NOVARTIS

Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Canakinumab

Trial Indication(s)

Non-small cell lung cancer

Protocol Number

CACZ885V2301

Protocol Title

A randomized, double-blind, placebo-controlled, phase III study evaluating the efficacy and safety of canakinumab in combination with docetaxel versus placebo in combination with docetaxel in adult subjects with non-small cell lung cancer (NSCLC) previously treated with PD-(L)1 inhibitors and platinum-based chemotherapy (CANOPY 2)

Clinical Trial Phase

Phase 3

Phase of Drug Development

Phase IV

Study Start/End Dates

Study Start Date: January 2019 (Actual)
Primary Completion Date: January 2021 (Actual)
Study Completion Date: December 2021 (Actual)

Reason for Termination (If applicable)

The results of the primary analysis showed that although canakinumab plus docetaxel has a manageable safety profile, it was not efficacious at the selected dose regimen for the patients in the study. Therefore, Novartis decided to halt the study.

Study Design/Methodology

This was a multicenter, Phase III study designed to evaluate the efficacy and safety of canakinumab in combination with docetaxel versus placebo in combination with docetaxel, as second- or third-line treatment. The study included adult subjects with advanced NSCLC whose disease had progressed after prior treatment with a PD-(L)1 inhibitor. Subjects had also been pre-treated with platinum-based chemotherapy, either given together with PD-(L)1 inhibitor or sequentially.

The study consisted of 2 parts:

- Part 1: Safety run-in. This part was conducted to confirm the Recommended Phase 3 Regimen (RP3R) of the canakinumab and docetaxel combination. Participants were treated for at least 2 complete cycles of treatment (21 days per cycle) for safety evaluation (DLT-Dose Limiting Toxicities) to define RP3R. Participants from the safety run-in part were treated until any discontinuation criteria were met. After treatment discontinuation, all participants were followed for safety evaluations during the safety follow up period (up to 130 days). Additionally, subjects who discontinued study treatment without prior documented disease progression continued efficacy assessments in the efficacy follow-up phase irrespective of the start of new antineoplastic therapy and until documented progressive disease as per protocol. After the RP3R was determined, enrollment in this part was closed and additional participants were enrolled in the randomized part (part 2) of the study. Ongoing patients from the safety run-in part continued their treatment at the assigned dose level according to the dose and schedule for the safety run-in part.

-Part 2: Randomized part. The randomized, double-blind, placebo-controlled part of the study opened after confirmation of the RP3R for the combination of canakinumab and docetaxel. Participants from the randomized part were treated until any discontinuation criteria were met as per protocol. After treatment discontinuation, all participants were followed for safety evaluations during the safety follow up period (up to 130 days). Additionally, subjects who discontinued study treatment without prior documented disease progression continued efficacy assessments in the efficacy follow-up phase irrespective of the start of new antineoplastic therapy and until documented progressive disease as per protocol.

Based on the lack of efficacy observed in the primary analysis, Novartis decided to halt canakinumab/placebo treatment. Subjects continued to receive docetaxel if they were deriving clinical benefit as per investigator assessment until discontinuation.

Centers

78 centers in 26 countries: Singapore(1), Belgium(5), Taiwan(2), Japan(5), Germany(7), France(5), Spain(8), Italy(3), Canada(2), Argentina(5), Korea, Republic of(3), Russia(2), Australia(2), Israel(1), United States(6), Czech Republic(2), Poland(3), Greece(2), Jordan(1), Netherlands(3), Chile(1), Hungary(1), Lebanon(1), China(2), Denmark(2), Brazil(3)

Objectives:

Primary Objectives:

- Safety Run-in: To confirm the Recommended Phase 3 Regimen (RP3R) of the canakinumab and docetaxel combination
- Randomized part: To compare overall survival (OS) in the docetaxel plus canakinumab and docetaxel plus placebo treatment arms

Secondary Objectives

- Safety Run-in:
  - To assess the preliminary clinical antitumor activity of the canakinumab and docetaxel combination
  - To characterize the safety and tolerability of the combination of canakinumab and docetaxel
  - To characterize the pharmacokinetics (PK) of canakinumab and docetaxel when given in combination
- Randomized part:
  - To evaluate the 2 treatment arms with regards to progression-free survival (PFS), overall response rate (ORR), disease control rate (DCR), time to response (TTR), and duration of response (DOR) per Investigator assessment according to RECIST1.1
  - To characterize the safety profile of the combination of docetaxel and canakinumab
  - To assess the effect of docetaxel plus canakinumab vs docetaxel plus placebo arms on patient-reported outcomes (EORTC QLQ-C30, lung specific module QLQ-LC13, and EQ-5D-5L) including lung cancer symptoms, health-related quality of life and health status
  - To characterize the PK of canakinumab when given in combination

- To characterize the immunogenicity (ADA) of canakinumab
- To assess the effect of docetaxel plus placebo vs docetaxel plus canakinumab on ECOG performance status

Test Product (s), Dose(s), and Mode(s) of Administration

- Canakinumab, 200 mg, administered subcutaneously with an injection using a pre-filled syringe on Day 1 of each 21-day cycle
- Docetaxel 75mg/m^2, intravenous, administered on Day 1 of each 21-day cycle
- Placebo administered subcutaneously with an injection using a pre-filled syringe on Day 1 of each 21-day cycle

Statistical Methods

Part 1- Safety run-in
The primary objective was to determine the RP3R of the combination of canakinumab and docetaxel for the randomized part. The primary endpoint was the incidence of dose limiting toxicities in the first 42 days of dosing associated with administration of canakinumab in combination with docetaxel.

Part 2- Randomized part
The primary objective was to compare the OS in the docetaxel plus canakinumab arm versus docetaxel plus placebo arm. The primary endpoint was OS, defined as the time from the date of randomization to the date of death due to any cause. The OS distribution was estimated using the Kaplan-Meier method and associated 95% confidence intervals were calculated for each treatment group. The hazard ratio (HR) was estimated using Cox proportional hazard model stratified by randomization stratification factors.

Secondary endpoints
Efficacy analyses:

- Overall Response Rate (ORR) defined as the percentage of participants with confirmed best overall response of complete response (CR) or partial response (PR), as per investigator's assessment by RECIST 1.1. The 95% confidence intervals (CIs) were computed using Clopper and Pearson method.

- Disease Control Rate (DCR) defined as the percentage of participants with CR or PR or with stable disease (SD) as per investigator assessment according to RECIST 1.1 criteria. The 95% CIs were computed using Clopper and Pearson method.
- Duration of Response (DOR) defined as the time from first documented response of CR or PR to date of first documented progression or death, by investigator's assessment according to RECIST 1.1 criteria. The DOR distribution was estimated using the Kaplan-Meier method and associated 95% confidence intervals were calculated for each treatment group.
- Progression-Free Survival (PFS) defined as the time from randomization to the date of the first documented radiological progression by investigator assessment according to RECIST 1.1 response criteria or death due to any cause. The PFS distribution was estimated using the Kaplan-Meier method and associated 95% confidence intervals were calculated for each treatment group. If a participant did not have disease progression or die at the analysis cut-off date, PFS was censored at the date of last adequate tumor assessment.
- Time To Response (TTR) defined as the time from the date of randomization to the date of first documented response of either CR or PR, by investigator's assessment according to RECIST 1.1 criteria. The TTR distribution was estimated using the Kaplan-Meier method and associated 95% confidence intervals were calculated for each treatment group. Subjects without a confirmed CR or PR at the time of the analysis cut-off date were censored at the study-maximum follow-up time for subjects with a PFS event (i.e., disease progression or death due to any cause), or at the date of the last adequate tumor assessment for subjects without a PFS event.

Pharmacokinetic (PK) analyses

- PK concentrations and parameters (for canakinumab and docetaxel) were summarized using descriptive statistics

Patient-reported outcomes (PRO) analyses

Three PRO questionnaires were assessed: EORTC QLQ-C30, with it’s QLQ-LC13 lung cancer module, and the EQ-5D-5L.

- Time to 10-point definitive deterioration in chest pain, cough and dyspnea per QLQ-LC13 questionnaire and in global health status/QoL, shortness of breath and pain per QLQ-C30 was calculated. The time to definitive 10-point deterioration is defined as the time from the date of randomization to the date of event, which is defined as at least 10 points absolute worsening from baseline of the corresponding scale score, with no later change below this threshold, i.e. <10 points was observed or if this worsening was observed at the last assessment for the subject, or death due to any cause (whichever occurs earlier).

