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Trial record **2 of 3** for: CACZ885H2357

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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 Colchicines Including a 12 Week Extension and a 1 Year Open-label Extension Study. (β-RELIEVED-II)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01080131

First received: March 2, 2010
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History of Changes

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Results First Received: August 30, 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
No text entered.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare. In the second extension study participants were to receive open-label on demand treatment with canakinumab 150 mg sc for any new flare for an additional year, for a total duration of 18 months.
Triamcinolone Acetonide 40 mg	

	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare. In the second extension study participants were to switch to open-label on demand treatment with canakinumab 150 mg sc for any new flare for an additional year. Triamcinolone acetonide was not to be administered in the second extension study.

Participant Flow for 3 periods

Period 1: Core Study (0- 12 Weeks)

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
STARTED	112	114
COMPLETED	99	103
NOT COMPLETED	13	11
Abnormal laboratory value(s)	1	1
Patient withdrew consent	6	4
Lost to Follow-up	5	3
Administrative problems	0	1
Death	1	0
Protocol deviation	0	2

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

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
STARTED	84	76
COMPLETED	78	72
NOT COMPLETED	6	4
Adverse Event	1	0
Unsatisfactory Therapeutic Effect	0	1
Withdrawal by Subject	4	3
Lost to Follow-up	1	0

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

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
STARTED	72	65
Re-treated With or Switch to Canakinumab	62 [1]	41 [2]
COMPLETED	64	54
NOT COMPLETED	8	11
Adverse Event	1	2
Withdrawal by Subject	3	4
Lost to Follow-up	4	5

[1] Includes patients re-treated with canakinumab at any time during the 72 weeks
[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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare. In the second extension study participants were to receive open-label on demand treatment with canakinumab 150 mg sc for any new flare for an additional year, for a total duration of 18 months.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare. In the second extension study participants were to switch to open-label on demand treatment with canakinumab 150 mg sc for any new flare for an additional year. Triamcinolone acetonide was not to be administered in the second extension study.
Total	Total of all reporting groups

Baseline Measures

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**	**Total**
Number of Participants [units: participants]	**112**	**114**	**226**
Age [units: years] Mean (Standard Deviation)	**50.6 (12.10)**	**52.6 (12.28)**	**51.6 (12.21)**
Gender [units: participants]			
Female	**12**	**9**	**21**
Male	**100**	**105**	**205**

Outcome Measures

Hide All Outcome Measures

1. Primary: Time to First New Flare: Survival Analysis During the 12 Weeks of Study [Time Frame: Baseline to 12 weeks]

Measure Type	Primary
Measure Title	Time to First New Flare: Survival Analysis During the 12 Weeks of Study
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	Baseline to 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.
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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**114**
Time to First New Flare: Survival Analysis During the 12 Weeks of Study [units: Days] Median (95% Confidence Interval)	**NA** [1]	**NA** [1]

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

No statistical analysis provided for Time to First New Flare: Survival Analysis During the 12 Weeks of Study

2. Primary: Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (VAS) at 72 Hours Post-dose [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 (VAS) at 72 Hours Post-dose
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 analysis of covariance (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.
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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**111**	**109**
Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (VAS) at 72 Hours Post-dose [units: mm] Least Squares Mean (Standard Error)	**22.1 (2.33)**	**31.9 (2.35)**

No statistical analysis provided for Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (VAS) at 72 Hours Post-dose

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

Measure Type	Primary
Measure Title	Number of Participants With Adverse Events, Death and Serious Adverse Events During 24 Weeks
Measure Description	This was primary endpoint of extension study 1. 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. A 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	During 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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**

Number of Participants Analyzed [units: participants]	**112**	**114**
Number of Participants With Adverse Events, Death and Serious Adverse Events During 24 Weeks [units: Participants]		
Adverse event	**78**	**65**
Death	**1**	**0**
Serious adverse event	**7**	**2**

No statistical analysis provided for Number of Participants With Adverse Events, Death and Serious Adverse Events During 24 Weeks

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

Measure Type	Primary
Measure Title	Number of Participants With Adverse Events, Death and Serious Adverse Events (72 Weeks Overall)
Measure Description	This was the primary endpoint of extension study 2. An adverse event was 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
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 Canakinumab	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study, participants completing the 12 week core study could continue to be treated on demand with the same study treatment for an additional 12 weeks for any new gout flare. In the second extension study participants were to receive open-label on demand treatment with canakinumab 150 mg sc upon new flare for 1 year, for a total duration of 18 months.
Canakinumab: Before Retreatment	Participants who received canakinumab in the core study and were re-treated with canakinumab during the core study or extension study 1 or 2. Reported data include adverse events that occurred in this re-treated population before re-treatment with canakinumab.
Canakinumab: After Retreatment	Participants who received canakinumab in the core study and were re-treated with canakinumab during the core study or extension study 1 or 2. Reported data include adverse events that occurred in this re-treated population after re-treatment with canakinumab.
All Triamcinolone Acetonide	Participants received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same study treatment another 12 weeks for any new gout flare.

	Reported data include all adverse events that occurred during the core study and extension studies 1 and 2, before participants were switched to canakinumab.
Triam: Before Switch to Canakinumab	Participants who were treated with triamcinolone acetonide (triam) during the core study and extension study 1 and who were switched to open-label on demand treatment with canakinumab 150 mg sc upon new flare in extension study 2. Data are reported for adverse events that occurred before the switch to canakinumab.
Triam: After Switch to Canakinumab	Participants who were treated with triamcinolone acetonide during the core study and extension study 1 and who were switched to open-label on demand treatment with canakinumab 150 mg sc upon new flare in extension study 2. Data are reported for adverse events that occurred after the switch to canakinumab.

Measured Values

	All Canakinumab	Canakinumab: Before Retreatment	Canakinumab: After Retreatment	All Triamcinolone Acetonide	Triam: Before Switch to Canakinumab	Triam: After Switch to Canakinumab
Number of Participants Analyzed [units: participants]	**112**	**62**	**62**	**114**	**41**	**41**
Number of Participants With Adverse Events, Death and Serious Adverse Events (72 Weeks Overall) [units: participants]						
Any adverse event	**85**	**44**	**39**	**70**	**29**	**27**
Death	**1**	**0**	**0**	**0**	**0**	**0**
Serious adverse event	**12**	**1**	**5**	**4**	**0**	**3**

No statistical analysis provided for Number of Participants With Adverse Events, 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 (VAS) [Time Frame: 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 (VAS)
Measure Description	Kaplan-Meier estimates of the time to at least a 50% reduction in self-assessed pain intensity in the joint most affected at Baseline and the confidence intervals were determined along with 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	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.
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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**111**	**109**
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 (VAS) [units: hours] Median (95% Confidence Interval)	**25.0 (23.0 to 48.0)**	**48.0 (24.0 to 49.0)**

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 (VAS)

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

Measure Type	Secondary
Measure Title	Time to Complete Resolution of Pain; Survival Analysis
Measure Description	Kaplan-Meier estimates of the time to complete resolution of self-assessed pain intensity in the joint most affected and the confidence interval was determined. Patients scored their pain intensity on a 5-point Likert scale (none, mild, moderate, severe, extreme). Pain was scored at Baseline; 6 and 12 hours; 1, 2, 3, 4, 5, 6, and 7 days post-dose.
Time Frame	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.
Full Analysis Set (FAS): All patients that received study drug.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**114**
	144.0 [1]	**NA** [2]

