



Clinical trial results:

A Phase 2b, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of JNJ-64304500 in Subjects with Moderately to Severely Active Crohn's Disease

Summary

EudraCT number	2016-000634-21
Trial protocol	DE GB HU PL FR IT
Global end of trial date	24 January 2022

Results information

Result version number	v1 (current)
This version publication date	09 February 2023
First version publication date	09 February 2023

Trial information

Trial identification

Sponsor protocol code	64304500CRD2001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02877134
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	920 Route 202, South Raritan New Jersey, United States, 08869
Public contact	Clinical Registry Group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 January 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	24 January 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to evaluate the efficacy of JNJ-64304500 to reduce the Crohn's Disease Activity Index (CDAI) score from baseline and to evaluate the safety of JNJ-64304500.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice (GCP) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 August 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	Bulgaria: 7
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	United Kingdom: 4
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Italy: 13
Country: Number of subjects enrolled	Japan: 25
Country: Number of subjects enrolled	Korea, Republic of: 6
Country: Number of subjects enrolled	Poland: 72
Country: Number of subjects enrolled	Romania: 10
Country: Number of subjects enrolled	Russian Federation: 109
Country: Number of subjects enrolled	Ukraine: 80
Country: Number of subjects enrolled	United States: 42
Worldwide total number of subjects	388
EEA total number of subjects	122

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	376
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

In subject disposition, data is reported in 2 periods, [Main Study" and "Part II LTE Phase"] depicts the information for the specified time period as: Part I: Through Week 38 (including safety follow-up); Part II: Through Week 24 for subjects who entered the LTE phase and through Week 36 for subjects who did not enter the LTE.

Pre-assignment

Screening details:

A total of 388 subjects with moderately to severely active Crohn's disease were randomised and treated. Of these, 304 completed main study phase and 95 completed long term extension (LTE) phase.

Period 1

Period 1 title	Main Study (Parts I,II): Up to Week 38
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Part I: Placebo

Arm description:

Subjects received placebo subcutaneously (SC) at Weeks 0, 2, 4, 6, 8, and 10. Subjects in clinical response at Week 12 continued to receive placebo every 2 weeks (Q2W) through Week 22. Subjects not in clinical response at Week 12 received JNJ-64304500 400 milligrams (mg) SC at Week 12 and then 200 mg SC Q2W from Week 14 through Week 22. Subjects were followed up for safety up to Week 38.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with Placebo subcutaneous injection on Weeks 0, 2, 4, 6, 8, 10. Subjects in clinical response at Week 12 continued to receive placebo every 2 weeks (Q2W) from Week 12 through Week 22.

Investigational medicinal product name	JNJ-64304500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects not in clinical response at Week 12 were administered with JNJ-64304500 400 mg SC at Week 12 and then 200 mg SC Q2W from Week 14 through Week 22.

Arm title	Part I: JNJ-64304500
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Arm description:

Subjects received JNJ-64304500 400 mg SC at Week 0 then 200 mg SC every two weeks through Week 22. All subjects were followed up for safety up to Week 38.

Arm type	Experimental
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Investigational medicinal product name	JNJ-64304500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with JNJ-64304500 400 mg SC injection at Week 0 then 200 mg SC every two weeks through Week 22.

Arm title	Part II: Placebo
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Arm description:

Subjects received placebo SC at Weeks 0, 2, 4, and 8. Subjects in clinical response at Week 12 continued to receive placebo at Weeks 12, 14, 16, and 20. Subjects not in clinical response at Week 12 received JNJ-64304500 150 mg SC at Week 12 and then JNJ-64304500 75 mg SC at Weeks 14, 16, and 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II long term extension (LTE) phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.

Arm type	Placebo
Investigational medicinal product name	JNJ-64304500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects not in clinical response at Week 12 were administered with JNJ-64304500 150 mg SC at Week 12 and then JNJ-64304500 75 mg SC at Weeks 14, 16, and 20.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with placebo SC injection at Weeks 0, 2, 4, and 8. Subjects in clinical response at Week 12 continued to receive placebo at Weeks 12, 14, 16, and 20.

Arm title	Part II: JNJ-64304500 Low Dose
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Arm description:

Subjects received JNJ-64304500 50 mg SC at Week 0 and 25 mg SC at Weeks 2 and 4, then 25 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.

Arm type	Experimental
Investigational medicinal product name	JNJ-64304500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with JNJ-64304500 50 mg SC at Week 0 and 25 mg SC at Weeks 2 and 4, then 25 mg SC every four weeks through Week 20.

Arm title	Part II: JNJ-64304500 Middle Dose
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Arm description:

Subjects received JNJ-64304500 150 mg SC at Week 0 and 75 mg SC at Weeks 2 and 4, then 75 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up

for safety up to Week 36.

Arm type	Experimental
Investigational medicinal product name	JNJ-64304500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with JNJ-64304500 150 mg SC at Week 0 and 75 mg SC at Weeks 2 and 4, then 75 mg SC every four weeks through Week 20.