- Change from baseline of the QLQ-C30, QLQ-LC13 and EQ-5D-5L was also calculated.

Study Population: Key Inclusion/Exclusion Criteria

Key Inclusion Criteria:
• Histologically confirmed advanced (stage IIIB) or metastatic NSCLC.
• Subject had received one prior platinum-based chemotherapy and one prior PD-(L)1 inhibitor therapy for locally advanced or metastatic disease.
• Subject with ECOG performance status (PS) of 0 or 1.
• Subject with at least 1 evaluable (measurable or non-measurable) lesion by RECIST 1.1 in solid tumors criteria.

Key Exclusion Criteria:
• Subject who previously received docetaxel, canakinumab (or another IL-1β inhibitor), or any systemic therapy for their locally advanced or metastatic NSCLC other than one platinum-based chemotherapy and one prior PD-(L)1 inhibitor.
• Subject with EGFRor ALK positive tumor.
• History of severe hypersensitivity reaction to monoclonal antibodies, taxanes or excipients of docetaxel or canakinumab.

Participant Flow Table

Overall Study

	Safety run-in part: Canakinumab+docetaxel	Randomized part: Canakinumab + docetaxel	Randomized part: Placebo + docetaxel	Total
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	
Started	8	120	117	245

Treated	8	120	114	242
Completed	0	0	0	0
Not Completed	8	120	117	245
Progressive disease	3	82	85	170
Adverse Event	3	13	10	26
Physician Decision	1	18	14	33
Subject Decision	0	5	5	10
Death	1	1	1	3
Protocol Deviation	0	1	1	2
Guardian Decision	0	0	1	1

Baseline Characteristics

	Safety run-in part: Canakinumab+docetaxel	**Randomized part: Canakinumab + docetaxel**	**Randomized part: Placebo + docetaxel**	**Total**
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of	Participants were randomized to receive canakinumab subcutaneous at RP3R and	Participants were randomized to receive placebo subcutaneous at RP3R and	

	each 21-Day cycle (dose level 1).	docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	
Number of Participants [units: participants]	8	120	117	245
Age Continuous (units: Years) Mean ± Standard Deviation				
	55.9±4.19	63.4±9.13	62.2±10.05	62.6±9.54
Sex: Female, Male (units: Participants) Count of Participants (Not Applicable)				
Female	2	38	32	72
Male	6	82	85	173
Race/Ethnicity, Customized (units: Participants) Count of Participants (Not Applicable)				
White	8	91	83	182
Asian	0	22	27	49
Unknown	0	4	7	11
Black or African American	0	3	0	3

Primary Outcome Result(s)

Safety run-in part: Percentage of participants with dose limiting toxicities (DLTs)

(Time Frame: During the first 42 days of dosing)

	Safety run-in part: Canakinumab+docetaxel

Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).
Number of Participants Analyzed [units: participants]	7
Safety run-in part: Percentage of participants with dose limiting toxicities (DLTs) (units: Participants) Count of Participants (Not Applicable)	
	1 (14.29%)

Randomized part: Overall Survival (OS)

(Time Frame: From randomization until death or final analysis data cutoff date (08-Jan-2021) whichever comes first (up to approximately (approx.) 18 months))

	Randomized part: Canakinumab + docetaxel	**Randomized part: Placebo + docetaxel**
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on

	Day 1 of each 21-Day cycle	Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	120	117
Randomized part: Overall Survival (OS) (units: Months) Median (95% Confidence Interval)		
	10.55 (8.15 to 12.39)	11.30 (8.54 to 13.80)

Statistical Analysis

Groups	Randomized part: Canakinumab + docetaxel, Randomized part: Placebo + docetaxel	
P Value	0.633	
Method	Log Rank	
Hazard Ratio (HR)	1.06	Hazard ratio was estimated using a Cox Proportional Hazards regression model stratified by line of therapy and histology
95 % Confidence Interval 2-Sided	0.76 to 1.48	

Secondary Outcome Result(s)

Overall response rate (ORR)

(Time Frame: Through final analysis data cutoff date of 08-Jan-2021 (assessed up to approx. 10 months for the safety run-in part and 18 months for the randomized part))

	Safety run-in part: Canakinumab+docetaxel	Randomized part: Canakinumab + docetaxel	Randomized part: Placebo + docetaxel
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	8	120	117
Overall response rate (ORR) (units: Percentage of participants) Number (95% Confidence Interval)			
	0.0 (NA to NA)[1]	15.0 (9.1 to 22.7)	13.7 (8.0 to 21.3)

[1] NA: Not estimable because no participants had best overall response of CR or PR

Duration of response (DOR)

(Time Frame: From first documented response of CR or PR to date of first documented progression, death or final analysis data cutoff date (08-Jan-2021) whichever comes first (up to approx. 10 months for the safety run-in and 18 months for the randomized))

	Safety run-in part: Canakinumab+docetaxel	Randomized part: Canakinumab + docetaxel	Randomized part: Placebo + docetaxel
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	0	18	16
Duration of response (DOR) (units: Months) Median (95% Confidence Interval)			
		4.14 (2.89 to 11.17)	5.42 (4.17 to NA)[1]

[1] Not estimable due to insufficient number of participants with events.

Disease control rate (DCR)

(Time Frame: Through final analysis data cutoff date of 08-Jan-2021 (assessed up to approx. 10 months for the safety run-in part and 18 months for the randomized part))

	Safety run-in part: Canakinumab+docetaxel	Randomized part: Canakinumab + docetaxel	Randomized part: Placebo + docetaxel
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2	Participants were randomized to	Participants were randomized to

	intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).	receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	8	120	117
Disease control rate (DCR) (units: Percentage of participants) Number (95% Confidence Interval)			
	62.5 (24.5 to 91.5)	65.8 (56.6 to 74.2)	61.5 (52.1 to 70.4)

Randomized part: Progression-Free Survival (PFS)

(Time Frame: From randomization until disease progression, death or final analysis data cutoff date (08-Jan-2021) whichever comes first (assessed up to approx. 18 months))

	Randomized part: Canakinumab + docetaxel	**Randomized part: Placebo + docetaxel**
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on

	Day 1 of each 21-Day cycle	Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	120	117
Randomized part: Progression-Free Survival (PFS) (units: Months) Median (95% Confidence Interval)		
	4.17 (2.96 to 5.42)	4.21 (3.06 to 5.13)

Randomized part: Time to Response (TTR)

(Time Frame: From randomization until first documented response or final analysis data cutoff date (08-Jan-2021) whichever comes first (up to approx. 18 months))

	Randomized part: Canakinumab + docetaxel	**Randomized part: Placebo + docetaxel**
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	120	117

Randomized part: Time to Response (TTR) (units: Months) Median (95% Confidence Interval)	NA (NA to NA)[12]	NA (NA to NA)[12]

[1] NA: Not evaluable due to the low number of participants with events
[2] NA: Not evaluable due to the low number of participants with events

Randomized part: Time to definitive 10-point deterioration (TTD) symptom scores of chest pain, cough and dyspnea per European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) Lung Cancer (LC13) questionnaire

(Time Frame: From baseline through final analysis data cutoff date of 08-Jan-2021 (assessed up to approx. 18 months))

	Randomized part: Canakinumab + docetaxel	Randomized part: Placebo + docetaxel
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	120	117

Randomized part: Time to definitive 10-point deterioration (TTD) symptom scores of chest pain, cough and dyspnea per European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) Lung Cancer (LC13) questionnaire

(units: Months) Median (95% Confidence Interval)		
Chest Pain	7.23 (4.96 to NA)[1]	13.14 (7.06 to NA)[2]
Cough	7.23 (5.09 to NA)[3]	13.14 (7.85 to NA)[4]
Dyspnea	3.45 (2.14 to 4.83)	4.27 (2.63 to 5.65)

[1] NA: Upper limit was not reached due to the insufficient number of participants with events
[2] NA: Upper limit was not reached due to the insufficient number of participants with events
[3] NA: Upper limit was not reached due to the insufficient number of participants with events
[4] NA: Upper limit was not reached due to the insufficient number of participants with events

Randomized part: Time to definitive 10-point deterioration in global health status (GHS)/quality of life (QoL), shortness of breath and pain per EORTC QLQ-C30 questionnaire