Time to Complete Resolution of Pain; Survival Analysis [units: hours] Number (95% Confidence Interval)		

[1] The upper limit was not estimable in the study as it is longer than duration of study.
[2] 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; Survival Analysis

7. Secondary: SF 36 Physical Function Score at Week 12 [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	SF 36 Physical Function Score at Week 12
Measure Description	SF-36 measures impact of disease on overall quality of life (QoL). 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 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. Analysis of covariance (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.
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 observations at Week 12 were included in the analysis.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**83**	**81**
SF 36 Physical Function Score at Week 12 [units: Units on a scale] Least Squares Mean (Standard Error)	**81.46 (2.786)**	**78.75 (2.820)**

No statistical analysis provided for SF 36 Physical Function Score at Week 12

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

Measure Type	Secondary
Measure Title	Percentage of Participants With at Least 1 New Gout Flare During the 12 Weeks of the Study

Measure Description	The percentage of participants who experienced at least 1 new gout flare during the 12 week study treatment period.
Time Frame	Baseline to 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.
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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**114**
Percentage of Participants With at Least 1 New Gout Flare During the 12 Weeks of the Study [units: percentage of participants]	**13.4**	**36.8**

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

9. Secondary: Pharmacokinetic Concentrations [Time Frame: 12 weeks post-dose]

Measure Type	Secondary
Measure Title	Pharmacokinetic Concentrations
Measure Description	Canakinumab concentration was analyzed in serum by means of a competitive Enzyme-linked immunosorbent assay (ELISA) assay with a lower limit of quantification (LOQ) at 100 ng/mL.
Time Frame	12 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 (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.

Measured Values

	Canakinumab 150 mg
Number of Participants Analyzed [units: participants]	**99**
Pharmacokinetic Concentrations [units: µg/mL] Mean (Standard Deviation)	**2.16 (2.375)**

No statistical analysis provided for Pharmacokinetic Concentrations

10. Secondary: Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100 mm VAS) [Time Frame: 6, 12, 24, 48, and 72 hours; and 4, 5, 6, and 7 days post-dose (randomization)]

Measure Type	Secondary
Measure Title	Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100 mm 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), from 6 hours to 7 days 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	6, 12, 24, 48, and 72 hours; and 4, 5, 6, and 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.
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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**112**	**114**
Self-assessed Pain Intensity in the Joint Most Affected at Baseline Measured on a Visual Analog Scale (0-100 mm VAS) [units: mm] Least Squares Mean (Standard Error)		
6 hours post-dose	**58.7 (1.94)**	**60.3 (1.96)**
12 hours post-dose	**50.8 (2.16)**	**52.0 (2.18)**
24 hours post-dose	**39.1 (2.39)**	**45.0 (2.41)**
48 hours post-dose	**29.5 (2.45)**	**38.9 (2.48)**

72 hours post-dose	**22.1 (2.33)**	**31.9 (2.35)**
4 days post-dose	**19.2 (2.25)**	**27.7 (2.27)**
5 days post-dose	**16.4 (2.23)**	**25.4 (2.25)**
6 days post-dose	**14.3 (2.20)**	**22.3 (2.22)**
7 days post-dose	**14.0 (2.18)**	**19.5 (2.20)**

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

11. Secondary: Self-assessed Pain Intensity in the Joint Most Affected at Last Post-Baseline Measured on a Visual Analog Scale (VAS) [Time Frame: 6, 12, 24, 48, and 72 hours; and 4, 5, 6, and 7 days post-dose for last post-baseline flare that occurred up until the end of the first extension study (24 weeks).]

Measure Type	Secondary
Measure Title	Self-assessed Pain Intensity in the Joint Most Affected at Last Post-Baseline Measured on a Visual Analog Scale (VAS)
Measure Description	Patient's assessment of gout pain intensity in the most affected joint (on a 0-100 mm VAS) for the last post-baseline flare, ranging from no pain (0) to unbearable pain (100), was summarized up to 7 days after receiving a re-dose of study drug by time point. Scores on the 100 mm linear scale were measured to the nearest millimeter from the left. The covariance analysis included treatment group, Baseline VAS score at that flare, and body mass index (BMI) at Baseline as covariates.
Time Frame	6, 12, 24, 48, and 72 hours; and 4, 5, 6, and 7 days post-dose for last post-baseline flare that occurred up until the end of the first extension study (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. For assessments made up to 7 days after re-dosing, pain values were imputed using the Last- Observation-Carried-Forward (LOCF) method.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**25**	**46**
Self-assessed Pain Intensity in the Joint Most Affected at Last Post-Baseline Measured on a Visual Analog Scale (VAS) [units: mm] Least Squares Mean (Standard Error)		

6 hours post-dose	**57.4 (3.07)**	**59.1 (2.26)**
12 hours post-dose	**50.7 (4.24)**	**53.3 (3.12)**
24 hours post-dose	**46.2 (4.74)**	**43.8 (3.49)**
48 hours post-dose	**42.3 (4.96)**	**34.2 (3.65)**
72 hours post-dose	**37.0 (5.12)**	**26.1 (3.77)**
4 days post-dose	**31.3 (4.75)**	**23.4 (3.49)**
5 days post-dose	**29.0 (5.11)**	**21.6 (3.76)**
6 days post-dose	**28.1 (5.04)**	**20.5 (3.71)**
7 days post-dose	**24.1 (5.03)**	**19.1 (3.70)**

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

12. Secondary: Time to the First New Gout Flare During 24 Weeks [Time Frame: From randomization to the end of the first extension period (24 weeks).]

Measure Type	Secondary
Measure Title	Time to the First New Gout Flare During 24 Weeks
Measure Description	Kaplan-Meier (KM) estimates of the time to first new flare and confidence intervals were determined. Participants met the definition of a 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. Participants did not meet the criterion of having a new gout flare if they had increasing/renewed gout pain in an affected joint before the flare had resolved completely.
Time Frame	From randomization to the end of the first extension period (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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
	112	**114**

Number of Participants Analyzed [units: participants]		
Time to the First New Gout Flare During 24 Weeks [units: days] Median (95% Confidence Interval)	**NA** [1]	**146** [1]

[1] Not estimable due to the low number of events at the time of the assessment (24 weeks).

No statistical analysis provided for Time to the First New Gout Flare During 24 Weeks

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

Measure Type	Secondary
Measure Title	Mean Number of New Gout Flares Per Patient During 24 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. Participants did not meet the criterion of having a new gout flare if they had increasing/renewed gout pain in an affected joint before the flare had 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.
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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**114**
Mean Number of New Gout Flares Per Patient During 24 Weeks [units: new flares per patient] Mean (Standard Deviation)	**0.35 (0.694)**	**0.80 (1.115)**

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

14. Secondary: Time to First Intake of Rescue Medication [Time Frame: For 7 days after the first dose for the baseline flare and 7 days post-dose for the last post-baseline flare that occurred up until the end of the first extension study (24 weeks).]

