, 107]	**32.7**	**28.0**
Mild (7 days post-dose) [N= 110, 107]	**48.2**	**41.1**
Moderate (7 days post-dose) [N= 110, 107]	**16.4**	**16.8**
Severe (7 days post-dose) [N= 110, 107]	**2.7**	**12.1**
Extreme (7 days post-dose) [N= 110, 107]	**0.0**	**1.9**
None (24 weeks post-dose) [N= 85, 78]	**47.1**	**46.2**
Mild (24 weeks post-dose) [N= 85, 78]	**38.8**	**37.2**
Moderate (24 weeks post-dose) [N= 85, 78]	**12.9**	**15.4**

Severe (24 weeks post-dose) [N= 85, 78]	**1.2**	**1.3**
Extreme (24 weeks post-dose) [N= 85, 78]	**0.0**	**0.0**

No statistical analysis provided for Patient's Assessment of Gout Pain Intensity in the Most Affected Joint (Likert Scale)

24. Secondary: Time to First New Flare: Survival Analysis by Treatment (72 Weeks Overall) [Time Frame: 72 weeks overall]

Measure Type	Secondary
Measure Title	Time to First New Flare: Survival Analysis by Treatment (72 Weeks Overall)
Measure Description	Kaplan-Meier estimates of time to first new flare and confidence intervals were determined. For patients with event, time to event = (date of event – date of first dose of study drug + 1). Patients met definition of new flare if they had: • Flare in joint, not a previously affected joint (at baseline or during study) • Flare in joint previously affected (at baseline or during study) after previous flare in joint has resolved completely. Patients did not meet criterion of having new gout flare if: · Increasing/renewed gout pain in an affected joint before flare has resolved completely.
Time Frame	72 weeks overall
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 in the core study who had taken at least one dose of study drug.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study. After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Time to First New Flare: Survival Analysis by Treatment (72 Weeks Overall) [units: days] Median (95% Confidence Interval)	**222.0 (190.0 to 274.0)**	**119.0 (94 to 224.0)**

No statistical analysis provided for Time to First New Flare: Survival Analysis by Treatment (72 Weeks Overall)

25. Secondary: Flare Rate Per Year [Time Frame: 72 weeks overall]

Measure Type	Secondary
Measure Title	Flare Rate Per Year
Measure Description	Flare rate was calculated as the number of new flares over the period of observation in years. Flare rate was calculated using only those new flares before switching to canakinumab. Patients met definition of new flare if they had: • Flare in joint, not a previously affected joint (at baseline or during study) • Flare in joint previously affected (at baseline or during study) after previous flare in joint has resolved completely. Patients did not meet criterion of having new gout flare if: · Increasing/renewed gout pain in an affected joint before the flare has resolved completely.
Time Frame	72 weeks overall
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 in the core study who had taken at least one dose of study drug.

Reporting Groups

	Description
Canakinumab 150 mg	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study. After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study.
Triamcinolone Acetonide 40 mg	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period. Note that flare rate was calculated using only those new flares before switching.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**113**	**115**
Flare Rate Per Year [units: New flares per patient per year] Mean (Standard Deviation)	**1.16 (1.511)**	**2.81 (4.399)**

No statistical analysis provided for Flare Rate Per Year

26. Secondary: High-sensitivity C-reactive Protein (hsCRP) Levels for Patients Re-treated With or Switched to Canakinumab [Time Frame: 24 hours, 72 hours, 7 days, 4 weeks, 8 weeks and 12 weeks post-dose for the last post-baseline flare for patients re-treated with canakinumab or first post-baseline flare treated with canakinumab for patients switched treatment (during 72 weeks overall)]

Measure Type	Secondary
Measure Title	High-sensitivity C-reactive Protein (hsCRP) Levels for Patients Re-treated With or Switched to Canakinumab
Measure Description	High sensitivity C-reactive protein (hsCRP) levels were determined in blood serum in order to identify the presence of inflammation, to determine its severity, and to monitor the response to treatment. Analytes were measured by a central laboratory. The treatment effect reported for canakinumab arm was for last post-baseline flare after re-treated with canakinumab and for patient which switched to Canakinumab arm was for first post-baseline flare after receiving the first dose of canakinumab.
Time Frame	24 hours, 72 hours, 7 days, 4 weeks, 8 weeks and 12 weeks post-dose for the last post-baseline flare for patients re-treated with canakinumab or first post-baseline flare treated with canakinumab for patients switched treatment (during 72 weeks overall)
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.
Modified Analysis Set (MAS) consists of all FAS patients who were either re-treated or switched to canakinumab during 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included