(Time Frame: From baseline through final analysis data cutoff date of 08-Jan-2021 (assessed up to approx. 18 months))

	Randomized part: Canakinumab + docetaxel	**Randomized part: Placebo + docetaxel**
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	120	117

Randomized part: Time to definitive 10-point deterioration in global health status (GHS)/quality of life

(QoL), shortness of breath and pain per EORTC QLQ-C30 questionnaire (units: Months) Median (95% Confidence Interval)		
GHS/QOL	4.83 (3.48 to 6.97)	7.16 (4.80 to 13.14)
Shortness of breath	6.57 (4.60 to 7.89)	5.78 (4.27 to NA)[1]
Pain	6.05 (4.47 to 7.72)	8.54 (4.27 to 10.38)

[1] NA: Upper limit was not reached due to the insufficient number of participants with events

Randomized part: Change from baseline in GHS/QoL, shortness of breath and pain scores as per the EORTC QLQ C30 questionnaire

(Time Frame: Baseline, every 3 weeks from Week 3 until end of treatment, every 6 or 12 weeks post-treatment until progression (post-treatment efficacy visits), 7 and 28 days post progression through final analysis cutoff date of 08Jan2021 (up to approx. 18 months))

	Randomized part: Canakinumab + docetaxel	**Randomized part: Placebo + docetaxel**
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	120	117

Randomized part: Change from baseline in GHS/QoL, shortness of breath and pain scores as per the EORTC QLQ C30 questionnaire
(units: Score on a scale)
Mean ± Standard Deviation

GHS/QoL: Week 3	-0.5 ± 18.34	1.8 ± 21.51
GHS/QoL: Week 6	-3.3 ± 17.48	1.4 ± 22.19
GHS/QoL: Week 9	-2.7 ± 20.04	-0.4 ± 23.50
GHS/QoL: Week 12	-7.4 ± 19.75	2.5 ± 22.14
GHS/QoL: Week 15	-2.9 ± 19.85	-4.2 ± 22.60
GHS/QoL: Week 18	-3.9 ± 22.75	2.8 ± 24.69
GHS/QoL: Week 21	-3.5 ± 25.31	-4.2 ± 27.25
GHS/QoL: Week 24	-3.6 ± 16.08	-0.7 ± 24.90
GHS/QoL: Week 27	-4.7 ± 16.25	-2.2 ± 26.51
GHS/QoL: Week 30	-3.7 ± 19.43	-5.7 ± 30.31
GHS/QoL: Week 33	-3.2 ± 15.79	0.4 ± 31.82
GHS/QoL: Week 36	-4.5 ± 15.97	3.3 ± 27.06
GHS/QoL: Week 39	-5.8 ± 18.02	1.2 ± 28.28
GHS/QoL: Week 42	-9.2 ± 16.41	2.8 ± 29.15
GHS/QoL: Week 45	-3.6 ± 16.57	-3.5 ± 22.32
GHS/QoL: Week 48	-8.3 ± 19.72	-13.9 ± 13.82
GHS/QoL: Week 51	-8.3 ± 16.67	-6.7 ± 21.80
GHS/QoL: Week 54	-6.9 ± 17.01	-4.8 ± 31.86
GHS/QoL: Week 57	-12.5 ± 14.43	-8.3 ± 36.32
GHS/QoL: Week 60	-8.3 ± 22.05	2.1 ± 38.71
GHS/QoL: Week 63	-5.6 ± 17.35	2.8 ± 4.81
GHS/QoL: Week 66	8.3 ± 11.79	-8.3 ± 11.79

GHS/QoL: Week 69	16.7 ± NA[1]	0.0 ± 23.57
GHS/QoL: Week 72		-8.3 ± 11.79
GHS/QoL: Week 75		-16.7 ± NA[2]
GHS/QoL: Week 78		-16.7 ± NA[3]
GHS/QoL: post treatment efficacy visit 1	-16.7 ± 11.79	5.6 ± 9.62
GHS/QoL: post treatment efficacy visit 2	-16.7 ± 16.67	16.7 ± NA[4]
GHS/QoL: post treatment efficacy visit 3		-8.3 ± 23.57
GHS/QoL: post treatment efficacy visit 5		25.0 ± NA[5]
GHS/QoL: 7 days post disease progression	-7.5 ± 26.65	-4.6 ± 22.11
GHS/QoL: 28 days post disease progression	-3.7 ± 29.60	-7.8 ± 20.08
Shortness of breath: Week 3	31.2 ± 28.30	31.7 ± 30.02
Shortness of breath: Week 6	7.3 ± 24.99	4.0 ± 28.06
Shortness of breath: Week 9	6.7 ± 27.13	5.7 ± 28.36
Shortness of breath: Week 12	12.2 ± 25.61	4.4 ± 29.73
Shortness of breath: Week 15	7.8 ± 21.69	7.3 ± 29.58
Shortness of breath: Week 18	8.5 ± 26.54	3.5 ± 30.93
Shortness of breath: Week 21	34.2 ± 29.71	29.8 ± 27.72

Shortness of breath: Week 24	4.8 ± 21.61	6.9 ± 32.60
Shortness of breath: Week 27	13.0 ± 24.08	-1.2 ± 36.38
Shortness of breath: Week 30	16.7 ± 20.61	5.3 ± 38.10
Shortness of breath: Week 33	17.9 ± 22.01	-1.7 ± 39.70
Shortness of breath: Week 36	9.1 ± 21.56	-2.2 ± 32.04
Shortness of breath: Week 39	33.3 ± 27.22	40.5 ± 26.73
Shortness of breath: Week 42	23.3 ± 27.44	-6.7 ± 31.37
Shortness of breath: Week 45	9.5 ± 31.71	8.3 ± 40.51
Shortness of breath: Week 48	22.2 ± 34.43	3.7 ± 26.06
Shortness of breath: Week 51	16.7 ± 18.26	0.0 ± 22.22
Shortness of breath: Week 54	11.1 ± 17.21	9.5 ± 37.09
Shortness of breath: Week 57	8.3 ± 31.91	20.0 ± 38.01
Shortness of breath: Week 60	0.0 ± 33.33	16.7 ± 43.03
Shortness of breath: Week 63	0.0 ± 33.33	0.0 ± 33.33
Shortness of breath: Week 66	-16.7 ± 23.57	0.0 ± 47.14
Shortness of breath: Week 69	0.0 ± NA[6]	-16.7 ± 70.71

Shortness of breath: Week 72		-16.7 ± 70.71
Shortness of breath: Week 75		33.3 ± NA[7]
Shortness of breath: Week 78		33.3 ± NA[8]
Shortness of breath: post treatment efficacy visit 1	33.3 ± 47.14	33.3 ± 33.33
Shortness of breath: post treatment efficacy visit 2	0.0 ± 33.33	0.0 ± NA[9]
Shortness of breath: post treatment efficacy visit 3		16.7 ± 23.57
Shortness of breath: post treatment efficacy visit 5		0.00 ± NA[10]
Shortness of breath: 7 days post disease progression	8.6 ± 21.03	8.0 ± 29.08
Shortness of breath: 28 days post disease progression	3.7 ± 27.75	15.7 ± 29.15
Pain: Week 3	-5.1 ± 21.07	-2.0 ± 22.53
Pain: Week 6	-5.1 ± 20.33	-1.6 ± 24.07
Pain: Week 9	-4.1 ± 19.33	-3.1 ± 21.85
Pain: Week 12	2.2 ± 24.61	-1.4 ± 27.32
Pain: Week 15	-0.7 ± 20.81	0.7 ± 22.07
Pain: Week 18	2.3 ± 23.34	0.7 ± 25.25
Pain: Week 21	3.3 ± 24.52	0.0 ± 25.70
Pain: Week 24	25.2 ± 25.36	19.1 ± 21.76
Pain: Week 27	1.4 ± 22.42	1.2 ± 19.57
Pain: Week 30	2.8 ± 19.17	4.0 ± 26.03