Measure Type	Secondary
Measure Title	Time to First Intake of Rescue Medication
Measure Description	Participants 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, participants were allowed to take a maximum of 30 mg of oral prednisolone 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. Use of these treatments during the first 7 days of a gout flare was recorded as rescue medication. Kaplan-Meier estimates of the time to first intake of rescue medication, in hours, and the confidence interval were determined for the flare experienced at study entry (Baseline flare) and the last new flare (last post-baseline flare) that occurred up until the end of the first extension period (24 weeks).
Time Frame	For 7 days after the first dose for the baseline flare and 7 days post-dose for the last post-baseline flare that occurred up until the end of the first extension study (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.
For the Baseline flare the population analyzed consisted of the Full Analysis Set (FAS). For the last post-baseline flare the population analyzed consisted of patients re-treated for at least one new flare. Patients who did not take rescue medication had the time-to-first rescue medication intake censored at 7 days post dosing and re-dosing.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**114**
Time to First Intake of Rescue Medication [units: hours] Median (95% Confidence Interval)		
Baseline flare [N= 112, 114]	**NA** [1]	**37.5** [2]
Last post-baseline flare [N=25, 46]	**32** [2]	**NA** [1]

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

[2] Upper bound did not cross the median value hence the upper limit was not estimable.

No statistical analysis provided for Time to First Intake of Rescue Medication

15. Secondary: Percentage of Participants Who Took Rescue Medication [Time Frame: For 7 days after the first dose for the baseline flare and 7 days post-dose for the last post-baseline flare that occurred up until the end of the first extension study (24 weeks).]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Took Rescue Medication
Measure Description	Participants 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, participants were allowed to take a maximum of 30 mg of oral prednisolone 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. Use of these treatments during the first 7 days of a gout flare was recorded as rescue medication.
Time Frame	For 7 days after the first dose for the baseline flare and 7 days post-dose for the last post-baseline flare that occurred up until the end of the first extension study (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.
For the Baseline flare the population analyzed consisted of the Full Analysis Set (FAS). For the last post-baseline flare the population analyzed consisted of patients re-treated for at least one new flare.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**114**
Percentage of Participants Who Took Rescue Medication [units: percentage of participants]		
Baseline flare [N= 112, 114]	**43.8**	**57.0**
Last post-baseline flare [N=25, 46]	**56.0**	**41.3**

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

16. Secondary: Amount of Rescue Medication Taken [Time Frame: For 7 days after the first dose for the baseline flare and 7 days post-dose for the last post-baseline flare that occurred up until the end of the first extension study (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 prednisolone 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	For 7 days after the first dose for the baseline flare and 7 days post-dose for the last post-baseline flare that occurred up until the end of the first extension study (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.
For the Baseline flare the population analyzed consisted of the Full Analysis Set (FAS). For the last post-baseline flare the population analyzed consisted of patients re-treated for at least one new flare.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**114**
Amount of Rescue Medication Taken [units: mg] Mean (Standard Deviation)		
Baseline flare: Acetaminophen [N=112, 114]	**1375.0 (2726.63)**	**2526.5 (3925.13)**
Baseline flare: Codeine [N=112, 114]	**27.2 (100.40)**	**60.6 (144.38)**
Baseline flare: Prednisone/Predinisone [N=112,114]	**9.2 (35.32)**	**19.3 (44.88)**
Last flare: Acetaminophen [N=25, 46]	**2292.0 (3462.65)**	**1541.3 (3771.33)**
Last flare: Codeine [N= 25, 46]	**64.8 (224.11)**	**65.2 (178.70)**
Last flare: Prednisolone/Predinisone [N= 25, 46]	**5.6 (14.46)**	**18.3 (48.00)**

No statistical analysis provided for Amount of Rescue Medication Taken

17. Secondary: Physician's Global Assessment of Response to Treatment [Time Frame: 72 hours post-dose and 24-weeks post-dose.]

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 own assessments (pain intensity and patient's global assessment of response to treatment).
Time Frame	72 hours post-dose and 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.
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 available for this endpoint at the specified time point.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**114**
Physician's Global Assessment of Response to Treatment [units: percentage of participants]		
72 hours - Very good [N= 107, 109]	**43.0**	**25.7**
72 hours - Good [N= 107, 109]	**43.0**	**35.8**
72 hours - Fair [N= 107, 109]	**11.2**	**26.6**
72 hours - Poor [N= 107, 109]	**2.8**	**6.4**
72 hours - Very poor [N= 107, 109]	**0.0**	**5.5**
24 weeks - Very good [N=79, 71]	**77.2**	**66.2**
24 weeks - Good [N=79, 71]	**16.5**	**29.6**
24 weeks - Fair [N=79, 71]	**5.1**	**4.2**
24 weeks - Poor [N=79, 71]	**1.3**	**0.0**
24 weeks - Very poor [N=79, 71]	**0.0**	**0.0**

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

18. Secondary: Patient's Global Assessment of Response to Treatment [Time Frame: 72 hours post-dose and 24 weeks post-dose]

Measure Type	Secondary
Measure Title	Patient's Global Assessment of Response to Treatment
Measure Description	Participants made a global assessment of response to treatment using a 5-point Likert scale: Excellent, good, acceptable, slight, poor. The percentage of participants in each category is reported.
Time Frame	72 hours post-dose and 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.
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 available at the specified time point.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**114**
Patient's Global Assessment of Response to Treatment [units: percentage of participants]		
72 hours - Excellent [N=108, 108]	**36.1**	**19.4**
72 hours - Good [N=108, 108]	**37.0**	**32.4**
72 hours - Acceptable [N=108, 108]	**18.5**	**13.9**
72 hours - Slight [N=108, 108]	**4.6**	**25.0**
72 hours - Poor [N=108, 108]	**3.7**	**9.3**
24 weeks - Excellent [N=79, 72]	**59.5**	**40.3**
24 weeks - Good [N=79, 72]	**26.6**	**44.4**
24 weeks - Acceptable [N=79, 72]	**6.3**	**13.9**
24 weeks - Slight [N=79, 72]	**6.3**	**1.4**
24 weeks - Poor [N=79, 72]	**1.3**	**0.0**

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

19. Secondary: Physician's Assessment of Tenderness, Swelling, and Erythema of the Most Affected Joint [Time Frame: 72 hours post-dose and 24 weeks post-dose]

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 participants in each category is reported.
Time Frame	72 hours post-dose and 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.
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 available at the specified time point.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
Number of Participants Analyzed [units: participants]	**112**	**114**
Physician's Assessment of Tenderness, Swelling, and Erythema of the Most Affected Joint [units: percentage of participants]		
72 hours - Tenderness: No pain [N=107, 109]	**47.7**	**30.3**
72 hours - Tenderness: Pain [N=107, 109]	**43.9**	**46.8**
72 hours - Tenderness: Pain & winces [N=107, 109]	**4.7**	**14.7**
72 hours - Tenderness:Winces/withdraws [N=107,109]	**3.7**	**8.3**
24 weeks - Tenderness: No pain [N=79, 71]	**88.6**	**91.5**
24 weeks - Tenderness: Pain [N=79, 71]	**8.9**	**5.6**
24 weeks - Tenderness: Pain and winces [N=79, 71]	**1.3**	**1.4**
24 weeks - Tenderness: Winces/withdraws [N=79, 71]	**1.3**	**1.4**

72 hours - Swelling: No swelling [N=107,109]	**47.7**	**35.8**
72 hours - Swelling: Palpable [N=107,109]	**28.0**	**29.4**
72 hours - Swelling: Visible [N=107,109]	**22.4**	**28.4**
72 hours - Swelling: Bulging [N=107,109]	**1.9**	**6.4**
24 weeks - Swelling: No swelling [N=79, 71]	**93.7**	**94.4**
24 weeks - Swelling: Palpable [N=79, 71]	**5.1**	**4.2**
24 weeks - Swelling: Visible [N=79, 71]	**1.3**	**1.4**
24 weeks - Swelling: Bulging [N=79, 71]	**0.0**	**0.0**
72 hours - Erythema: Absent [N=107, 108]	**74.8**	**66.7**
72 hours - Erythema: Present [N=107, 108]	**25.2**	**33.3**
24 weeks - Erythema: Absent [N=79, 71]	**97.5**	**97.2**
24 weeks - Erythema: Present [N=79, 71]	**2.5**	**2.8**