Arm title	Part II: JNJ-64304500 High Dose
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Arm description:

Subjects received JNJ-64304500 400 mg SC at Week 0 and 200 mg SC at Weeks 2 and 4, then 200 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.

Arm type	Experimental
Investigational medicinal product name	JNJ-64304500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with JNJ-64304500 400 mg SC at Week 0 and 200 mg SC at Weeks 2 and 4, then 200 mg SC every four weeks through Week 20.

Arm title	Part II: Ustekinumab
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Arm description:

Subjects received Ustekinumab (tiered doses approximating 6 milligrams/kilograms (mg/kg) intravenously [IV]) at Week 0 (as indicated in the bullets below), followed by 90 mg SC at Weeks 8 and 16. - Ustekinumab 260 mg (weight [less than or equal to [\leq] 55 kg). - Ustekinumab 390 mg (weight greater than [$>$] 55 kg and less than or equal to [\leq] 85 kg). Ustekinumab 520 mg (weight >85 kg). Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.

Arm type	Experimental
Investigational medicinal product name	Ustekinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received Ustekinumab (tiered doses approximating 6 mg/kg IV at Week 0 (as indicated in the bullets below), followed by 90 mg SC at Weeks 8 and 16. - Ustekinumab 260 mg (weight ≤ 55 kg). - Ustekinumab 390 mg (weight >55 kg and ≤ 85 kg). - Ustekinumab 520 mg (weight >85 kg).

Number of subjects in period 1	Part I: Placebo	Part I: JNJ-64304500	Part II: Placebo
Started	72	73	48
Placebo Non Responders at Week 12	44 ^[1]	0 ^[2]	31 ^[3]
Completed	58	48	40
Not completed	14	25	8
Death	-	1	-
Unspecified	1	1	3
Lost to follow-up	-	4	-
Withdrawal by subject	13	19	5

Number of subjects in period 1	Part II: JNJ-64304500 Low Dose	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose
Started	50	49	49
Placebo Non Responders at Week 12	0 ^[4]	0 ^[5]	0 ^[6]
Completed	35	42	39
Not completed	15	7	10
Death	-	-	1
Unspecified	6	4	3
Lost to follow-up	1	-	-
Withdrawal by subject	8	3	6

Number of subjects in period 1	Part II: Ustekinumab
Started	47
Placebo Non Responders at Week 12	0 ^[7]
Completed	42
Not completed	5
Death	-
Unspecified	2
Lost to follow-up	1
Withdrawal by subject	2

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only placebo non responders at Week 12 were reported.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only placebo non responders at Week 12 were reported.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only placebo non responders at Week 12 were reported.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that

completed, minus those who left.

Justification: Only placebo non responders at Week 12 were reported.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only placebo non responders at Week 12 were reported.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only placebo non responders at Week 12 were reported.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only placebo non responders at Week 12 were reported.

Period 2

Period 2 title	Part II LTE Phase: From Week 24-88
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part II LTE: Placebo

Arm description:

Subjects randomized to placebo group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received placebo or JNJ-64304500 middle dose (JNJ-64304500 75 mg SC) at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with placebo SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72.

Arm title	Part II LTE: JNJ-64304500 Low Dose
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Arm description:

Subjects randomized to the 'JNJ-64304500 Low Dose' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received JNJ-64304500 25 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.

Arm type	Experimental
Investigational medicinal product name	JNJ-64304500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with JNJ-64304500 25 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72.

Arm title	Part II LTE: JNJ-64304500 Middle Dose
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Arm description:

Subjects randomized to the 'JNJ-64304500 Middle Dose' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received JNJ-64304500

75 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.

Arm type	Experimental
Investigational medicinal product name	JNJ-64304500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with JNJ-64304500 75 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72.

Arm title	Part II LTE: JNJ-64304500 High Dose
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Arm description:

Subjects randomized to the 'JNJ-64304500 High Dose' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received JNJ-64304500 200 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.

Arm type	Experimental
Investigational medicinal product name	JNJ-64304500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects were administered with JNJ-64304500 200 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72.

Arm title	Part II LTE: Ustekinumab
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Arm description:

Subjects randomized to the 'Ustekinumab' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received Ustekinumab 90 mg IV at Weeks 24, 32, 40, 48, 56, 64 and 72. Subjects were followed up for safety up to Week 88.

Arm type	Experimental
Investigational medicinal product name	JNJ-64304500
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use, Intravenous use

Dosage and administration details:

Subjects were administered with Ustekinumab 90 mg IV at Weeks 24, 32, 40, 48, 56, 64 and 72.

Number of subjects in period 2 ^[8]	Part II LTE: Placebo	Part II LTE: JNJ-64304500 Low Dose	Part II LTE: JNJ-64304500 Middle Dose
Started	22	21	27
Completed	20	17	20
Not completed	2	4	7
Not specified	-	-	3
Study terminated by sponsor	1	1	1
Lost to follow-up	-	1	-
Withdrawal by subject	1	2	3

Number of subjects in period 2 ^[8]	Part II LTE: JNJ-64304500 High Dose	Part II LTE: Ustekinumab
Started	24	28
Completed	14	24
Not completed	10	4
Not specified	1	1
Study terminated by sponsor	-	-
Lost to follow-up	-	-
Withdrawal by subject	9	3

Notes:

[8] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Only eligible subjects from main study phase, entered into Part II LTE phase.