Pain: Week 33	-8.3 ± 19.46	6.7 ± 21.22
Pain: Week 36	22.7 ± 17.12	26.7 ± 23.40
Pain: Week 39	-10.0 ± 21.08	10.7 ± 31.08
Pain: Week 42	-3.3 ± 10.54	11.1 ± 30.65
Pain: Week 45	-11.9 ± 23.00	15.3 ± 30.53
Pain: Week 48	-5.6 ± 22.77	5.6 ± 20.41
Pain: Week 51	2.8 ± 24.53	8.3 ± 18.00
Pain: Week 54	8.3 ± 20.41	-2.4 ± 32.53
Pain: Week 57	0.0 ± 13.61	6.7 ± 19.00
Pain: Week 60	16.7 ± 16.67	0.0 ± 36.00
Pain: Week 63	5.6 ± 25.46	-16.7 ± 16.7
Pain: Week 66	0.0 ± 0.00	0.0 ± 0.00
Pain: Week 69	33.3 ± NA[11]	8.3 ± 11.79
Pain: Week 72		0.0 ± 0.00
Pain: Week 75		0.0 ± NA[12]
Pain: Week 78		0.0 ± NA[13]
Pain: post treatment efficacy visit 1	-33.3 ± 23.57	-11.1 ± 19.25
Pain: post treatment efficacy visit 2	0.0 ± 16.67	0.0 ± NA[14]
Pain: post treatment efficacy visit 3		33.3 ± 0.00
Pain: post treatment efficacy visit 5		0.0 ± NA[15]
Pain: 7 days post disease progression	1.6 ± 18.44	2.3 ± 31.41

Pain: 28 days post disease progression	9.3 ± 23.02	13.7 ± 20.61

[1] NA: The standard deviation was not estimable as there was only one participant.
[2] NA: The standard deviation was not estimable as there was only one participant.
[3] NA: The standard deviation was not estimable as there was only one participant.
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[11] NA: The standard deviation was not estimable as there was only one participant.
[12] NA: The standard deviation was not estimable as there was only one participant.
[13] NA: The standard deviation was not estimable as there was only one participant.
[14] NA: The standard deviation was not estimable as there was only one participant.
[15] NA: The standard deviation was not estimable as there was only one participant.

Randomized part: Change from baseline in chest pain, cough and dyspnea scores as per the EORTC-QLQ LC13 questionnaire

(Time Frame: Baseline, every 3 weeks from Week 3 until end of treatment, every 6 or 12 weeks post-treatment until progression (post-treatment efficacy visits), 7 and 28 days post progression through final analysis cutoff date of 08Jan2021 (up to approx. 18 months))

	Randomized part: Canakinumab + docetaxel	Randomized part: Placebo + docetaxel
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle

Number of Participants Analyzed [units: participants]	120	117
Randomized part: Change from baseline in chest pain, cough and dyspnea scores as per the EORTC-QLQ LC13 questionnaire (units: Score on a scale) Mean ± Standard Deviation		
Chest pain: Week 3	-2.2 ± 16.24	-3.2 ± 24.48
Chest pain: Week 6	0.4 ± 19.73	-3.9 ± 24.89
Chest pain: Week 9	0.5 ± 19.09	-3.8 ± 22.37
Chest pain: Week 12	1.1 ± 23.16	-3.3 ± 24.32
Chest pain: Week 15	0.7 ± 25.38	-0.7 ± 24.05
Chest pain: Week 18	0.7 ± 21.59	-4.1 ± 26.90
Chest pain: Week 21	2.5 ± 26.57	0.9 ± 18.15
Chest pain: Week 24	1.9 ± 21.30	-1.0 ± 17.38
Chest pain: Week 27	2.9 ± 19.88	6.2 ± 27.79
Chest pain: Week 30	3.7 ± 19.43	6.7 ± 23.57
Chest pain: Week 33	-5.1 ± 18.49	0.0 ± 15.71
Chest pain: Week 36	-9.1 ± 15.57	0.0 ± 21.82
Chest pain: Week 39	0.0 ± 22.22	9.5 ± 30.46
Chest pain: Week 42	0.0 ± 15.71	0.0 ± 17.82
Chest pain: Week 45	0.0 ± 19.25	8.3 ± 15.08
Chest pain: Week 48	0.0 ± 21.08	11.1 ± 16.67
Chest pain: Week 51	0.0 ± 21.08	10.0 ± 22.50
Chest pain: Week 54	0.0 ± 21.08	9.5 ± 31.71
Chest pain: Week 57	0.0 ± 0.00	20.0 ± 18.26
Chest pain: Week 60	-11.1 ± 19.25	25.0 ± 16.67

Chest pain: Week 63	0.0 ± 33.33	0.0 ± 0.00
Chest pain: Week 66	0.0 ± 47.14	0.0 ± 0.00
Chest pain: Week 69	0.0 ± NA[1]	0.0 ± 0.00
Chest pain: Week 72		0.0 ± 0.00
Chest pain: Week 75		0.0 ± NA[2]
Chest pain: Week 78		33.3 ± NA[3]
Chest pain:Post treatment efficacy visit 1	0.0 ± 0.00	-22.2 ± 19.25
Chest pain: Post treatment efficacy visit 2	11.1 ± 19.25	0.0 ± NA[4]
Chest pain: Post treatment efficacy visit 3		16.7 ± 23.57
Chest pain: Post treatment efficacy visit 5		0.0 ± NA[5]
Chest pain: 7 days post disease progression	5.4 ± 17.42	-5.7 ± 21.95
Chest pain: 28 days post disease progression	14.8 ± 26.13	-2.1 ± 25.73
Coughing: Week 3	0.0 ± 21.54	-3.2 ± 24.03
Coughing: Week 6	3.0 ± 26.42	-4.7 ± 27.77
Coughing: Week 9	2.6 ± 32.44	0.5 ± 25.69
Coughing: Week 12	4.8 ± 33.79	0.0 ± 26.75
Coughing: Week 15	2.0 ± 27.82	-0.7 ± 24.05
Coughing: Week 18	-1.3 ± 26.63	0.0 ± 31.18
Coughing: Week 21	-4.2 ± 30.37	-4.4 ± 28.13
Coughing: Week 24	-1.0 ± 31.81	-3.9 ± 24.29
Coughing: Week 27	-4.3 ± 25.23	-1.2 ± 28.47

Coughing: Week 30	-5.6 ± 36.60	-4.0 ± 26.03
Coughing: Week 33	2.6 ± 16.45	-3.5 ± 26.98
Coughing: Week 36	12.1 ± 16.82	-6.7 ± 28.73
Coughing: Week 39	3.3 ± 18.92	-4.8 ± 25.68
Coughing: Week 42	6.7 ± 26.29	-8.9 ± 29.46
Coughing: Week 45	0.0 ± 19.25	2.8 ± 17.16
Coughing: Week 48	11.1 ± 17.21	3.7 ± 20.03
Coughing: Week 51	16.7 ± 18.26	-3.3 ± 18.92
Coughing: Week 54	16.7 ± 18.26	-4.8 ± 23.00
Coughing: Week 57	-8.3 ± 16.67	6.7 ± 27.89
Coughing: Week 60	0.0 ± 0.00	-8.3 ± 31.91
Coughing: Week 63	0.0 ± 0.00	-11.1 ± 19.25
Coughing: Week 66	-16.7 ± 23.57	-16.7 ± 23.57
Coughing: Week 69	0.0 ± NA[6]	-33.3 ± 47.14
Coughing: Week 72		-33.3 ± 47.14
Coughing: Week 75		0.0 ± NA[7]
Coughing: Week 78		0.0 ± NA[8]
Coughing: Post treatment efficacy visit 1	0.0 ± 0.00	0.0 ± 0.00
Coughing: Post treatment efficacy visit 2	-22.2 ± 19.25	33.3 ± NA[9]
Coughing: Post treatment efficacy visit 3		-16.7 ± 23.57
Coughing: Post treatment efficacy visit 5		0.0 ± NA[10]
Coughing: 7 days post disease progression	-1.1 ± 25.07	3.4 ± 31.30