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

20. Secondary: Physician's Assessment of Range of Motion of the Most Affected Joint [Time Frame: 72 hours post-dose and 24 weeks post-dose]

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 participants in each category is reported.
Time Frame	72 hours post-dose and 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.
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 available at the specified time point.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	**Triamcinolone Acetonide 40 mg**
	112	**114**

Number of Participants Analyzed [units: participants]		
Physician's Assessment of Range of Motion of the Most Affected Joint [units: percentage of participants]		
72 hours - Normal [N=107,109]	47.7	28.4
72 hours - Mildly restricted [N=107,109]	37.4	45.9
72 hours - Moderately restricted [N=107,109]	13.1	20.2
72 hours - Severely restricted [N=107,109]	1.9	5.5
72 hours - Immobilized [N=107,109]	0.0	0.0
24 weeks - Normal [N=79, 71]	86.1	97.2
24 weeks - Mildly restricted [N=79, 71]	10.1	2.8
24 weeks - Moderately restricted [N=79, 71]	2.5	0.0
24 weeks - Severely restricted [N=79, 71]	1.3	0.0
24 weeks - Immobilized [N=79, 71]	0.0	0.0

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

21. Secondary: High-sensitivity C-reactive Protein (hsCRP) and Serum Amyloid A Protein (SAA) Levels [Time Frame: 72 hours after the first dose for the baseline flare and 72 hours post-dose for the last post-baseline flare that occurred up until the end of the first extension study (24 weeks).]

Measure Type	Secondary
Measure Title	High-sensitivity C-reactive Protein (hsCRP) and Serum Amyloid A Protein (SAA) Levels
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. Analyses 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 after the first dose for the baseline flare and 72 hours post-dose for the last post-baseline flare that occurred up until the end of the first extension study (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.
For the Baseline flare the population analyzed consisted of the Full Analysis Set (FAS). For the last post-baseline flare the population analyzed consisted of patients re-treated for at least one new flare. "N" indicates the number of participants with available data in each analysis.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**112**	**114**
High-sensitivity C-reactive Protein (hsCRP) and Serum Amyloid A Protein (SAA) Levels [units: mg/L] Least Squares Mean (95% Confidence Interval)		
Baseline flare: hsCRP [N=107, 110]	**3.84 (3.26 to 4.53)**	**6.38 (5.43 to 7.50)**
Baseline flare: SAA [N=95, 104]	**6.31 (4.95 to 8.04)**	**15.85 (12.58 to 19.98)**
Last post-baseline flare: hsCRP [N= 22, 42]	**3.69 (2.44 to 5.60)**	**4.32 (3.23 to 5.60)**
Last post-baseline flare: SAA, [N= 19, 39]	**6.74 (3.56 to 12.78)**	**11.04 (7.17 to 17.02)**

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

22. Secondary: Patient's Assessment of Gout Pain Intensity in the Most Affected Joint [Time Frame: 72 hours post-dose and 24 weeks post-dose]

Measure Type	Secondary
Measure Title	Patient's Assessment of Gout Pain Intensity in the Most Affected Joint
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).
Time Frame	72 hours post-dose and 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.
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 available at the specified time point.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg

Number of Participants Analyzed [units: participants]	**112**	**114**
Patient's Assessment of Gout Pain Intensity in the Most Affected Joint [units: percentage of participants]		
72 hours - None [N=108, 111]	**30.6**	**18.0**
72 hours - Mild [N=108, 111]	**48.1**	**45.0**
72 hours - Moderate [N=108, 111]	**20.4**	**27.0**
72 hours - Severe [N=108, 111]	**0.9**	**8.1**
72 hours - Extreme [N=108, 111]	**0.0**	**1.8**
24 weeks - None [N=79, 70]	**72.2**	**67.1**
24 weeks - Mild [N=79, 70]	**19.0**	**25.7**
24 weeks - Moderate [N=79, 70]	**6.3**	**7.1**
24 weeks - Severe [N=79, 70]	**2.5**	**0.0**
24 weeks - Extreme [N=79, 70]	**0.0**	**0.0**

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

23. Secondary: Percentage of Patients With Maximum Severity of New Gout Flares as Severe or Extreme [Time Frame: From the onset of a new flare until re-dosing. First post-baseline new flare during 12 week core study and the last post-baseline flare that occurred up until the end of the first extension study (24 weeks).]

Measure Type	Secondary
Measure Title	Percentage of Patients With Maximum Severity of New Gout Flares as Severe or Extreme
Measure Description	For each new flare, participants scored the maximum amount of acute gout pain in the most affected joint since the onset of the new flare and the time they were re-dosed on a 5 point Likert scale as None, Mild, Moderate, Severe or Extreme. The percentage of participants with a maximum new flare severity of severe or extreme is reported for the first post-baseline flare that occurred during the 12-week core study and for the last post-baseline flare that occurred up until the end of the first extension period.
Time Frame	From the onset of a new flare until re-dosing. First post-baseline new flare during 12 week core study and the last post-baseline flare that occurred up until the end of the first extension study (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 number of participants analyzed (indicated by 'N') for the first new post-baseline flare includes patients who were re-treated for a new flare during the 12-week core study. For the last post-baseline flare the population analyzed includes patients re-treated for at least one new flare during the first 24 weeks.

Reporting Groups

	Description
Canakinumab 150 mg	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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.

	In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**25**	**46**
Percentage of Patients With Maximum Severity of New Gout Flares as Severe or Extreme [units: Percentage of participants]		
First post-baseline flare [N= 12, 37]	**66.7**	**78.4**
Last post-baseline flare [N= 25, 46]	**64.0**	**78.3**

No statistical analysis provided for Percentage of Patients With Maximum Severity of New Gout Flares as Severe or Extreme

24. Secondary: Time to First New Flare: Survival Analysis by Treatment Over 72 Weeks [Time Frame: From randomization to the end of the second extension period (72 weeks).]

Measure Type	Secondary
Measure Title	Time to First New Flare: Survival Analysis by Treatment Over 72 Weeks
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	From randomization to the end of the second extension period (72 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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare. In the second extension study participants were to receive open-label on demand treatment with canakinumab 150 mg sc for any new flare for an additional year, for a total duration of 18 months.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare.

	In the second extension study participants were to switch to open-label on demand treatment with canakinumab 150 mg sc for any new flare for an additional year. Triamcinolone acetonide was not to be administered in the second extension study.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**112**	**114**
Time to First New Flare: Survival Analysis by Treatment Over 72 Weeks [units: days] Median (95% Confidence Interval)	**254.0 (209.0 to 284.0)**	**146.0 (94.0 to 202.0)**

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

25. Secondary: Flare Rate Per Year [Time Frame: From randomization to the end of the second extension period (72 weeks).]