Reporting Groups

	Description
Randomized to Canakinumab and Re-treated With Canakinumab	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Randomized to Triamcinolone and Switched to Canakinumab	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period

Measured Values

	Randomized to Canakinumab and Re-treated With Canakinumab	**Randomized to Triamcinolone and Switched to Canakinumab**
Number of Participants Analyzed [units: participants]	**69**	**39**
High-sensitivity C-reactive Protein (hsCRP) Levels for Patients Re-treated With or Switched to Canakinumab [units: mg/L] Mean (Standard Deviation)		

24 hours post dose (n= 45, 24)	**28.9 (42.26)**	**26.0 (29.07)**
72 hours post dose (n=45, 34)	**10.6 (14.69)**	**7.0 (8.06)**
7 days post dose (n=67, 39)	**3.3 (3.38)**	**3.2 (3.57)**
4 weeks post dose (n=52, 35)	**9.2 (48.57)**	**3.2 (4.95)**
8 weeks post dose (n=45, 37)	**2.6 (3.00)**	**3.0 (6.74)**
12 weeks post dose (n=42, 33)	**6.5 (12.99)**	**4.3 (11.90)**

No statistical analysis provided for High-sensitivity C-reactive Protein (hsCRP) Levels for Patients Re-treated With or Switched to Canakinumab

27. Secondary: Serum Amyloid A Protein (SAA) Levels for Patients Re-treated With or Switched to Canakinumab [Time Frame: 24 hours, 72 hours, 7 days, 4 weeks, 8 weeks and 12 weeks post-dose for the last post-baseline flare for patients re-treated with canakinumab or first post-baseline flare treated with canakinumab for patients switched treatment (during 72 weeks overall)]

Measure Type	Secondary
Measure Title	Serum Amyloid A Protein (SAA) Levels for Patients Re-treated With or Switched to Canakinumab
Measure Description	Serum Amyloid A Protein (SAA) levels were determined in blood serum in order to identify the presence of inflammation, to determine its severity, and to monitor the response to treatment. Analytes were measured by a central laboratory. The treatment effect reported for canakinumab arm was for last post-baseline flare after re-treated with canakinumab and for patient which switched to Canakinumab arm was for first post-baseline flare after receiving the first dose of canakinumab.
Time Frame	24 hours, 72 hours, 7 days, 4 weeks, 8 weeks and 12 weeks post-dose for the last post-baseline flare for patients re-treated with canakinumab or first post-baseline flare treated with canakinumab for patients switched treatment (during 72 weeks overall)
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.
Modified Analysis Set (MAS) consists of all FAS patients who were either re-treated or switched to canakinumab during 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included

Reporting Groups

	Description
Randomized to Canakinumab and Re-treated With Canakinumab	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.
Randomized to Triamcinolone and Switched to Canakinumab	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period

Measured Values

	Randomized to Canakinumab and Re-treated With Canakinumab	Randomized to Triamcinolone and Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**69**	**39**
Serum Amyloid A Protein (SAA) Levels for Patients Re-treated With or Switched to Canakinumab [units: mg/L] Mean (Standard Deviation)		
24 hours post dose (n= 45, 27)	**151.4 (310.09)**	**86.5 (188.46)**
72 hours post dose (n=45, 36)	**42.5 (116.89)**	**26.9 (73.37)**
7 days post dose (n=67, 39)	**5.4 (8.83)**	**4.9 (6.56)**
4 weeks post dose (n=52, 35)	**31.0 (193.64)**	**8.5 (19.75)**
8 weeks post dose (n=45, 37)	**4.2 (4.26)**	**5.4 (8.36)**
12 weeks post dose (n=42, 33)	**10.7 (24.62)**	**7.8 (22.98)**

No statistical analysis provided for Serum Amyloid A Protein (SAA) Levels for Patients Re-treated With or Switched to Canakinumab