Coughing: 28 days post disease progression	-3.7 ± 27.75	-4.2 ± 31.91
Dyspnea: Week 3	4.8 ± 17.84	2.9 ± 18.47
Dyspnea: Week 6	4.4 ± 16.83	5.0 ± 19.59
Dyspnea: Week 9	4.8 ± 19.44	5.2 ± 20.17
Dyspnea: Week 12	7.4 ± 19.25	6.9 ± 20.57
Dyspnea: Week 15	6.5 ± 16.66	10.9 ± 21.69
Dyspnea: Week 18	10.2 ± 19.98	4.3 ± 22.43
Dyspnea: Week 21	8.9 ± 19.36	6.7 ± 21.07
Dyspnea: Week 24	7.9 ± 23.89	9.2 ± 20.19
Dyspnea: Week 27	10.1 ± 21.43	8.6 ± 20.52
Dyspnea: Week 30	8.0 ± 14.66	8.0 ± 21.40
Dyspnea: Week 33	13.7 ± 17.66	7.0 ± 22.89
Dyspnea: Week 36	12.1 ± 22.47	7.4 ± 21.28
Dyspnea: Week 39	14.4 ± 16.60	10.3 ± 25.21
Dyspnea: Week 42	20.0 ± 27.62	3.0 ± 23.18
Dyspnea: Week 45	20.6 ± 26.00	13.0 ± 20.56
Dyspnea: Week 48	20.4 ± 30.97	14.8 ± 13.61
Dyspnea: Week 51	22.2 ± 29.81	7.8 ± 15.76
Dyspnea: Week 54	22.2 ± 26.29	12.7 ± 13.50
Dyspnea: Week 57	19.4 ± 31.91	11.1 ± 11.11
Dyspnea: Week 60	25.9 ± 44.91	-2.8 ± 24.64
Dyspnea: Week 63	18.5 ± 44.91	-3.7 ± 12.83
Dyspnea: Week 66	-11.1 ± 15.71	0.0 ± 15.71
Dyspnea: Week 69	-22.2 ± NA[11]	-11.1 ± 47.14
Dyspnea: Week 72		-11.1 ± 47.14

Dyspnea: Week 75		22.2 ± NA[12]
Dyspnea: Week 78		22.2 ± NA[13]
Dyspnea: Post treatment efficacy visit 1	16.7 ± 23.57	3.7 ± 16.97
Dyspnea: Post treatment efficacy visit 2	-3.7 ± 44.91	22.2 ± NA[14]
Dyspnea: Post treatment efficacy visit 3		16.7 ± 7.86
Dyspnea: Post treatment efficacy visit 5		-11.1 ± NA[15]
Dyspnea: 7 days post disease progression	5.0 ± 17.88	2.3 ± 20.22
Dyspnea: 28 days post disease progression	3.7 ± 16.61	10.4 ± 19.23

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[12] NA: The standard deviation was not estimable as there was only one participant.
[13] NA: The standard deviation was not estimable as there was only one participant.
[14] NA: The standard deviation was not estimable as there was only one participant.
[15] NA: The standard deviation was not estimable as there was only one participant.

Randomized part: Change from baseline in European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) Health State Scores

(Time Frame: Baseline, every 3 weeks from Week 3 until end of treatment, every 6 or 12 weeks post-treatment until progression (post-treatment efficacy visits), 7 and 28 days post progression through final analysis cutoff date of 08Jan2021 (up to approx. 18 months))

	Randomized part:	Randomized part: Placebo + docetaxel

	Canakinumab + docetaxel	
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	120	117
Randomized part: Change from baseline in European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) Health State Scores (units: Score on a scale) Mean ± Standard Deviation		
Week 3	-0.017 ± 0.1960	-0.007 ± 0.1731
Week 6	-0.016 ± 0.1972	0.001 ± 0.2283
Week 9	-0.006 ± 0.1759	0.011 ± 0.1865
Week 12	-0.028 ± 0.1849	0.014 ± 0.2315
Week 15	-0.057 ± 0.2229	-0.042 ± 0.1827
Week 18	-0.062 ± 0.1835	0.009 ± 0.2810
Week 21	-0.097 ± 0.2234	0.005 ± 0.1952

Week 24	-0.070 ± 0.2075	0.027 ± 0.1900
Week 27	-0.043 ± 0.1820	0.008 ± 0.2272
Week 30	-0.023 ± 0.2378	-0.014 ± 0.2068
Week 33	-0.031 ± 0.2148	0.029 ± 0.2361
Week 36	0.017 ± 0.1942	0.050 ± 0.2743
Week 39	-0.007 ± 0.1898	-0.012 ± 0.2842
Week 42	-0.010 ± 0.2286	0.116 ± 0.2180
Week 45	0.017 ± 0.1866	-0.036 ± 0.1801
Week 48	-0.087 ± 0.3178	0.003 ± 0.2424
Week 51	-0.151 ± 0.2663	0.071 ± 0.2197
Week 54	-0.102 ± 0.3527	0.056 ± 0.2011
Week 57	0.476 ± 0.2190	0.652 ± 0.1308
Week 60	-0.193 ± 0.3653	0.149 ± 0.1616
Week 63	-0.140 ± 0.3435	0.165 ± 0.1717
Week 66	0.034 ± 0.0481	0.124 ± 0.0085
Week 69	0.000 ± NA[1]	0.340 ± 0.1230

Week 72		0.168 ± 0.0530
Week 75		0.130 ± NA[2]
Week 78		0.130 ± NA[3]
Post treatment efficacy visit 1	0.100 ± 0.0955	-0.026 ± 0.0368
Post treatment efficacy visit 2	0.644 ± 0.1749	0.704 ± NA[4]
Post treatment efficacy visit 3		0.601 ± 0.0990
Post treatment efficacy visit 5		1.000 ± NA[5]
7 days post disease progression	0.639 ± 0.2558	0.657 ± 0.2654
28 days post disease progression	0.692 ± 0.1633	0.692 ± 0.2149

[1] NA: The standard deviation was not estimable as there was only one participant.
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[4] NA: The standard deviation was not estimable as there was only one participant.
[5] NA: The standard deviation was not estimable as there was only one participant.

Safety run-in part: Maximum plasma concentration (Cmax) of canakinumab

(Time Frame: Cycle 1 Day 1 at pre-dose and end of infusion and 24, 48, 168 and 336 hours (h) post-infusion. Each cycle is 21 days)

	Safety run-in part: Canakinumab+docetaxel
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).

Number of Participants Analyzed [units: participants]	6
Safety run-in part: Maximum plasma concentration (Cmax) of canakinumab (units: microgram/milliliter (ug/mL)) Geometric Mean (Geometric Coefficient of Variation)	
	13.4 (29.9%)

Safety run-in part: Time of maximum plasma concentration (Tmax) of canakinumab

(Time Frame: Cycle 1 Day 1 at pre-dose and end of infusion and 24, 48, 168 and 336 hours (h) post-infusion. Each cycle is 21 days)

	Safety run-in part: Canakinumab+docetaxel
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).
Number of Participants Analyzed [units: participants]	6
Safety run-in part: Time of maximum plasma concentration (Tmax) of canakinumab (units: Hours (h)) Median (Full Range)	

169
(48.2 to 336)

Safety run-in part: Area Under the plasma Concentration-time Curve From Time Zero to the Last Quantifiable Concentration (AUClast) of canakinumab

(Time Frame: Cycle 1 Day 1 at pre-dose and end of infusion and 24, 48, 168 and 336 hours (h) post-infusion. Each cycle is 21 days)

	Safety run-in part: Canakinumab+docetaxel
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).
Number of Participants Analyzed [units: participants]	6
Safety run-in part: Area Under the plasma Concentration-time Curve From Time Zero to the Last Quantifiable Concentration (AUClast) of canakinumab (units: hour*microgram/mililiter (hr*ug/mL)) Geometric Mean (Geometric Coefficient of Variation)	
	5470 (30.5%)

Safety run-in part: Cmax of docetaxel

(Time Frame: Cycle 1 Day 1 and Cycle 2 Day 1 at pre-infusion, end of infusion, and 2, 4, 6 and 8 hours post-dose. Each cycle is 21 days)

	Safety run-in part: Canakinumab+docetaxel
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).
Number of Participants Analyzed [units: participants]	8
Safety run-in part: Cmax of docetaxel (units: nanogram/miliLiter (ng/mL)) Geometric Mean (Geometric Coefficient of Variation)	
Cycle 1 Day 1	476 (182.5%)
Cycle 2 Day 1	1630 (117.2%)

Safety run-in part: Tmax of docetaxel

(Time Frame: Cycle 1 Day 1 and Cycle 2 Day 1 at pre-infusion, end of infusion, and 2, 4, 6 and 8 hours post-dose. Each cycle is 21 days)

	Safety run-in part: Canakinumab+docetaxel
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).