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. Participants met the 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. Participants did not meet criterion of having new gout flare if: • Increasing/renewed gout pain in an affected joint before the flare has resolved completely. Flare rates were estimated from a negative binomial model with body mass index at baseline as a covariate.
Time Frame	From randomization to the end of the second extension period (72 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	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare. In the second extension study participants were to receive open-label on demand treatment with canakinumab 150 mg sc for any new flare for an additional year, for a total duration of 18 months.
Triamcinolone Acetonide 40 mg	Participants received 1 intramuscular injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same treatment for another 12 weeks for any new gout flare. In the second extension study participants were to switch to open-label on demand treatment with canakinumab 150 mg sc for any new flare for an additional year. Triamcinolone acetonide was not to be administered in the second extension study.

Measured Values

	Canakinumab 150 mg	Triamcinolone Acetonide 40 mg
Number of Participants Analyzed [units: participants]	**112**	**114**
Flare Rate Per Year [units: flares per patient per year] Mean (95% Confidence Interval)	**1.18 (0.96 to 1.45)**	**2.02 (1.65 to 2.47)**

No statistical analysis provided for Flare Rate Per Year

26. Secondary: Patient's Assessment of Gout Pain Intensity for Participants Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 weeks.]

Measure Type	Secondary
Measure Title	Patient's Assessment of Gout Pain Intensity for Participants Re-treated or Switched to Canakinumab
Measure Description	Participants scored their current pain intensity in the most affected joint of the gout flare on a 5-point Likert Scale (none, mild, moderate, severe or extreme). Data are reported for the last post-baseline flare for participants who were randomized to and re-treated with canakinumab, and for the first post-baseline flare treated with canakinumab for participants randomized to triamcinolone acetonide and who were switched to canakinumab in extension study 2.
Time Frame	72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 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.
Modified Analysis Set (MAS) consisting of all FAS patients who were either re-treated or switched to canakinumab during the 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Re-treated With Canakinumab 150 mg	Participants who received canakinumab 150 mg in the core study and who were re-treated with canakinumab 150 mg for new flares during the overall 72 weeks. Data are reported for the last post-baseline flare for participants in this arm.
Triam Switched to Canakinumab	Participants who received triamcinolone acetonide (triam) 40 mg in the core study and who were switched to canakinumab 150 mg for treatment of new flares in extension study 2. Data are reported for the first post-baseline flare treated with canakinumab.

Measured Values

	Re-treated With Canakinumab 150 mg	Triam Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**62**	**41**
Patient's Assessment of Gout Pain Intensity for Participants Re-treated or Switched to Canakinumab [units: percentage of participants]		
72 hours - None [N=59, 40]	**30.5**	**25.0**
72 hours - Mild [N=59, 40]	**44.1**	**62.5**

72 hours - Moderate [N=59, 40]	**22.0**	**12.5**
72 hours - Severe [N=59, 40]	**3.4**	**0.0**
72 hours - Extreme [N=59, 40]	**0.0**	**0.0**
7 days - None [N=57, 37]	**64.9**	**59.5**
7 days - Mild [N=57, 37]	**21.1**	**35.1**
7 days - Moderate [N=57, 37]	**10.5**	**5.4**
7 days - Severe [N=57, 37]	**3.5**	**0.0**
7 days - Extreme [N=57, 37]	**0.0**	**0.0**

No statistical analysis provided for Patient's Assessment of Gout Pain Intensity for Participants Re-treated or Switched to Canakinumab

27. Secondary: Patient's Global Assessment of Response to Treatment for Participants Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 weeks.]

Measure Type	Secondary
Measure Title	Patient's Global Assessment of Response to Treatment for Participants Re-treated or Switched to Canakinumab
Measure Description	Participants made a global assessment of response to treatment using a 5-point Likert scale: Excellent, good, acceptable, slight or poor. Data are reported for the last post-baseline flare for participants who were randomized to and re-treated with canakinumab, and for the first post-baseline flare treated with canakinumab for participants randomized to triamcinolone acetonide and who were switched to canakinumab in extension study 2.
Time Frame	72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 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.
Modified Analysis Set (MAS) consisting of all FAS patients who were either re-treated or switched to canakinumab during the 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Re-treated With Canakinumab 150 mg	Participants who received canakinumab 150 mg in the core study and who were re-treated with canakinumab 150 mg for new flares during the overall 72 weeks. Data are reported for the last post-baseline flare for participants in this arm.
Triam Switched to Canakinumab	Participants who received triamcinolone acetonide (triam) 40 mg in the core study and who were switched to canakinumab 150 mg for treatment of new flares in extension study 2. Data are reported for the first post-baseline flare treated with canakinumab.

Measured Values

	Re-treated With Canakinumab 150 mg	**Triam Switched to Canakinumab**
Number of Participants Analyzed [units: participants]	**62**	**41**
Patient's Global Assessment of Response to Treatment for Participants Re-treated or Switched to Canakinumab [units: percentage of participants]		
72 hours - Excellent [N=58, 38]	**41.4**	**36.8**
72 hours - Good [N=58, 38]	**32.8**	**39.5**

72 hours - Acceptable [N=58, 38]	**12.1**	**21.1**
72 hours - Slight [N=58, 38]	**13.8**	**2.6**
72 hours - Poor [N=58, 38]	**0.0**	**0.0**
7 days - Excellent [N=56, 39]	**51.8**	**51.3**
7 days - Good [N=56, 39]	**26.8**	**33.3**
7 days - Acceptable [N=56, 39]	**10.7**	**7.7**
7 days - Slight [N=56, 39]	**7.1**	**7.7**
7 days - Poor [N=56, 39]	**3.6**	**0.0**

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

28. Secondary: Physician's Global Assessment of Response to Treatment for Participants Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 weeks.]

Measure Type	Secondary
Measure Title	Physician's Global Assessment of Response to Treatment for Participants 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 or very poor. The physician completed the physician's global assessment of response to treatment without viewing any of the patient's assessments. Data are reported for the last post-baseline flare for participants who were randomized to and re-treated with canakinumab, and for the first post-baseline flare treated with canakinumab for participants randomized to triamcinolone acetonide and who were switched to canakinumab in extension study 2.
Time Frame	72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 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.
Modified Analysis Set (MAS) consisting of all FAS patients who were either re-treated or switched to canakinumab during the 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Re-treated With Canakinumab 150 mg	Participants who received canakinumab 150 mg in the core study and who were re-treated with canakinumab 150 mg for new flares during the overall 72 weeks. Data are reported for the last post-baseline flare for participants in this arm.
Triam Switched to Canakinumab	Participants who received triamcinolone acetonide (triam) 40 mg in the core study and who were switched to canakinumab 150 mg for treatment of new flares in extension study 2. Data are reported for the first post-baseline flare treated with canakinumab.

Measured Values

	Re-treated With Canakinumab 150 mg	**Triam Switched to Canakinumab**
Number of Participants Analyzed [units: participants]	**62**	**41**

Physician's Global Assessment of Response to Treatment for Participants Re-treated or Switched to Canakinumab [units: percentage of participants]		
72 hours - Very good [N=56, 38]	39.3	42.1
72 hours - Good [N=56, 38]	39.3	39.5
72 hours - Fair [N=56, 38]	16.1	18.4
72 hours - Poor [N=56, 38]	5.4	0.0
72 hours - Very poor [N=56, 38]	0.0	0.0
7 days - Very good [N=58, 39]	56.9	59.0
7 days - Good [N=58, 39]	25.9	38.5
7 days - Fair [N=58, 39]	15.5	2.6
7 days - Poor [N=58, 39]	1.7	0.0
7 days - Very poor [N=58, 39]	0.0	0.0

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

29. Secondary: Physician's Assessment of Joint Tenderness for Participants Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 weeks.]