28. Secondary: Physician's Global Assessment of Response to Treatment for Patients Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose , 7 days post-dose for the last post-baseline flare for patients re-treated with canakinumab or first post-baseline flare treated with canakinumab for patients switched treatment (during 72 weeks overall)]

Measure Type	Secondary
Measure Title	Physician's Global Assessment of Response to Treatment for Patients Re-treated or Switched to Canakinumab
Measure Description	The study physician made a global assessment of the patient's response to treatment using a 5-point Likert scale: Very good, good, fair, poor, very poor. The percentage of patients in each category is reported. The physician completed the assessment without viewing any of the patient's assessments (pain intensity [Visual Analog Scale and Likert scale] and patient's global assessment of response to treatment). The treatment effect reported for canakinumab arm was for last post-baseline flare after re-treated with canakinumab and for patient which switched to Canakinumab arm was for first post-baseline flare after receiving the first dose of canakinumab.
Time Frame	72 hours post-dose , 7 days post-dose for the last post-baseline flare for patients re-treated with canakinumab or first post-baseline flare treated with canakinumab for patients switched treatment (during 72 weeks overall)
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.
Modified Analysis Set (MAS) consists of all FAS patients who were either re-treated or switched to canakinumab during 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Randomized to Canakinumab and Re-treated With Canakinumab	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study.

	After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study.
Randomized to Triamcinolone and Switched to Canakinumab	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period

Measured Values

	Randomized to Canakinumab and Re-treated With Canakinumab	Randomized to Triamcinolone and Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**69**	**39**
Physician's Global Assessment of Response to Treatment for Patients Re-treated or Switched to Canakinumab [units: Percentage of participants]		
Very good (72 hours post dose) (n=61, 34)	**21.3**	**22.9**
Good (72 hours post dose) (n=61, 34)	**41.0**	**57.1**
Fair (72 hours post dose) (n=61, 34)	**31.1**	**17.1**
Poor (72 hours post dose) (n=61, 34)	**6.6**	**2.9**
Very poor (72 hours post dose) (n=61, 34)	**0.0**	**0.0**
Very Good (7 days post dose) (n=68, 34)	**36.8**	**33.3**
Good (7 days post dose) (n=68, 34)	**52.9**	**63.9**
Fair (7 days post dose) (n=68, 34)	**10.3**	**0.0**
Poor (7 days post dose) (n=68, 34)	**0.0**	**0.0**
Very Poor (7 days post dose) (n=68, 34)	**0.0**	**2.8**

No statistical analysis provided for Physician's Global Assessment of Response to Treatment for Patients Re-treated or Switched to Canakinumab

29. Secondary: Patient's Assessment of Gout Pain Intensity in the Currently Most-affected Joint (Likert Scale) [Time Frame: 72 hours post-dose , 7 days post dose for the last post-baseline flare for patients re-treated with canakinumab or the first post-baseline flare treated with canakinumab for patients who switched treatment (during 72 weeks overall)]

Measure Type	Secondary
Measure Title	Patient's Assessment of Gout Pain Intensity in the Currently Most-affected Joint (Likert Scale)
Measure Description	Participant scored their current pain intensity in the most affected joint of the gout flare on a 5-point Likert Scale (none, mild, moderate, severe, extreme). It participant had a new flare, they also scored the maximum amount of acute gout pain in the most affected joint since the onset of a new flare on 5 point Likert scale (none, mild, moderate, severe, extreme). The treatment effect reported for canakinumab arm was for last post-baseline flare after re-treated with canakinumab and for patient which switched to Canakinumab arm was for first post-baseline flare after receiving the first dose of canakinumab.
Time Frame	72 hours post-dose , 7 days post dose for the last post-baseline flare for patients re-treated with canakinumab or the first post-baseline flare treated with canakinumab for patients who switched treatment (during 72 weeks overall)

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.
Modified Analysis Set (MAS) consists of all FAS patients who were either re-treated or switched to canakinumab during 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Randomized to Canakinumab and Re-treated With Canakinumab	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study. After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study.
Randomized to Triamcinolone and Switched to Canakinumab	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period