Baseline characteristics

Reporting groups

Reporting group title	Part I: Placebo
Reporting group description:	
Subjects received placebo subcutaneously (SC) at Weeks 0, 2, 4, 6, 8, and 10. Subjects in clinical response at Week 12 continued to receive placebo every 2 weeks (Q2W) through Week 22. Subjects not in clinical response at Week 12 received JNJ-64304500 400 milligrams (mg) SC at Week 12 and then 200 mg SC Q2W from Week 14 through Week 22. Subjects were followed up for safety up to Week 38.	
Reporting group title	Part I: JNJ-64304500
Reporting group description:	
Subjects received JNJ-64304500 400 mg SC at Week 0 then 200 mg SC every two weeks through Week 22. All subjects were followed up for safety up to Week 38.	
Reporting group title	Part II: Placebo
Reporting group description:	
Subjects received placebo SC at Weeks 0, 2, 4, and 8. Subjects in clinical response at Week 12 continued to receive placebo at Weeks 12, 14, 16, and 20. Subjects not in clinical response at Week 12 received JNJ-64304500 150 mg SC at Week 12 and then JNJ-64304500 75 mg SC at Weeks 14, 16, and 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II long term extension (LTE) phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.	
Reporting group title	Part II: JNJ-64304500 Low Dose
Reporting group description:	
Subjects received JNJ-64304500 50 mg SC at Week 0 and 25 mg SC at Weeks 2 and 4, then 25 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.	
Reporting group title	Part II: JNJ-64304500 Middle Dose
Reporting group description:	
Subjects received JNJ-64304500 150 mg SC at Week 0 and 75 mg SC at Weeks 2 and 4, then 75 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.	
Reporting group title	Part II: JNJ-64304500 High Dose
Reporting group description:	
Subjects received JNJ-64304500 400 mg SC at Week 0 and 200 mg SC at Weeks 2 and 4, then 200 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.	
Reporting group title	Part II: Ustekinumab
Reporting group description:	
Subjects received Ustekinumab (tiered doses approximating 6 milligrams/kilograms (mg/kg) intravenously [IV]) at Week 0 (as indicated in the bullets below), followed by 90 mg SC at Weeks 8 and 16. - Ustekinumab 260 mg (weight [less than or equal to [\leq] 55 kg). - Ustekinumab 390 mg (weight greater than [$>$] 55 kg and less than or equal to [\leq] 85 kg). Ustekinumab 520 mg (weight >85 kg). Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.	

Reporting group values	Part I: Placebo	Part I: JNJ-64304500	Part II: Placebo
Number of subjects	72	73	48

Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	71	70	45
From 65 to 84 years	1	3	3
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	38.9	38	40.6
standard deviation	± 13.3	± 13.25	± 13.69
Title for Gender Units: subjects			
Female	31	33	24
Male	41	40	24

Reporting group values	Part II: JNJ-64304500 Low Dose	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose
Number of subjects	50	49	49
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	48	47	49
From 65 to 84 years	2	2	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	36.4	37.1	37.2
standard deviation	± 11.14	± 15.04	± 12.87
Title for Gender Units: subjects			
Female	16	27	20
Male	34	22	29

Reporting group values	Part II: Ustekinumab	Total	
Number of subjects	47	388	
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	46	376	
From 65 to 84 years	1	12	
85 years and over	0	0	
Title for AgeContinuous Units: years			
arithmetic mean	42	-	
standard deviation	± 12.62	-	
Title for Gender Units: subjects			
Female	23	174	