Measure Type	Secondary
Measure Title	Physician's Assessment of Joint Tenderness for Participants Re-treated or Switched to Canakinumab
Measure Description	The study physician assessed the most affected joint for tenderness on the following 4-point scale: • no pain; • participant states that "there is pain; • participant states "there is pain and winces"; • participant states "there is pain, winces and withdraws" on palpation or passive movement of the affected study joint. Data are reported for the last post-baseline flare for participants who were randomized to and re-treated with canakinumab, and for the first post-baseline flare treated with canakinumab for participants randomized to triamcinolone acetonide and who were switched to canakinumab in extension study 2.
Time Frame	72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 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.
Modified Analysis Set (MAS) consisting of all FAS patients who were either re-treated or switched to canakinumab during the 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Re-treated With Canakinumab 150 mg	Participants who received canakinumab 150 mg in the core study and who were re-treated with canakinumab 150 mg for new flares during the overall 72 weeks. Data are reported for the last post-baseline flare for participants in this arm.
Triam Switched to Canakinumab	Participants who received triamcinolone acetonide (triam) 40 mg in the core study and who were switched to canakinumab 150 mg for treatment of new flares in extension study 2. Data are reported for the first post-baseline flare treated with canakinumab.

Measured Values

	Re-treated With Canakinumab 150 mg	Triam Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**62**	**41**
Physician's Assessment of Joint Tenderness for Participants Re-treated or Switched to Canakinumab [units: percentage of participants]		
72 hours - No pain [N=56, 38]	**51.8**	**42.1**
72 hours - Pain [N=56, 38]	**37.5**	**50.0**
72 hours - Pain and winces [N=56, 38]	**5.4**	**5.3**
72 hours - Pain, winces and withdraws [N=56, 38]	**5.4**	**2.6**
7 days - No pain [N=58, 39]	**74.1**	**79.5**
7 days - Pain [N=58, 39]	**22.4**	**20.5**
7 days - Pain and winces [N=58, 39]	**3.4**	**0.0**
7 days - Pain, winces and withdraws [N=58, 39]	**0.0**	**0.0**

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

30. Secondary: Physician's Assessment of Joint Swelling for Participants Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 weeks.]

Measure Type	Secondary
Measure Title	Physician's Assessment of Joint Swelling for Participants Re-treated or Switched to Canakinumab
Measure Description	The study physician assessed the most affected joint for swelling on the following 4-point scale: • no swelling; • palpable; • visible; • bulging beyond the joint margins. Data are reported for the last post-baseline flare for participants who were randomized to and re-treated with canakinumab, and for the first post-baseline flare treated with canakinumab for participants randomized to triamcinolone acetonide and who were switched to canakinumab in extension study 2.
Time Frame	72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 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.
Modified Analysis Set (MAS) consisting of all FAS patients who were either re-treated or switched to canakinumab during the 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Re-treated With Canakinumab 150 mg	Participants who received canakinumab 150 mg in the core study and who were re-treated with canakinumab 150 mg for new flares during the overall 72 weeks. Data are reported for the last post-baseline flare for participants in this arm.

Triam Switched to Canakinumab	Participants who received triamcinolone acetonide (triam) 40 mg in the core study and who were switched to canakinumab 150 mg for treatment of new flares in extension study 2. Data are reported for the first post-baseline flare treated with canakinumab.

Measured Values

	Re-treated With Canakinumab 150 mg	Triam Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**62**	**41**
Physician's Assessment of Joint Swelling for Participants Re-treated or Switched to Canakinumab [units: percentage of participants]		
72 hours - No swelling [N=56, 38]	**55.4**	**47.4**
72 hours - Palpable [N=56, 38]	**26.8**	**34.2**
72 hours - Visible [N=56, 38]	**12.5**	**15.8**
72 hours - Bulging beyond joint margins [N=56, 38]	**5.4**	**2.6**
7 days - No swelling [N=58, 39]	**70.7**	**79.5**
7 days - Palpable [N=58, 39]	**17.2**	**17.9**
7 days - Visible [N=58, 39]	**10.3**	**2.6**
7 days - Bulging beyond joint margins [N=58, 39]	**1.7**	**0.0**

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

31. Secondary: Physician's Assessment of Erythema for Participants Re-treated or Switched to Canakinumab [Time Frame: 72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 weeks.]

Measure Type	Secondary
Measure Title	Physician's Assessment of Erythema for Participants Re-treated or Switched to Canakinumab
Measure Description	The study physician assessed the most affected joint for erythema (redness of the skin) as either present, absent or not assessable. Data are reported for the last post-baseline flare for participants who were randomized to and re-treated with canakinumab, and for the first post-baseline flare treated with canakinumab for participants randomized to triamcinolone acetonide and who were switched to canakinumab in extension study 2.
Time Frame	72 hours post-dose and 7 days post dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 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.
Modified Analysis Set (MAS) consisting of all FAS patients who were either re-treated or switched to canakinumab during the 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Re-treated With Canakinumab 150 mg	Participants who received canakinumab 150 mg in the core study and who were re-treated with canakinumab 150 mg for new flares during the overall 72 weeks. Data are reported for the last post-baseline flare for participants in this arm.

Triam Switched to Canakinumab	Participants who received triamcinolone acetonide (triam) 40 mg in the core study and who were switched to canakinumab 150 mg for treatment of new flares in extension study 2. Data are reported for the first post-baseline flare treated with canakinumab.

Measured Values

	Re-treated With Canakinumab 150 mg	Triam Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**62**	**41**
Physician's Assessment of Erythema for Participants Re-treated or Switched to Canakinumab [units: percentage of participants]		
72 hours - Absent [N=56, 38]	**73.2**	**92.1**
72 hours - Present [N=56, 38]	**26.8**	**7.9**
7 days - Absent [N=58, 39]	**84.5**	**94.9**
7 days - Present [N=58, 39]	**15.5**	**5.1**

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

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

Measure Type	Secondary
Measure Title	High-sensitivity C-reactive Protein (hsCRP) Levels for Participants Re-treated With or Switched to Canakinumab
Measure Description	High sensitivity C-reactive protein (hsCRP) levels in blood serum were measured by a central laboratory in order to identify the presence of inflammation, to determine its severity, and to monitor the response to treatment. Data are reported for the last post-baseline flare for participants who were randomized to and re-treated with canakinumab, and for the first post-baseline flare treated with canakinumab for participants randomized to triamcinolone acetonide and who were switched to canakinumab in extension study 2.
Time Frame	24 hours, 72 hours, 7 days, 4, 8 and 12 weeks post-dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 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.
Modified Analysis Set (MAS) consisting of all FAS patients who were either re-treated or switched to canakinumab during the 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Re-treated With Canakinumab 150 mg	Participants who received canakinumab 150 mg in the Ccre study and who were re-treated with canakinumab 150 mg for new flares during the overall 72 weeks. Data are reported for the last post-baseline flare for participants in this arm.
Triam Switched to Canakinumab	Participants who received triamcinolone acetonide (triam) 40 mg in the core study and who were switched to canakinumab 150 mg for treatment of new flares in extension study 2. Data are reported for the first post-baseline flare treated with canakinumab.