Number of Participants Analyzed [units: participants]	8
Safety run-in part: Tmax of docetaxel (units: Hour (hr)) Median (Full Range)	
Cycle 1 Day 1	1.08 (0.917 to 6.12)
Cycle 2 Day 1	1.00 (0.917 to 1.00)

Safety run-in part: AUClast of docetaxel

(Time Frame: Cycle 1 Day 1 and Cycle 2 Day 1 at pre-infusion, end of infusion, and 2, 4, 6 and 8 hours post-dose. Each cycle is 21 days)

	Safety run-in part: Canakinumab+docetaxel
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).
Number of Participants Analyzed [units: participants]	8
Safety run-in part: AUClast of docetaxel (units: Hour *nanogram/miliLiter (hr*ng/mL)) Geometric Mean (Geometric Coefficient of Variation)	
Cycle 1 Day 1	884 (70.8%)
Cycle 2 Day 1	2120 (86.5%)

Randomized part: Pre-dose plasma trough concentration (CTrough) of canakinumab

(Time Frame: Pre-dose on Cycle 1 Day 1, Cycle 4 Day 1, Cycle 6 Day 1, Cycle 12 Day 1 and Cycle 18 Day 1. Each cycle is 21 days.)

	Randomized part: Canakinumab + docetaxel
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	112
Randomized part: Pre-dose plasma trough concentration (CTrough) of canakinumab (units: microgram/miliLiter (ug/mL)) Geometric Mean (Geometric Coefficient of Variation)	
Cycle 1 Day 1	0 (0%)
Cycle 4 Day 1	20.5 (36.6%)
Cycle 6 Day 1	23.7 (32.3%)
Cycle 12 Day 1	25.6 (56.7%)
Cycle 18 Day 1	28.3 (118.0%)

Randomized part: Cmax of docetaxel

(Time Frame: Cycle 1 Day 1 and Cycle 4 Day 1 at pre-infusion, end of infusion, and 2, 4 and 6 hours post-dose. Each cycle is 21 days)

	Randomized part: Canakinumab + docetaxel	Randomized part: Placebo + docetaxel
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	26	23
Randomized part: Cmax of docetaxel (units: nanogram/miliLiter (ng/mL)) Geometric Mean (Geometric Coefficient of Variation)		
Cycle 1 Day 1	1570 (116.3%)	1190 (265.3%)
Cycle 4 Day 1	1530 (118.7%)	940 (215.8%)

Randomized part: Tmax of docetaxel

(Time Frame: Cycle 1 Day 1 and Cycle 4 Day 1 at pre-infusion, end of infusion, and 2, 4 and 6 hours post-dose. Each cycle is 21 days)

	Randomized part: Canakinumab + docetaxel	Randomized part: Placebo + docetaxel
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous	Participants were randomized to receive placebo subcutaneous

	at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	26	23
Randomized part: Tmax of docetaxel (units: Hour) Median (Full Range)		
Cycle 1 Day 1	1.09 (0.517 to 5.83)	1.10 (0.933 to 6.08)
Cycle 4 Day 1	1.15 (0.0833 to 3.83)	1.08 (1.00 to 1.42)

Randomized part: AUClast of docetaxel

(Time Frame: Cycle 1 Day 1 and Cycle 4 Day 1 at pre-infusion, end of infusion, and 2, 4 and 6 hours post-dose. Each cycle is 21 days)

	Randomized part: Canakinumab + docetaxel	**Randomized part: Placebo + docetaxel**
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle

Number of Participants Analyzed [units: participants]	22	19
Randomized part: AUClast of docetaxel (units: hour*nanogram/miliLiter (h*ng/mL)) Geometric Mean (Geometric Coefficient of Variation)		
Cycle 1 Day 1	2530 (79.3%)	1790 (157.4%)
Cycle 4 Day 1	2210 (66.4%)	1530 (130.9%)

Randomized part: Canakinumab Antidrug antibodies (ADA) at baseline

(Time Frame: Baseline)

	Randomized part: Canakinumab + docetaxel
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	120
Randomized part: Canakinumab Antidrug antibodies (ADA) at baseline (units: Participants)	

Count of Participants (Not Applicable)
1 (.83%)

Randomized part: Canakinumab ADA incidence on-treatment

(Time Frame: Pre-dose at Cycle 1 Day 1, Cycle 4 Day 1, Cycle 6 Day 1, Cycle 12 Day 1 , end of treatment, and 130 days after end of treatment through final analysis data cutoff date of 08-Jan-2021 (assessed up to 18 months). Each cycle is 21 days)

	Randomized part: Canakinumab + docetaxel
Arm/Group Description	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	120
Randomized part: Canakinumab ADA incidence on-treatment (units: Participants) Count of Participants (Not Applicable)	
	0 (%)

All collected deaths

(Time Frame: Pre-treatment: up to 28 days before Day 1;On-treatment: up to approximately 10 months (safety run-in) or 25 months (randomized); post-treatment deaths: Up to approximately 16 months (safety run in) or 25 months (randomized))

	Safety run-in part: Canakinumab+docetaxel	Randomized part: Canakinumab + docetaxel	Randomized part: Placebo + docetaxel
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Number of Participants Analyzed [units: participants]	8	120	117
All collected deaths (units: Participants) Count of Participants (Not Applicable)			
Pre-treatment deaths	0 (%)	0 (%)	1 (.85%)
On-treatment deaths	6 (75%)	45 (37.5%)	37 (31.62%)
Post-treatment deaths	2 (25%)	40 (33.33%)	38 (32.48%)
All deaths	8 (100%)	85 (70.83%)	76 (64.96%)

Safety Results

All-Cause Mortality

	Safety run-in part: Canakinumab+docetaxel N = 8	Randomized part: Canakinumab + docetaxel N = 120	Randomized part: Placebo + docetaxel N = 114
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Total participants affected	6 (75.00%)	45 (37.50%)	37 (32.46%)

Serious Adverse Events by System Organ Class

Time Frame	From date of first administration of study treatment to 130 days after date of last administration, up to approximately 10 months (safety run-in part) or 25 months (randomized part)
Additional Description	Any sign or symptom that occurs during the study treatment plus the 130 days post treatment (on-treatment period). Safety analyses performed in the safety set including all subjects to whom study treatment was assigned (safety run-in part) / randomized (randomized part) and who received at least one dose of any study treatment (including incomplete infusion) All deaths (sum of on-treatment and post-treatment period) are captured in Outcome Measure 25 (post-hoc: All collected deaths)
Source Vocabulary for Table Default	MedDRA (23.1)

Assessment Type for Table Default Systematic Assessment

	Safety run-in part: Canakinumab+docetaxel N = 8	Randomized part: Canakinumab + docetaxel N = 120	Randomized part: Placebo + docetaxel N = 114
Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Total participants affected	6 (75.00%)	55 (45.83%)	50 (43.86%)
Blood and lymphatic system disorders			
Anaemia	0 (0.00%)	1 (0.83%)	0 (0.00%)
Febrile neutropenia	0 (0.00%)	6 (5.00%)	8 (7.02%)
Leukopenia	0 (0.00%)	1 (0.83%)	1 (0.88%)
Neutropenia	1 (12.50%)	4 (3.33%)	5 (4.39%)
Thrombocytopenia	0 (0.00%)	0 (0.00%)	1 (0.88%)
Cardiac disorders			
Atrial fibrillation	0 (0.00%)	2 (1.67%)	1 (0.88%)
Cardiac tamponade	0 (0.00%)	1 (0.83%)	0 (0.00%)