Male	24	214	
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End points

End points reporting groups

Reporting group title	Part I: Placebo
Reporting group description: Subjects received placebo subcutaneously (SC) at Weeks 0, 2, 4, 6, 8, and 10. Subjects in clinical response at Week 12 continued to receive placebo every 2 weeks (Q2W) through Week 22. Subjects not in clinical response at Week 12 received JNJ-64304500 400 milligrams (mg) SC at Week 12 and then 200 mg SC Q2W from Week 14 through Week 22. Subjects were followed up for safety up to Week 38.	
Reporting group title	Part I: JNJ-64304500
Reporting group description: Subjects received JNJ-64304500 400 mg SC at Week 0 then 200 mg SC every two weeks through Week 22. All subjects were followed up for safety up to Week 38.	
Reporting group title	Part II: Placebo
Reporting group description: Subjects received placebo SC at Weeks 0, 2, 4, and 8. Subjects in clinical response at Week 12 continued to receive placebo at Weeks 12, 14, 16, and 20. Subjects not in clinical response at Week 12 received JNJ-64304500 150 mg SC at Week 12 and then JNJ-64304500 75 mg SC at Weeks 14, 16, and 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II long term extension (LTE) phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.	
Reporting group title	Part II: JNJ-64304500 Low Dose
Reporting group description: Subjects received JNJ-64304500 50 mg SC at Week 0 and 25 mg SC at Weeks 2 and 4, then 25 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.	
Reporting group title	Part II: JNJ-64304500 Middle Dose
Reporting group description: Subjects received JNJ-64304500 150 mg SC at Week 0 and 75 mg SC at Weeks 2 and 4, then 75 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.	
Reporting group title	Part II: JNJ-64304500 High Dose
Reporting group description: Subjects received JNJ-64304500 400 mg SC at Week 0 and 200 mg SC at Weeks 2 and 4, then 200 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.	
Reporting group title	Part II: Ustekinumab
Reporting group description: Subjects received Ustekinumab (tiered doses approximating 6 milligrams/kilograms (mg/kg) intravenously [IV]) at Week 0 (as indicated in the bullets below), followed by 90 mg SC at Weeks 8 and 16. - Ustekinumab 260 mg (weight [less than or equal to [\leq] 55 kg). - Ustekinumab 390 mg (weight greater than [$>$] 55 kg and less than or equal to [\leq] 85 kg). Ustekinumab 520 mg (weight >85 kg). Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.	
Reporting group title	Part II LTE: Placebo
Reporting group description: Subjects randomized to placebo group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received placebo or JNJ-64304500 middle dose (JNJ-64304500 75 mg SC) at Weeks 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.	
Reporting group title	Part II LTE: JNJ-64304500 Low Dose

Reporting group description:

Subjects randomized to the 'JNJ-64304500 Low Dose' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received JNJ-64304500 25 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.

Reporting group title	Part II LTE: JNJ-64304500 Middle Dose
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Reporting group description:

Subjects randomized to the 'JNJ-64304500 Middle Dose' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received JNJ-64304500 75 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.

Reporting group title	Part II LTE: JNJ-64304500 High Dose
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Reporting group description:

Subjects randomized to the 'JNJ-64304500 High Dose' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received JNJ-64304500 200 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.

Reporting group title	Part II LTE: Ustekinumab
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Reporting group description:

Subjects randomized to the 'Ustekinumab' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received Ustekinumab 90 mg IV at Weeks 24, 32, 40, 48, 56, 64 and 72. Subjects were followed up for safety up to Week 88.

Primary: Part I: Change From Baseline in the Crohn's Disease Activity Index (CDAI) Score at Week 8

End point title	Part I: Change From Baseline in the Crohn's Disease Activity Index (CDAI) Score at Week 8 ^{[1][2]}
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End point description:

The CDAI is a validated multi-item measure of severity of illness derived as a weighted sum of 8 different Crohn's disease-related variables. The CDAI score was assessed by collecting information on 8 different Crohn's disease-related variables: extra-intestinal manifestations, abdominal mass, weight, hematocrit, total number of liquid stools, abdominal pain/cramping, use of antidiarrheal drug(s), and/or opiates, and general well-being. The last 4 variables were scored over 7 days by the subject on a diary card. In general, CDAI score ranges from 0 to approximately 600; higher score indicates higher disease activities. The efficacy analyses were based on the Full analysis set (FAS) included all randomised subjects in Part 1 who received at least 1 dose of study agent.

End point type	Primary
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End point timeframe:

Baseline to Week 8

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Descriptive statistics was done, no inferential statistical analysis was performed.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Part I: Placebo	Part I: JNJ-64304500		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	72	73		
Units: units on a scale				
arithmetic mean (standard deviation)	-60.0 (± 77.08)	-103.6 (± 93.54)		

Statistical analyses

No statistical analyses for this end point

Primary: Part II: Change From Baseline in the CDAI Score at Week 12

End point title	Part II: Change From Baseline in the CDAI Score at Week
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End point description:

The CDAI is a validated multi-item measure of severity of illness derived as a weighted sum of 8 different Crohn's disease-related variables. The CDAI was assessed by collecting information on 8 different Crohn's disease-related variables: extra-intestinal manifestations, abdominal mass, weight, hematocrit, total number of liquid stools, abdominal pain/cramping, use of antidiarrheal drug(s) and/or opiates, and general well-being. The last 4 variables are scored over 7 days by the subject on a diary card. In general, CDAI score ranges from 0 to approximately 600; higher score indicates higher disease activities. FAS included all randomised subjects in Part II who received at least 1 dose of study agent. Here 'N' (Number of subjects analysed) refers to number of subjects analysed for this endpoint.