Measured Values

	Re-treated With Canakinumab 150 mg	Triam Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**62**	**41**
High-sensitivity C-reactive Protein (hsCRP) Levels for Participants Re-treated With or Switched to Canakinumab [units: mg/L] Mean (Standard Deviation)		
24-hours post-dose [N=48, 36]	**30.1 (64.11)**	**39.4 (41.10)**
72-hours post-dose [N=56, 38]	**10.4 (31.11)**	**12.6 (15.80)**
7 days post-dose [N=55, 40]	**2.8 (4.97)**	**3.5 (5.00)**
4 weeks post-dose [N=46, 37]	**1.6 (2.30)**	**2.2 (3.54)**
8 weeks post-dose [N=37, 35]	**2.1 (4.41)**	**2.4 (4.62)**
12 weeks post-dose [N=38, 31]	**1.3 (0.79)**	**2.9 (4.90)**

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

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

Measure Type	Secondary
Measure Title	Serum Amyloid A Protein (SAA) Levels for Participants Re-treated With or Switched to Canakinumab
Measure Description	Serum Amyloid A Protein (SAA) levels in blood serum were measured by a central laboratory in order to identify the presence of inflammation, to determine its severity, and to monitor the response to treatment. Data are reported for the last post-baseline flare for participants who were randomized to and re-treated with canakinumab, and for the first post-baseline flare treated with canakinumab for participants randomized to triamcinolone acetonide and who were switched to canakinumab in extension study 2.
Time Frame	24 hours, 72 hours, 7 days, 4, 8 and 12 weeks post-dose for the last post-baseline flare for the canakinumab re-treated arm and for the first post-baseline flare treated with canakinumab in the triamcinolone acetonide arm during the overall 72 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.
Modified Analysis Set (MAS) consisting of all FAS patients who were either re-treated or switched to canakinumab during the 72 weeks. At each timepoint only patients with a value at both baseline flare and the new flare are included.

Reporting Groups

	Description
Re-treated With Canakinumab 150 mg	Participants who received canakinumab 150 mg in the core study and who were re-treated with canakinumab 150 mg for new flares during the overall 72 weeks. Data are reported for the last post-baseline flare for participants in this arm.
Triam Switched to Canakinumab	Participants who received triamcinolone acetonide (triam) 40 mg in the core study and who were switched to canakinumab 150 mg for treatment of new flares in extension study 2. Data are reported for the first post-baseline flare treated with canakinumab.

Measured Values

	Re-treated With Canakinumab 150 mg	Triam Switched to Canakinumab
Number of Participants Analyzed [units: participants]	**62**	**41**
Serum Amyloid A Protein (SAA) Levels for Participants Re-treated With or Switched to Canakinumab [units: mg/L] Mean (Standard Deviation)		
24-hours post-dose [N=47, 36]	**129.0 (324.45)**	**145.9 (257.44)**
72-hours post-dose [N=54, 37]	**45.6 (163.45)**	**45.4 (97.00)**
7 days post-dose [N=56, 39]	**5.7 (8.90)**	**5.9 (8.34)**
4 weeks post-dose [N=47, 37]	**3.4 (3.67)**	**5.0 (7.02)**
8 weeks post-dose [N=38, 35]	**3.5 (4.24)**	**5.3 (13.41)**
12 weeks post-dose [N=38, 29]	**3.4 (2.37)**	**4.8 (5.94)**

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

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
All Canakinumab	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study, participants completing the 12 week core study could continue to be treated on demand with the same study treatment for an additional 12 weeks for any new gout flare. In the second extension study participants were to receive open-label on demand treatment with canakinumab 150 mg sc upon new flare for 1 year, for a total duration of 18 months.
Canakinumab: Before Retreatment	Participants who received canakinumab in the core study and were re-treated with canakinumab during the core study or extension study 1 or 2. Reported data include adverse events that occurred in this re-treated population before re-treatment with canakinumab.
Canakinumab: After Retreatment	Participants who received canakinumab in the core study and were re-treated with canakinumab during the core study or extension study 1 or 2. Reported data include adverse events that occurred in this re-treated population after re-treatment with canakinumab.
All Triamcinolone Acetonide	Participants received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same study treatment another 12 weeks for any new gout flare. Reported data include all adverse events that occurred during the core study and extension studies 1 and 2, before participants were switched to canakinumab.
Triam: Before Switch to Canakinumab	Participants who were treated with triamcinolone acetonide (triam) during the core study and extension study 1 and who were switched to open-label on demand treatment with canakinumab 150 mg sc upon new flare in extension study 2. Data are reported for adverse events that occurred before the switch to canakinumab.

Triam: After Switch to Canakinumab	Participants who were treated with triamcinolone acetonide during the core study and extension study 1 and who were switched to open-label on demand treatment with canakinumab 150 mg sc upon new flare in extension study 2. Data are reported for adverse events that occurred after the switch to canakinumab.

Serious Adverse Events

	All Canakinumab	Canakinumab: Before Retreatment	Canakinumab: After Retreatment	All Triamcinolone Acetonide	Triam: Before Switch to Canakinumab	Triam: After Switch to Canakinumab
Total, serious adverse events						
# participants affected / at risk	**12/112 (10.71%)**	**1/62 (1.61%)**	**5/62 (8.06%)**	**4/114 (3.51%)**	**0/41 (0.00%)**	**3/41 (7.32%)**
Blood and lymphatic system disorders						
Anaemia †1						
# participants affected / at risk	**0/112 (0.00%)**	**0/62 (0.00%)**	**0/62 (0.00%)**	**0/114 (0.00%)**	**0/41 (0.00%)**	**1/41 (2.44%)**
Haemorrhagic anaemia †1						
# participants affected / at risk	**0/112 (0.00%)**	**0/62 (0.00%)**	**0/62 (0.00%)**	**0/114 (0.00%)**	**0/41 (0.00%)**	**1/41 (2.44%)**
Cardiac disorders						
Angina pectoris †1						
# participants affected / at risk	**1/112 (0.89%)**	**0/62 (0.00%)**	**1/62 (1.61%)**	**0/114 (0.00%)**	**0/41 (0.00%)**	**1/41 (2.44%)**
Aortic valve incompetence †1						
# participants affected / at risk	**0/112 (0.00%)**	**0/62 (0.00%)**	**0/62 (0.00%)**	**1/114 (0.88%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
Atrial fibrillation †1						
# participants affected / at risk	**1/112 (0.89%)**	**0/62 (0.00%)**	**0/62 (0.00%)**	**0/114 (0.00%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
Cardiomyopathy †1						
# participants affected / at risk	**0/112 (0.00%)**	**0/62 (0.00%)**	**0/62 (0.00%)**	**1/114 (0.88%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
Congenital, familial and genetic disorders						
Bicuspid aortic valve †1						
# participants affected / at risk	**0/112 (0.00%)**	**0/62 (0.00%)**	**0/62 (0.00%)**	**1/114 (0.88%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
Gastrointestinal disorders						
Diarrhoea †1						
# participants affected / at risk	**0/112 (0.00%)**	**0/62 (0.00%)**	**0/62 (0.00%)**	**1/114 (0.88%)**	**0/41 (0.00%)**	**0/41 (0.00%)**
Lower gastrointestinal haemorrhage †1						
# participants affected / at risk	**0/112 (0.00%)**	**0/62 (0.00%)**	**0/62 (0.00%)**	**0/114 (0.00%)**	**0/41 (0.00%)**	**1/41 (2.44%)**