Cardio-respiratory arrest	0 (0.00%)	0 (0.00%)	1 (0.88%)
Pericardial effusion	0 (0.00%)	0 (0.00%)	1 (0.88%)
Endocrine disorders			
Hypopituitarism	0 (0.00%)	1 (0.83%)	0 (0.00%)
Gastrointestinal disorders			
Abdominal pain	0 (0.00%)	0 (0.00%)	1 (0.88%)
Abdominal pain upper	0 (0.00%)	0 (0.00%)	1 (0.88%)
Colitis ulcerative	0 (0.00%)	1 (0.83%)	0 (0.00%)
Diarrhoea	0 (0.00%)	2 (1.67%)	2 (1.75%)
Dysphagia	0 (0.00%)	1 (0.83%)	0 (0.00%)
Gastrointestinal haemorrhage	0 (0.00%)	0 (0.00%)	1 (0.88%)
Ileus	0 (0.00%)	0 (0.00%)	1 (0.88%)
Lower gastrointestinal haemorrhage	0 (0.00%)	1 (0.83%)	0 (0.00%)
Nausea	0 (0.00%)	1 (0.83%)	0 (0.00%)
Small intestine ulcer	0 (0.00%)	1 (0.83%)	0 (0.00%)
Stomatitis	0 (0.00%)	0 (0.00%)	2 (1.75%)
Vomiting	0 (0.00%)	1 (0.83%)	0 (0.00%)
General disorders and administration site conditions			
Asthenia	0 (0.00%)	0 (0.00%)	1 (0.88%)
Chest pain	0 (0.00%)	2 (1.67%)	0 (0.00%)
Disease progression	0 (0.00%)	0 (0.00%)	1 (0.88%)
Fatigue	0 (0.00%)	0 (0.00%)	1 (0.88%)

Generalised oedema	0 (0.00%)	1 (0.83%)	0 (0.00%)
Malaise	0 (0.00%)	0 (0.00%)	1 (0.88%)
Mucosal inflammation	0 (0.00%)	0 (0.00%)	1 (0.88%)
Oedema peripheral	0 (0.00%)	0 (0.00%)	1 (0.88%)
Pyrexia	0 (0.00%)	6 (5.00%)	2 (1.75%)
Infections and infestations			
Abdominal sepsis	0 (0.00%)	1 (0.83%)	0 (0.00%)
Bacteraemia	0 (0.00%)	0 (0.00%)	1 (0.88%)
Bacterial infection	1 (12.50%)	0 (0.00%)	0 (0.00%)
Bronchitis	0 (0.00%)	1 (0.83%)	0 (0.00%)
Clostridium difficile colitis	0 (0.00%)	0 (0.00%)	1 (0.88%)
COVID-19	0 (0.00%)	1 (0.83%)	1 (0.88%)
COVID-19 pneumonia	0 (0.00%)	1 (0.83%)	1 (0.88%)
Device related infection	0 (0.00%)	1 (0.83%)	0 (0.00%)
Diverticulitis	0 (0.00%)	1 (0.83%)	0 (0.00%)
Erysipelas	0 (0.00%)	1 (0.83%)	1 (0.88%)
Escherichia sepsis	0 (0.00%)	1 (0.83%)	0 (0.00%)
Escherichia urinary tract infection	0 (0.00%)	1 (0.83%)	0 (0.00%)
Febrile infection	0 (0.00%)	1 (0.83%)	0 (0.00%)
Gastroenteritis	0 (0.00%)	1 (0.83%)	1 (0.88%)
Gastroenteritis viral	0 (0.00%)	0 (0.00%)	1 (0.88%)
Infection	0 (0.00%)	1 (0.83%)	1 (0.88%)
Infectious pleural effusion	0 (0.00%)	0 (0.00%)	1 (0.88%)

Influenza	1 (12.50%)	0 (0.00%)	0 (0.00%)
Lower respiratory tract infection	0 (0.00%)	1 (0.83%)	0 (0.00%)
Neutropenic sepsis	0 (0.00%)	0 (0.00%)	1 (0.88%)
Pneumonia	2 (25.00%)	13 (10.83%)	8 (7.02%)
Pneumonia pneumococcal	1 (12.50%)	0 (0.00%)	0 (0.00%)
Pneumonia pseudomonal	0 (0.00%)	1 (0.83%)	0 (0.00%)
Post procedural sepsis	0 (0.00%)	1 (0.83%)	0 (0.00%)
Pulmonary sepsis	0 (0.00%)	1 (0.83%)	0 (0.00%)
Respiratory tract infection	0 (0.00%)	3 (2.50%)	4 (3.51%)
Sepsis	0 (0.00%)	2 (1.67%)	1 (0.88%)
Septic shock	0 (0.00%)	3 (2.50%)	1 (0.88%)
Spinal cord infection	0 (0.00%)	0 (0.00%)	1 (0.88%)
Upper respiratory tract infection	0 (0.00%)	1 (0.83%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	4 (3.51%)
Urosepsis	0 (0.00%)	0 (0.00%)	1 (0.88%)
Vulvovaginitis	0 (0.00%)	0 (0.00%)	1 (0.88%)
Injury, poisoning and procedural complications			
Femur fracture	1 (12.50%)	0 (0.00%)	0 (0.00%)
Hip fracture	0 (0.00%)	1 (0.83%)	0 (0.00%)
Lumbar vertebral fracture	0 (0.00%)	0 (0.00%)	1 (0.88%)

Procedural pneumothorax	0 (0.00%)	0 (0.00%)	1 (0.88%)
Investigations			
Aspartate aminotransferase increased	0 (0.00%)	0 (0.00%)	1 (0.88%)
Gamma-glutamyltransferase increased	0 (0.00%)	0 (0.00%)	1 (0.88%)
Neutrophil count decreased	0 (0.00%)	1 (0.83%)	1 (0.88%)
White blood cell count decreased	0 (0.00%)	1 (0.83%)	0 (0.00%)
Metabolism and nutrition disorders			
Decreased appetite	0 (0.00%)	0 (0.00%)	1 (0.88%)
Dehydration	0 (0.00%)	0 (0.00%)	1 (0.88%)
Diabetic ketoacidosis	0 (0.00%)	0 (0.00%)	1 (0.88%)
Hypercalcaemia	0 (0.00%)	1 (0.83%)	0 (0.00%)
Musculoskeletal and connective tissue disorders			
Back pain	0 (0.00%)	0 (0.00%)	3 (2.63%)
Bone pain	0 (0.00%)	0 (0.00%)	2 (1.75%)
Fistula	0 (0.00%)	1 (0.83%)	0 (0.00%)
Musculoskeletal chest pain	0 (0.00%)	0 (0.00%)	1 (0.88%)
Pain in extremity	0 (0.00%)	0 (0.00%)	1 (0.88%)
Neoplasms benign, malignant and			

unspecified (incl cysts and polyps)			
Cancer pain	0 (0.00%)	0 (0.00%)	1 (0.88%)
Nervous system disorders			
Cerebrovascular accident	0 (0.00%)	0 (0.00%)	1 (0.88%)
Dizziness	0 (0.00%)	0 (0.00%)	1 (0.88%)
Ischaemic stroke	0 (0.00%)	1 (0.83%)	0 (0.00%)
Monoplegia	0 (0.00%)	0 (0.00%)	1 (0.88%)
Syncope	0 (0.00%)	1 (0.83%)	1 (0.88%)
Renal and urinary disorders			
Acute kidney injury	0 (0.00%)	2 (1.67%)	0 (0.00%)
Reproductive system and breast disorders			
Balanoposthitis	0 (0.00%)	0 (0.00%)	1 (0.88%)
Respiratory, thoracic and mediastinal disorders			
Asthma	0 (0.00%)	1 (0.83%)	0 (0.00%)
Dyspnoea	0 (0.00%)	4 (3.33%)	5 (4.39%)
Haemoptysis	1 (12.50%)	3 (2.50%)	1 (0.88%)
Hypoxia	0 (0.00%)	2 (1.67%)	0 (0.00%)
Interstitial lung disease	0 (0.00%)	0 (0.00%)	1 (0.88%)
Pleural effusion	0 (0.00%)	2 (1.67%)	1 (0.88%)
Pneumonitis	0 (0.00%)	0 (0.00%)	1 (0.88%)
Pneumothorax	0 (0.00%)	1 (0.83%)	0 (0.00%)

Pulmonary embolism	1 (12.50%)	0 (0.00%)	3 (2.63%)
Respiratory failure	0 (0.00%)	3 (2.50%)	1 (0.88%)
Vascular disorders			
Aneurysm	0 (0.00%)	0 (0.00%)	1 (0.88%)
Haematoma	0 (0.00%)	0 (0.00%)	1 (0.88%)
Hypotension	0 (0.00%)	1 (0.83%)	0 (0.00%)
Superior vena cava syndrome	0 (0.00%)	1 (0.83%)	0 (0.00%)
Thrombosis	0 (0.00%)	1 (0.83%)	0 (0.00%)