End point type	Primary
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End point timeframe:

Baseline to Week 12

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Descriptive statistics was done, no inferential statistical analysis was performed.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Part II: Placebo	Part II: JNJ-64304500 Low Dose	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	44	47	48
Units: units on a scale				
arithmetic mean (standard deviation)	-59.2 (± 89.51)	-93.2 (± 117.91)	-72.2 (± 92.79)	-84.3 (± 103.28)

End point values	Part II: Ustekinumab			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: units on a scale				
arithmetic mean (standard deviation)	-148.8 (± 84.59)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Percentage of Subjects in Clinical Remission at Week 12 as Measured by CDAI (CDAI Less than [$<$] 150)

End point title	Part II: Percentage of Subjects in Clinical Remission at Week 12 as Measured by CDAI (CDAI Less than [$<$] 150) ^[5]
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End point description:

Clinical Remission was defined as a CDAI score of <150 point. The CDAI score is used to quantify the symptoms of subjects with Crohn's Disease. The CDAI is a validated multi-item measure of severity of illness derived as a weighted sum of 8 different Crohn's disease-related variables: extra-intestinal manifestations, abdominal mass, weight, hematocrit, total number of liquid stools, abdominal pain/cramping, use of antidiarrheal drug(s) and/or opiates, and general well-being. A decrease in CDAI over time indicates improvement in disease activity. In general, CDAI score ranges from 0 to approximately 600; higher score indicates higher disease activities. FAS included all randomised subjects in Part II who received at least 1 dose of study agent.

End point type	Secondary
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End point timeframe:

Week 12

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Part II: Placebo	Part II: JNJ-64304500 Low Dose	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	50	49	49
Units: percentage of subjects				
number (not applicable)	14.6	30	18.4	22.4

End point values	Part II: Ustekinumab			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: percentage of subjects				
number (not applicable)	53.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Percentage of Subjects in Clinical Response at Week 12 as Measured by CDAI (Greater than or Equal to [\geq] 100-point Reduction from Baseline in CDAI or CDAI <150)

End point title	Part II: Percentage of Subjects in Clinical Response at Week 12 as Measured by CDAI (Greater than or Equal to [\geq] 100-point Reduction from Baseline in CDAI or CDAI <150) ^[6]
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End point description:

Clinical response was defined as a ≥ 100 -point reduction from the baseline CDAI score, or a CDAI score < 150 . The CDAI score is used to quantify the symptoms of subjects with Crohn's Disease. The CDAI is a validated multi-item measure of severity of illness derived as a weighted sum of 8 different Crohn's disease-related variables: extra-intestinal manifestations, abdominal mass, weight, hematocrit, total number of liquid stools, abdominal pain/cramping, use of antidiarrheal drug(s) and/or opiates, and general well-being. The CDAI score is used to quantify the symptoms of subjects with Crohn's Disease. A decrease in CDAI over time indicates improvement in disease activity. In general, CDAI score ranges from 0 to approximately 600; higher score indicates higher disease activities. FAS included all randomised subjects in Part II who received at least 1 dose of study agent.

End point type	Secondary
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End point timeframe:

Week 12

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Part II: Placebo	Part II: JNJ-64304500 Low Dose	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	50	49	49
Units: percentage of subjects				
number (not applicable)	22.9	42.0	40.8	30.6

End point values	Part II: Ustekinumab			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: percentage of subjects				
number (not applicable)	72.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Change from Baseline in Patient-Reported Outcome (PRO)-2 at Week 12

End point title	Part II: Change from Baseline in Patient-Reported Outcome (PRO)-2 at Week 12 ^[7]
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End point description:

The PRO-2 score is defined as the sum of the abdominal pain and stool frequency components of the CDAI. PRO-2 scores ranges from 0 to approximately 300, higher score indicates higher disease activity. FAS included all randomised subjects in Part II who received at least 1 dose of study agent. Here 'N' (Number of subjects analysed) refers to number of subjects analysed for this endpoint.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Part II: Placebo	Part II: JNJ-64304500 Low Dose	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	46	44	47	48
Units: units on scale				
arithmetic mean (standard deviation)	-28.8 (± 47.72)	-46.1 (± 59.14)	-39.8 (± 52.59)	-42.9 (± 47.33)

End point values	Part II: Ustekinumab			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: units on scale				
arithmetic mean (standard deviation)	-70.1 (± 52.97)			

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Percentage of Subjects in Clinical remission at Week 12 as measured by PRO-2 (PRO-2 <75)

End point title	Part II: Percentage of Subjects in Clinical remission at Week 12 as measured by PRO-2 (PRO-2 <75) ^[8]
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End point description:

Clinical remission was defined as a PRO-2 score of <75 point. FAS included all randomised subjects in Part II who received at least 1 dose of study agent. FAS included all randomised subjects in Part II who received at least 1 dose of study agent.

End point type	Secondary
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End point timeframe:

Week 12

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Part II: Placebo	Part II: JNJ-64304500 Low Dose	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	50	49	49
Units: percentage of subjects				
number (not applicable)	16.7	32.0	30.6	44.9

End point values	Part II: Ustekinumab			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: percentage of subjects				
number (not applicable)	53.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Percentage of Subjects in Clinical response at Week 12 as measured by PRO-2 (≥ 50 -point reduction from baseline in PRO-2 Score or PRO-2 Score < 75)

End point title	Part II: Percentage of Subjects in Clinical response at Week 12 as measured by PRO-2 (≥ 50 -point reduction from baseline in PRO-2 Score or PRO-2 Score < 75) ^[9]
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End point description:

Clinical response was defined as ≥ 50 -point reduction from baseline in PRO-2 or Score or PRO-2 Score < 75 . FAS included all randomised subjects in Part II who received at least 1 dose of study agent.