Measured Values

	Randomized to Canakinumab and Re-treated With Canakinumab	**Randomized to Triamcinolone and Switched to Canakinumab**
Number of Participants Analyzed [units: participants]	**69**	**39**
Patient's Assessment of Gout Pain Intensity in the Currently Most-affected Joint (Likert Scale) [units: Percentage of participants]		
None (72 hours post dose) (n=66, 39)	**19.7**	**20.5**
Mild (72 hours post dose) (n=66, 39)	**30.0**	**61.5**
Moderate (72 hours post dose) (n=66, 39)	**45.5**	**15.4**
Severe (72 hours post dose) (n=66, 39)	**4.5**	**0.0**
Extreme (72 hours post dose) (n=66, 39)	**0.0**	**2.6**
None (7 days post dose) (n=65, 35)	**41.5**	**57.1**
Mild (7 days post dose) (n=65, 35)	**38.5**	**34.3**
Moderate (7 days post dose) (n=65, 35)	**18.5**	**5.7**
Severe (7 days post dose) (n=65, 35)	**1.5**	**0.0**
Extreme (7 days post dose) (n=65, 35)	**0.0**	**2.9**

No statistical analysis provided for Patient's Assessment of Gout Pain Intensity in the Currently Most-affected Joint (Likert Scale)

30. Secondary: Patient's Global Assessment of Response to Treatment for Patients Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose , 7 days post dose for the last post-baseline flare for patients re-treated with canakinumab or the first post-baseline flare treated with canakinumab for patients who switched treatment (during 72 weeks overall)]

Measure Type	Secondary
Measure Title	Patient's Global Assessment of Response to Treatment for Patients Re-treated or Switched to Canakinumab
Measure Description	Patients made a global assessment of response to treatment using a 5-point Likert scale: Excellent, good, acceptable, slight, poor. Percentage of participants in each category for both core and extension periods were measured. The treatment effect reported for canakinumab arm was for last post-baseline flare after re-treated with canakinumab and for patient which switched to Canakinumab arm was for first post-baseline flare after receiving the first dose of canakinumab.
Time Frame	72 hours post-dose , 7 days post dose for the last post-baseline flare for patients re-treated with canakinumab or the first post-baseline flare treated with canakinumab for patients who switched treatment (during 72 weeks overall)
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.
Modified Analysis Set (MAS) consists of all FAS patients who were either re-treated or switched to canakinumab during 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Randomized to Canakinumab and Re-treated With Canakinumab	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study. After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study.
Randomized to Triamcinolone and Switched to Canakinumab	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period

Measured Values

	Randomized to Canakinumab and Re-treated With Canakinumab	**Randomized to Triamcinolone and Switched to Canakinumab**
Number of Participants Analyzed [units: participants]	**69**	**39**

Patient's Global Assessment of Response to Treatment for Patients Re-treated or Switched to Canakinumab [units: Percentage of participants]		
Excellent (72 hours post dose) (n=60, 36)	15.0	19.4
Good (72 hours post dose) (n=60, 36)	26.7	44.4
Acceptable (72 hours post dose) (n=60, 36)	50.0	27.8
Slight (72 hours post dose) (n=60, 36)	6.7	2.8
Poor (72 hours post dose) (n=60, 36)	1.7	5.6
Excellent (7 days post dose) (n=68, 36)	23.5	27.8
Good (7 days post dose) (n=68, 36)	41.2	52.8
Acceptable (7 days post dose) (n=68, 36)	27.9	16.7
Slight (7 days post dose) (n=68, 36)	7.4	2.8
Poor (7 days post dose) (n=68, 36)	0.0	0.0

No statistical analysis provided for Patient's Global Assessment of Response to Treatment for Patients Re-treated or Switched to Canakinumab

31. Secondary: Physician's Assessment of Joint Tenderness for Patients Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose , 7 days post dose last post-baseline flare for patients re-treated with canakinumab or the first post-baseline flare treated with canakinumab for patients who switched treatment (during 72 weeks overall)]