Other Adverse Events by System Organ Class

Time Frame	From date of first administration of study treatment to 130 days after date of last administration, up to approximately 10 months (safety run-in part) or 25 months (randomized part)
Additional Description	Any sign or symptom that occurs during the study treatment plus the 130 days post treatment (on-treatment period). Safety analyses performed in the safety set including all subjects to whom study treatment was assigned (safety run-in part) / randomized (randomized part) and who received at least one dose of any study treatment (including incomplete infusion) All deaths (sum of on-treatment and post-treatment period) are captured in Outcome Measure 25 (post-hoc: All collected deaths)
Source Vocabulary for Table Default	MedDRA (23.1)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

	Safety run-in part: Canakinumab+docetaxel N = 8	**Randomized part: Canakinumab + docetaxel N = 120**	**Randomized part: Placebo + docetaxel N = 114**

Arm/Group Description	Participants were treated with full doses of docetaxel 75mg/m^2 intravenous and canakinumab 200 mg subcutaneous on Day 1 of each 21-Day cycle (dose level 1).	Participants were randomized to receive canakinumab subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle	Participants were randomized to receive placebo subcutaneous at RP3R and docetaxel at 75 mg/m^2 on Day 1 of each 21-Day cycle
Total participants affected	7 (87.50%)	111 (92.50%)	109 (95.61%)
Blood and lymphatic system disorders			
Anaemia	1 (12.50%)	32 (26.67%)	33 (28.95%)
Leukopenia	1 (12.50%)	6 (5.00%)	15 (13.16%)
Neutropenia	2 (25.00%)	22 (18.33%)	25 (21.93%)
Cardiac disorders			
Atrial fibrillation	1 (12.50%)	0 (0.00%)	0 (0.00%)
Tachycardia	1 (12.50%)	1 (0.83%)	2 (1.75%)
Endocrine disorders			
Cushingoid	1 (12.50%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders			
Abdominal pain	1 (12.50%)	7 (5.83%)	4 (3.51%)
Constipation	0 (0.00%)	22 (18.33%)	24 (21.05%)
Diarrhoea	3 (37.50%)	41 (34.17%)	31 (27.19%)
Dyspepsia	0 (0.00%)	7 (5.83%)	0 (0.00%)
Nausea	1 (12.50%)	28 (23.33%)	29 (25.44%)

Odynophagia	1 (12.50%)	1 (0.83%)	1 (0.88%)
Stomatitis	0 (0.00%)	9 (7.50%)	6 (5.26%)
Vomiting	2 (25.00%)	15 (12.50%)	14 (12.28%)
General disorders and administration site conditions			
Asthenia	2 (25.00%)	28 (23.33%)	37 (32.46%)
Chest pain	0 (0.00%)	5 (4.17%)	10 (8.77%)
Fatigue	1 (12.50%)	33 (27.50%)	19 (16.67%)
Influenza like illness	1 (12.50%)	1 (0.83%)	3 (2.63%)
Malaise	0 (0.00%)	7 (5.83%)	7 (6.14%)
Mucosal inflammation	0 (0.00%)	4 (3.33%)	12 (10.53%)
Oedema	1 (12.50%)	5 (4.17%)	2 (1.75%)
Oedema peripheral	3 (37.50%)	22 (18.33%)	25 (21.93%)
Pyrexia	1 (12.50%)	14 (11.67%)	18 (15.79%)
Infections and infestations			
Bronchitis	1 (12.50%)	4 (3.33%)	3 (2.63%)
Folliculitis	1 (12.50%)	0 (0.00%)	1 (0.88%)
Nasopharyngitis	1 (12.50%)	5 (4.17%)	2 (1.75%)
Pneumonia	0 (0.00%)	7 (5.83%)	4 (3.51%)
Respiratory tract infection	1 (12.50%)	7 (5.83%)	3 (2.63%)
Upper respiratory tract infection	0 (0.00%)	5 (4.17%)	6 (5.26%)
Urinary tract infection	0 (0.00%)	8 (6.67%)	7 (6.14%)
Investigations			

Alanine aminotransferase increased	0 (0.00%)	7 (5.83%)	3 (2.63%)
Aspartate aminotransferase increased	0 (0.00%)	7 (5.83%)	0 (0.00%)
Gamma-glutamyltransferase increased	2 (25.00%)	5 (4.17%)	6 (5.26%)
Haemoglobin decreased	1 (12.50%)	1 (0.83%)	2 (1.75%)
Neutrophil count decreased	0 (0.00%)	17 (14.17%)	11 (9.65%)
SARS-CoV-2 test negative	0 (0.00%)	10 (8.33%)	13 (11.40%)
Weight decreased	1 (12.50%)	9 (7.50%)	8 (7.02%)
White blood cell count decreased	2 (25.00%)	12 (10.00%)	8 (7.02%)
Metabolism and nutrition disorders			
Decreased appetite	0 (0.00%)	32 (26.67%)	31 (27.19%)
Hyperglycaemia	0 (0.00%)	7 (5.83%)	5 (4.39%)
Hypoalbuminaemia	0 (0.00%)	8 (6.67%)	7 (6.14%)
Hyponatraemia	0 (0.00%)	7 (5.83%)	7 (6.14%)
Steroid diabetes	1 (12.50%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders			
Arthralgia	0 (0.00%)	11 (9.17%)	10 (8.77%)
Back pain	1 (12.50%)	8 (6.67%)	6 (5.26%)
Muscular weakness	1 (12.50%)	0 (0.00%)	0 (0.00%)

Musculoskeletal pain	0 (0.00%)	1 (0.83%)	6 (5.26%)
Myalgia	0 (0.00%)	9 (7.50%)	9 (7.89%)
Pain in extremity	0 (0.00%)	6 (5.00%)	7 (6.14%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain	1 (12.50%)	0 (0.00%)	2 (1.75%)
Nervous system disorders			
Dysgeusia	0 (0.00%)	8 (6.67%)	3 (2.63%)
Headache	0 (0.00%)	8 (6.67%)	6 (5.26%)
Neuropathy peripheral	1 (12.50%)	9 (7.50%)	15 (13.16%)
Paraesthesia	0 (0.00%)	12 (10.00%)	8 (7.02%)
Taste disorder	1 (12.50%)	1 (0.83%)	0 (0.00%)
Psychiatric disorders			
Anxiety	1 (12.50%)	5 (4.17%)	2 (1.75%)
Insomnia	1 (12.50%)	7 (5.83%)	8 (7.02%)
Respiratory, thoracic and mediastinal disorders			
Cough	2 (25.00%)	16 (13.33%)	19 (16.67%)
Dyspnoea	2 (25.00%)	27 (22.50%)	26 (22.81%)
Dyspnoea exertional	1 (12.50%)	3 (2.50%)	5 (4.39%)
Epistaxis	0 (0.00%)	5 (4.17%)	6 (5.26%)
Haemoptysis	1 (12.50%)	10 (8.33%)	10 (8.77%)
Pleural effusion	1 (12.50%)	4 (3.33%)	6 (5.26%)

Productive cough	1 (12.50%)	6 (5.00%)	3 (2.63%)
Skin and subcutaneous tissue disorders			
Alopecia	1 (12.50%)	31 (25.83%)	44 (38.60%)
Dry skin	0 (0.00%)	4 (3.33%)	7 (6.14%)
Nail disorder	0 (0.00%)	7 (5.83%)	8 (7.02%)
Night sweats	1 (12.50%)	0 (0.00%)	0 (0.00%)
Pruritus	0 (0.00%)	10 (8.33%)	9 (7.89%)
Psoriasis	1 (12.50%)	0 (0.00%)	1 (0.88%)
Rash	0 (0.00%)	12 (10.00%)	10 (8.77%)
Vascular disorders			
Hypotension	1 (12.50%)	6 (5.00%)	5 (4.39%)
Phlebitis	1 (12.50%)	0 (0.00%)	0 (0.00%)

Other Relevant Findings

None

Conclusion:

The study did not meet its primary endpoint of overall survival in subjects with non-small cell lung cancer previously treated with PD-(L)1 inhibitors and platinum-based chemotherapy.
The efficacy results of the canakinumab plus docetaxel group were either similar or in favor of the placebo plus docetaxel group.
The safety data are consistent with the known well-characterized safety profile of canakinumab or docetaxel.
Canakinumab in combination with docetaxel is associated with a manageable and predictable safety profile.

Date of Clinical Trial Report

22-Apr-2022 (Final CSR); 19-Jul-2021 (Primary CSR)