End point type	Secondary
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End point timeframe:

Week 12

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Part II: Placebo	Part II: JNJ-64304500 Low Dose	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	50	49	49
Units: percentage of subjects				
number (not applicable)	31.3	44.0	46.9	49.0

End point values	Part II: Ustekinumab			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: percentage of subjects				
number (not applicable)	68.1			

Statistical analyses

No statistical analyses for this end point

Secondary: Part II: Change from Baseline in Simple Endoscopic Score for Crohn's Disease (SES-CD) at Week 12

End point title	Part II: Change from Baseline in Simple Endoscopic Score for Crohn's Disease (SES-CD) at Week 12 ^[10]
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End point description:

SES-CD is a validated instrument reflecting an endoscopist global appraisal of mucosal lesions in Crohn's disease. SES-CD grades lesions by location (5 bowel segments: ileum, right colon, transverse colon, left colon, and rectum) using 4 endoscopic variables: ulcer size, extent of ulcerated surface, extent of affected surface, and presence/type of narrowing. The total SES-CD was calculated as the sum of the 4 variables for the 5 bowel segments: rectum, left colon, transverse colon, right colon, and ileum. Scores range from 0 to 60, with higher scores indicating more severe disease. FAS included all randomised subjects in Part II who received at least 1 dose of study agent. Here 'N' (Number of subjects analysed) refers to number of subjects analysed for this endpoint.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Endpoint was planned to be analyzed for specified arms only.

End point values	Part II: Placebo	Part II: JNJ-64304500 Low Dose	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	33	33	38
Units: units on a scale				
arithmetic mean (standard deviation)	-2.2 (± 6.58)	-0.7 (± 6.47)	-1.2 (± 4.89)	-2.7 (± 6.93)

End point values	Part II: Ustekinumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: units on a scale				
arithmetic mean (standard deviation)	-2.6 (± 5.32)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Part I: Through Week 38; Part II: Through Week 24 for subjects who entered the LTE and through Week 36 for subjects who did not enter the LTE; Part II LTE: from Week 24 through Week 88

Adverse event reporting additional description:

The safety analysis set included all randomised subjects who received at least 1 dose of study agent (placebo or JNJ-64304500 or ustekinumab, including a partial dose).

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Reporting groups

Reporting group title	Part I: Placebo
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Reporting group description:

Subjects received placebo subcutaneously (SC) at Weeks 0, 2, 4, 6, 8, and 10. Subjects in clinical response at Week 12 continued to receive placebo every 2 weeks (Q2W) through Week 22. Subjects not in clinical response at Week 12 received JNJ-64304500 400 mg SC at Week 12 and then 200 mg SC Q2W from Week 14 through Week 22. Safety results included data up to the time of receiving JNJ-64304500 for those who received JNJ-64304500 at Week 12 and included all data for those who did not receive JNJ-64304500 at Week 12. Subjects were followed up for safety up to Week 38.

Reporting group title	Part I: Placebo to JNJ-64304500
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Reporting group description:

Subjects received placebo SC at Weeks 0, 2, 4, 6, 8, and 10. Subjects in clinical response at Week 12 continued to receive placebo Q2W through Week 22. Subjects not in clinical response at Week 12 received JNJ-64304500 400 mg SC at Week 12 and then 200 mg SC Q2W from Week 14 through Week 22. Safety results included data from the time of receiving JNJ-64304500 at Week 12 onward. Subjects were followed up for safety up to Week 38.

Reporting group title	Part I: JNJ-64304500
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Reporting group description:

Subjects received JNJ-64304500 400 mg SC at Week 0 then 200 mg SC every two weeks through Week 22. Subjects were followed up for safety up to Week 38.

Reporting group title	Part II: Placebo
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Reporting group description:

Subjects received placebo SC at Weeks 0, 2, 4, and 8. Subjects in clinical response at Week 12 continued to receive placebo at Weeks 12, 14, 16, and 20. Subjects not in clinical response at Week 12 received JNJ-64304500 150 mg SC at Week 12 and then JNJ-64304500 75 mg SC at Weeks 14, 16, and 20. Safety results included data up to the time of receiving JNJ-64304500 for those who received JNJ-64304500 at Week 12 and included all data for those who did not receive JNJ-64304500 at Week 12. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.

Reporting group title	Part II: Placebo to JNJ-64304500 Middle Dose
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Reporting group description:

Subjects received placebo SC at Weeks 0, 2, 4, and 8. Subjects in clinical response at Week 12 continued to receive placebo at Weeks 12, 14, 16, and 20. Subjects not in clinical response at Week 12 received JNJ-64304500 150 mg SC at Week 12 and then JNJ-64304500 75 mg SC at Weeks 14, 16, and 20. Safety results included data from the time of receiving JNJ-64304500 at Week 12 onward. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.

Reporting group title	Part II: JNJ-64304500 Low Dose
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Reporting group description:

Subjects received JNJ-64304500 50 mg SC at Week 0 and 25 mg SC at Weeks 2 and 4, then 25 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefited from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up

for safety up to Week 36.