Measure Type	Secondary
Measure Title	Physician's Assessment of Joint Tenderness for Patients Re-treated or Switched to Canakinumab
Measure Description	The study physician assessed the most affected joint for: Tenderness on a 0-3 point scale: No pain, patient states that “there is pain”, patient states “there is pain and winces”, and patient states “there is pain, winces, and withdraws” on palpation or passive movement of the affected study joint; The percentage of patients in each category is reported. The treatment effect reported for canakinumab arm was for last post-baseline flare after re-treated with canakinumab and for patient which switched to Canakinumab arm was for first post-baseline flare after receiving the first dose of canakinumab.
Time Frame	72 hours post-dose , 7 days post dose last post-baseline flare for patients re-treated with canakinumab or the first post-baseline flare treated with canakinumab for patients who switched treatment (during 72 weeks overall)
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.
Modified Analysis Set (MAS) consists of all FAS patients who were either re-treated or switched to canakinumab during 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Randomized to Canakinumab and Re-treated With Canakinumab	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study. After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on

	demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study.
Randomized to Triamcinolone and Switched to Canakinumab	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period

Measured Values

	Randomized to Canakinumab and Re-treated With Canakinumab	Randomized to Triamcinolone and Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**69**	**39**
Physician's Assessment of Joint Tenderness for Patients Re-treated or Switched to Canakinumab [units: Percentage of participants]		
No Pain (72 hours post dose) (n=61, 35)	**27.9**	**28.6**
Pain (72 hours post dose) (n=61, 35)	**54.1**	**68.6**
Pain and winces (72 hours post dose) (n=61, 35)	**16.4**	**2.9**
Pain, winces, withdraw(72 hrs post dose)(n=61, 35)	**1.6**	**0.0**
No pain (7 days post dose) (n=68, 36)	**52.9**	**69.4**
Pain (7 days post dose) (n=68, 36)	**44.1**	**27.8**
Pain and winces (7 days post dose) (n=68, 36)	**2.9**	**2.8**
Pain, winces, withdraw(72 hrs post dose)(n=61, 36)	**0.0**	**0.0**

No statistical analysis provided for Physician's Assessment of Joint Tenderness for Patients Re-treated or Switched to Canakinumab

32. Secondary: Physician's Assessment of Joint Swelling for Patients Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose , 7 days post dose last post-baseline flare for patients re-treated with canakinumab or the first post-baseline flare treated with canakinumab for patients who switched treatment (during 72 weeks overall)]

Measure Type	Secondary
Measure Title	Physician's Assessment of Joint Swelling for Patients Re-treated or Switched to Canakinumab
Measure Description	The study physician assessed the most affected joint for: Swelling on a 0-3 point scale: No swelling, palpable, visible, and bulging beyond the joint margins; The percentage of patients in each category is reported. The treatment effect reported for canakinumab arm was for last post-baseline flare after re-treated with canakinumab and for patient which switched to Canakinumab arm was for first post-baseline flare after receiving the first dose of canakinumab.
Time Frame	72 hours post-dose , 7 days post dose last post-baseline flare for patients re-treated with canakinumab or the first post-baseline flare treated with canakinumab for patients who switched treatment (during 72 weeks overall)
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.

Modified Analysis Set (MAS) consists of all FAS patients who were either re-treated or switched to canakinumab during 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Randomized to Canakinumab and Re-treated With Canakinumab	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study. After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study.
Randomized to Triamcinolone and Switched to Canakinumab	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period

Measured Values

	Randomized to Canakinumab and Re-treated With Canakinumab	Randomized to Triamcinolone and Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**69**	**39**
Physician's Assessment of Joint Swelling for Patients Re-treated or Switched to Canakinumab [units: Percentage of participants]		
No Pain (72 hours post dose) (n=61, 35)	**29.5**	**42.9**
Pain (72 hours post dose) (n=61, 35)	**42.6**	**48.6**
Pain and winces (72 hours post dose) (n=61, 35)	**24.6**	**8.6**
Pain, winces, withdraw(72 hrs post dose)(n=61, 35)	**3.3**	**0.0**
No pain (7 days post dose) (n=68, 36)	**64.7**	**75.0**
Pain (7 days post dose) (n=68, 36)	**25.0**	**16.7**
Pain and winces (7 days post dose) (n=68, 36)	**7.4**	**5.6**
Pain, winces, withdraw(72 hrs post dose)(n=68, 36)	**2.9**	**2.8**

No statistical analysis provided for Physician's Assessment of Joint Swelling for Patients Re-treated or Switched to Canakinumab