Nausea [†1]						
# participants affected / at risk	0/112 (0.00%)	0/62 (0.00%)	0/62 (0.00%)	1/114 (0.88%)	0/41 (0.00%)	0/41 (0.00%)
Pancreatitis [†1]						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	0/62 (0.00%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Vomiting [†1]						
# participants affected / at risk	0/112 (0.00%)	0/62 (0.00%)	0/62 (0.00%)	1/114 (0.88%)	0/41 (0.00%)	0/41 (0.00%)
General disorders						
Cyst [†1]						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	0/62 (0.00%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Infections and infestations						
Abscess limb [†1]						
# participants affected / at risk	2/112 (1.79%)	1/62 (1.61%)	0/62 (0.00%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Gastroenteritis [†1]						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	0/62 (0.00%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Metabolism and nutrition disorders						
Diabetes mellitus [†1]						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	1/62 (1.61%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Musculoskeletal and connective tissue disorders						
Back pain [†1]						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	0/62 (0.00%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Intervertebral disc protrusion [†1]						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	0/62 (0.00%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Prostate cancer [†1]						
# participants affected / at risk	0/112 (0.00%)	0/62 (0.00%)	0/62 (0.00%)	1/114 (0.88%)	0/41 (0.00%)	0/41 (0.00%)
Squamous cell carcinoma [†1]						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	1/62 (1.61%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Nervous system disorders						
Cerebrovascular accident [†1]						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	0/62 (0.00%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)

Convulsion † 1						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	1/62 (1.61%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Haemorrhage intracranial † 1						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	0/62 (0.00%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Trigeminal neuralgia † 1						
# participants affected / at risk	1/112 (0.89%)	0/62 (0.00%)	1/62 (1.61%)	0/114 (0.00%)	0/41 (0.00%)	0/41 (0.00%)
Psychiatric disorders						
Alcohol withdrawal syndrome † 1						
# participants affected / at risk	0/112 (0.00%)	0/62 (0.00%)	0/62 (0.00%)	1/114 (0.88%)	0/41 (0.00%)	0/41 (0.00%)
Renal and urinary disorders						
Acute prerenal failure † 1						
# participants affected / at risk	0/112 (0.00%)	0/62 (0.00%)	0/62 (0.00%)	0/114 (0.00%)	0/41 (0.00%)	1/41 (2.44%)
Vascular disorders						
Aortic stenosis † 1						
# participants affected / at risk	0/112 (0.00%)	0/62 (0.00%)	0/62 (0.00%)	1/114 (0.88%)	0/41 (0.00%)	0/41 (0.00%)

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

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
All Canakinumab	Participants received 1 subcutaneous (sc) injection of canakinumab 150 mg and 1 intramuscular (im) injection of placebo to triamcinolone acetonide on Day 1. Participants 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. In the first extension study, participants completing the 12 week core study could continue to be treated on demand with the same study treatment for an additional 12 weeks for any new gout flare. In the second extension study participants were to receive open-label on demand treatment with canakinumab 150 mg sc upon new flare for 1 year, for a total duration of 18 months.
Canakinumab: Before Retreatment	Participants who received canakinumab in the core study and were re-treated with canakinumab during the core study or extension study 1 or 2. Reported data include adverse events that occurred in this re-treated population before re-treatment with canakinumab.

Canakinumab: After Retreatment	Participants who received canakinumab in the core study and were re-treated with canakinumab during the core study or extension study 1 or 2. Reported data include adverse events that occurred in this re-treated population after re-treatment with canakinumab.
All Triamcinolone Acetonide	Participants received 1 intramuscular (im) injection of triamcinolone acetonide 40 mg and 1 sc injection of placebo to canakinumab on Day 1. Participants 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. In the first extension study participants completing the 12 week core study could continue to be treated on demand with the same study treatment another 12 weeks for any new gout flare. Reported data include all adverse events that occurred during the core study and extension studies 1 and 2, before participants were switched to canakinumab.
Triam: Before Switch to Canakinumab	Participants who were treated with triamcinolone acetonide (triam) during the core study and extension study 1 and who were switched to open-label on demand treatment with canakinumab 150 mg sc upon new flare in extension study 2. Data are reported for adverse events that occurred before the switch to canakinumab.
Triam: After Switch to Canakinumab	Participants who were treated with triamcinolone acetonide during the core study and extension study 1 and who were switched to open-label on demand treatment with canakinumab 150 mg sc upon new flare in extension study 2. Data are reported for adverse events that occurred after the switch to canakinumab.

Other Adverse Events

	All Canakinumab	Canakinumab: Before Retreatment	Canakinumab: After Retreatment	All Triamcinolone Acetonide	Triam: Before Switch to Canakinumab	Triam: After Switch to Canakinumab
Total, other (not including serious) adverse events						
# participants affected / at risk	**42/112 (37.50%)**	**15/62 (24.19%)**	**19/62 (30.65%)**	**36/114 (31.58%)**	**15/41 (36.59%)**	**8/41 (19.51%)**
Gastrointestinal disorders						
Nausea † 1						
# participants affected / at risk	**3/112 (2.68%)**	**2/62 (3.23%)**	**1/62 (1.61%)**	**3/114 (2.63%)**	**1/41 (2.44%)**	**3/41 (7.32%)**
Infections and infestations						
Nasopharyngitis † 1						
# participants affected / at risk	**0/112 (0.00%)**	**0/62 (0.00%)**	**0/62 (0.00%)**	**5/114 (4.39%)**	**4/41 (9.76%)**	**2/41 (4.88%)**
Upper respiratory tract infection † 1						
# participants affected / at risk	**9/112 (8.04%)**	**4/62 (6.45%)**	**7/62 (11.29%)**	**3/114 (2.63%)**	**1/41 (2.44%)**	**1/41 (2.44%)**
Injury, poisoning and procedural complications						
Muscle strain † 1						
# participants affected / at risk	**1/112 (0.89%)**	**0/62 (0.00%)**	**0/62 (0.00%)**	**3/114 (2.63%)**	**3/41 (7.32%)**	**3/41 (7.32%)**

Musculoskeletal and connective tissue disorders						
Arthralgia † 1						
# participants affected / at risk	**8/112 (7.14%)**	**1/62 (1.61%)**	**5/62 (8.06%)**	**10/114 (8.77%)**	**3/41 (7.32%)**	**2/41 (4.88%)**
Back pain † 1						
# participants affected / at risk	**12/112 (10.71%)**	**2/62 (3.23%)**	**6/62 (9.68%)**	**2/114 (1.75%)**	**1/41 (2.44%)**	**0/41 (0.00%)**
Muscle spasms † 1						
# participants affected / at risk	**4/112 (3.57%)**	**2/62 (3.23%)**	**1/62 (1.61%)**	**7/114 (6.14%)**	**4/41 (9.76%)**	**0/41 (0.00%)**
Pain in extremity † 1						
# participants affected / at risk	**2/112 (1.79%)**	**1/62 (1.61%)**	**0/62 (0.00%)**	**6/114 (5.26%)**	**4/41 (9.76%)**	**1/41 (2.44%)**
Nervous system disorders						
Headache † 1						
# participants affected / at risk	**5/112 (4.46%)**	**3/62 (4.84%)**	**2/62 (3.23%)**	**6/114 (5.26%)**	**2/41 (4.88%)**	**1/41 (2.44%)**
Vascular disorders						
Hypertension † 1						
# participants affected / at risk	**14/112 (12.50%)**	**3/62 (4.84%)**	**7/62 (11.29%)**	**7/114 (6.14%)**	**2/41 (4.88%)**	**1/41 (2.44%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

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

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

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

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
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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.

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