Reporting group title	Part II: JNJ-64304500 Middle Dose
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Reporting group description:

Subjects received JNJ-64304500 150 mg SC at Week 0 and 75 mg SC at Weeks 2 and 4, then 75 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefitted from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.

Reporting group title	Part II: JNJ-64304500 High Dose
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Reporting group description:

Subjects received JNJ-64304500 400 mg SC at Week 0 and 200 mg SC at Weeks 2 and 4, then 200 mg SC every four weeks through Week 20. Subjects who completed Part II Week 24 assessments and who were benefitted from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.

Reporting group title	Part II: Ustekinumab
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Reporting group description:

Subjects received Ustekinumab (tiered doses approximating 6 milligrams/kilograms (mg/kg) intravenously [IV]) at Week 0 (as indicated in the bullets below), followed by 90 mg SC at Weeks 8 and 16. - Ustekinumab 260 mg (weight [less than or equal to [\leq] 55 kg). - Ustekinumab 390 mg (weight greater than [$>$] 55 kg and less than or equal to [\leq] 85 kg). Ustekinumab 520 mg (weight >85 kg). Subjects who completed Part II Week 24 assessments and who were benefitted from continued treatment, in the opinion of the investigator, were eligible to enter the Part II LTE phase at Week 24. Subjects who did not enter into LTE phase at Week 24 were followed up for safety up to Week 36.

Reporting group title	Part II LTE: Placebo
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Reporting group description:

Subjects randomized to the 'Placebo' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received placebo at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72. Subjects were followed up to Week 88 for safety.

Reporting group title	Part II LTE: Placebo to JNJ-64304500 Middle Dose
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Reporting group description:

Subjects randomized to placebo group and had dose adjustment to JNJ-64304500 middle dose at Week 12, continued to receive JNJ-64304500 middle dose (received JNJ-64304500 75 mg SC) at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72 in the Part II LTE. Subjects were followed up for safety up to Week 88.

Reporting group title	Part II LTE: JNJ-64304500 Low Dose
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Reporting group description:

Subjects randomized to the 'JNJ-64304500 Low Dose' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received JNJ-64304500 25 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.

Reporting group title	Part II LTE: JNJ-64304500 Middle Dose
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Reporting group description:

Subjects randomized to the 'JNJ-64304500 Middle Dose' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received JNJ-64304500 75 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.

Reporting group title	Part II LTE: JNJ-64304500 High Dose
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Reporting group description:

Subjects randomized to the 'JNJ-64304500 High Dose' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received JNJ-64304500 200 mg SC at Weeks 24, 28, 32, 36, 40, 44, 48, 52 56, 60, 64, 68, and 72. Subjects were followed up for safety up to Week 88.

Reporting group title	Part II LTE: Ustekinumab
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Reporting group description:

Subjects randomized to 'Ustekinumab' group and who were benefitted from continued treatment in the opinion of the investigator, entered the Part II LTE phase and received Ustekinumab 90 mg IV at Weeks 24, 32, 40, 48, 56, 64 and 72. Subjects were followed up for safety up to Week 88.

Serious adverse events	Part I: Placebo	Part I: Placebo to JNJ-64304500	Part I: JNJ-64304500
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 72 (1.39%)	2 / 44 (4.55%)	8 / 73 (10.96%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Ovarian Tumour			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian Cyst Ruptured			

subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression Suicidal			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Lipase Increased			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hand Fracture			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			

subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	1 / 73 (1.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myocardial Infarction			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	1 / 73 (1.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 72 (1.39%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	1 / 73 (1.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's Disease			
subjects affected / exposed	0 / 72 (0.00%)	1 / 44 (2.27%)	5 / 73 (6.85%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Perforation			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Stenosis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ileus			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Stenosis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute Hepatic Failure			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	1 / 73 (1.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			

subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Sepsis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	1 / 73 (1.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	1 / 73 (1.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	1 / 73 (1.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	1 / 73 (1.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypokalaemia			

subjects affected / exposed	0 / 72 (0.00%)	1 / 44 (2.27%)	0 / 73 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	1 / 73 (1.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part II: Placebo	Part II: Placebo to JNJ-64304500 Middle Dose	Part II: JNJ-64304500 Low Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 48 (6.25%)	0 / 31 (0.00%)	3 / 50 (6.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Ovarian Tumour			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			

subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian Cyst Ruptured			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression Suicidal			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Lipase Increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hand Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute Myocardial Infarction			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's Disease			
subjects affected / exposed	1 / 48 (2.08%)	0 / 31 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Perforation			

subjects affected / exposed	1 / 48 (2.08%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Stenosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	1 / 48 (2.08%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Stenosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute Hepatic Failure			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Foot Deformity			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Sepsis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 48 (2.08%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			

subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose	Part II: Ustekinumab
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)	6 / 49 (12.24%)	2 / 47 (4.26%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Ovarian Tumour			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			

subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Reproductive system and breast disorders			
Ovarian Cyst Ruptured			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression Suicidal			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Lipase Increased			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hand Fracture			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's Disease			