33. Secondary: Physician's Assessment of Erythema for Patients Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose , 7 days post dose for the last post-baseline flare for patients re-treated with canakinumab or the first post-baseline flare treated with canakinumab for patients who switched treatment (during 72 weeks overall)]

Measure Type	Secondary

Measure Title	Physician's Assessment of Erythema for Patients Re-treated or Switched to Canakinumab
Measure Description	The study physician assessed the most affected joint for Erythema: Present or absent. The percentage of patients in each category is reported. The treatment effect reported for canakinumab arm was for last post-baseline flare after re-treated with canakinumab and for patient which switched to Canakinumab arm was for first post-baseline flare after receiving the first dose of canakinumab.
Time Frame	72 hours post-dose , 7 days post dose for the last post-baseline flare for patients re-treated with canakinumab or the first post-baseline flare treated with canakinumab for patients who switched treatment (during 72 weeks overall)
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.
Modified Analysis Set (MAS) consists of all FAS patients who were either re-treated or switched to canakinumab during 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Randomized to Canakinumab and Re-treated With Canakinumab	Patients received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 weeks extension study for any new gout flare on demand with the same treatment as assigned in the core study. After completing the first extension study, patients were offered to enter the second extension study, whereby all patients were treated open-label "on demand" with canakinumab 150 mg sc upon new flare for 1 year for a total duration of 18 months following randomization in the core study.
Randomized to Triamcinolone and Switched to Canakinumab	Patients received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 subcutaneous (sc) injection of placebo to canakinumab on Day 1. Patients could receive a re-dose of study drug on demand upon the occurrence of new flares, but re-dosing could not occur until 14 days had elapsed after the previous dose. Patients completing the 12 weeks core study were allowed to continue to be treated in another 12 week extension study for any new gout flare on demand with the same treatment as assigned in the core study. Patients under this arm who agreed to continue to 2nd extension period of 12 months, were switched to canakinumab 150 mg sc for any new gout flare during this period

Measured Values

	Randomized to Canakinumab and Re-treated With Canakinumab	**Randomized to Triamcinolone and Switched to Canakinumab**
Number of Participants Analyzed [units: participants]	**69**	**39**
Physician's Assessment of Erythema for Patients Re-treated or Switched to Canakinumab [units: Percentage of participants]		
Absent (72 hours post dose) (n=61, 35)	**82.0**	**80.0**
Present (72 hours post dose) (n=61, 35)	**18.0**	**20.0**
Absent (7 days post dose) (n=67, 36)	**95.5**	**94.4**
Present (7 days post dose) (n=67, 36)	**4.5**	**5.6**

No statistical analysis provided for Physician's Assessment of Erythema for Patients Re-treated or Switched to Canakinumab

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

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
Bioanalytical results: With analytical method used, anti-canakinumab antibodies were detected in 10 patients. However, no patients showed any unexpected PK/ PD profile nor had adverse events suggestive of immunogenicity.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (ie, data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862 778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

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.

Responsible Party: Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier: NCT01029652 History of Changes
Obsolete Identifiers: NCT01071213, NCT01160016
Other Study ID Numbers:

	CACZ885H2356
	2009-015018-23 (EudraCT Number)
	CACZ885H2356E1 (Other Identifier: Novartis)
	CACZ885H2356E2 (Other Identifier: Novartis)
Study First Received:	December 9, 2009
Results First Received:	July 26, 2011
Last Updated:	December 24, 2013
Health Authority:	United States: Food and Drug Administration
	Australia: Department of Health and Ageing Therapeutic Goods Administration
	Lithuania: State Medicine Control Agency - Ministry of Health
	Belgium: Federal Agency for Medicinal Products and Health Products
	Canada: Health Canada
	Colombia: INVIMA Instituto Nacional de Vigilancia de Medicamentos y Alimentos
	Estonia: The State Agency of Medicine
	Germany: Paul-Ehrlich-Institut
	Guatemala: Ministry of Public Health and Social Assistance
	Mexico: Ministry of Health
	Norway: Norwegian Medicines Agency
	Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
	Russia: Pharmacological Committee, Ministry of Health
	Singapore: Health Sciences Authority
	Sweden: Medical Products Agency
	Switzerland: Swissmedic
	Ukraine: Ministry of Health