subjects affected / exposed	0 / 49 (0.00%)	2 / 49 (4.08%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Perforation			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Stenosis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Stenosis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute Hepatic Failure			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Sepsis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sepsis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part II LTE: Placebo	Part II LTE: Placebo to JNJ-64304500 Middle Dose	Part II LTE: JNJ-64304500 Low Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)	3 / 12 (25.00%)	2 / 21 (9.52%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Ovarian Tumour			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			

subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian Cyst Ruptured			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression Suicidal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Lipase Increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Hand Fracture			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			

subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's Disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Perforation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Stenosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Stenosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute Hepatic Failure			

subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Salmonellosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part II LTE: JNJ-64304500 Middle Dose	Part II LTE: JNJ-64304500 High Dose	Part II LTE: Ustekinumab
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 27 (18.52%)	5 / 24 (20.83%)	5 / 28 (17.86%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Ovarian Tumour			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			

subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian Cyst Ruptured			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression Suicidal			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Lipase Increased			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hand Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's Disease			
subjects affected / exposed	4 / 27 (14.81%)	0 / 24 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 4	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Perforation			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal Stenosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 27 (0.00%)	1 / 24 (4.17%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Stenosis			

subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute Hepatic Failure			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 27 (0.00%)	1 / 24 (4.17%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			
subjects affected / exposed	0 / 27 (0.00%)	1 / 24 (4.17%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 27 (0.00%)	3 / 24 (12.50%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Sepsis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Peritonitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Part I: Placebo	Part I: Placebo to JNJ-64304500	Part I: JNJ-64304500
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 72 (33.33%)	10 / 44 (22.73%)	38 / 73 (52.05%)
Investigations			
Blood Alkaline Phosphatase Increased			

subjects affected / exposed occurrences (all)	0 / 72 (0.00%) 0	0 / 44 (0.00%) 0	4 / 73 (5.48%) 4
Lymphocyte Count Decreased subjects affected / exposed occurrences (all)	2 / 72 (2.78%) 2	0 / 44 (0.00%) 0	7 / 73 (9.59%) 7
Neutrophil Count Decreased subjects affected / exposed occurrences (all)	0 / 72 (0.00%) 0	0 / 44 (0.00%) 0	2 / 73 (2.74%) 2
Platelet Count Increased subjects affected / exposed occurrences (all)	1 / 72 (1.39%) 1	0 / 44 (0.00%) 0	0 / 73 (0.00%) 0
Weight Decreased subjects affected / exposed occurrences (all)	0 / 72 (0.00%) 0	0 / 44 (0.00%) 0	0 / 73 (0.00%) 0
White Blood Cell Count Decreased subjects affected / exposed occurrences (all)	0 / 72 (0.00%) 0	0 / 44 (0.00%) 0	4 / 73 (5.48%) 5
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Tumour Inflammation subjects affected / exposed occurrences (all)	0 / 72 (0.00%) 0	0 / 44 (0.00%) 0	0 / 73 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	5 / 72 (6.94%) 7	2 / 44 (4.55%) 3	8 / 73 (10.96%) 11
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	3 / 72 (4.17%) 3	1 / 44 (2.27%) 1	9 / 73 (12.33%) 16
Iron Deficiency Anaemia subjects affected / exposed occurrences (all)	2 / 72 (2.78%) 2	0 / 44 (0.00%) 0	1 / 73 (1.37%) 1
Lymphopenia subjects affected / exposed occurrences (all)	1 / 72 (1.39%) 1	1 / 44 (2.27%) 2	4 / 73 (5.48%) 5
General disorders and administration site conditions			

Fatigue subjects affected / exposed occurrences (all)	4 / 72 (5.56%) 4	1 / 44 (2.27%) 1	1 / 73 (1.37%) 1
Pyrexia subjects affected / exposed occurrences (all)	1 / 72 (1.39%) 2	1 / 44 (2.27%) 1	3 / 73 (4.11%) 3
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	0 / 72 (0.00%) 0	0 / 44 (0.00%) 0	0 / 73 (0.00%) 0
Gastrointestinal disorders Abdominal Pain subjects affected / exposed occurrences (all)	3 / 72 (4.17%) 3	3 / 44 (6.82%) 4	5 / 73 (6.85%) 5
Crohn's Disease subjects affected / exposed occurrences (all)	4 / 72 (5.56%) 4	0 / 44 (0.00%) 0	6 / 73 (8.22%) 8
Diarrhoea subjects affected / exposed occurrences (all)	2 / 72 (2.78%) 2	1 / 44 (2.27%) 1	2 / 73 (2.74%) 2
Enterovesical Fistula subjects affected / exposed occurrences (all)	0 / 72 (0.00%) 0	0 / 44 (0.00%) 0	0 / 73 (0.00%) 0
Gastric Ulcer subjects affected / exposed occurrences (all)	0 / 72 (0.00%) 0	0 / 44 (0.00%) 0	0 / 73 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 72 (0.00%) 0	1 / 44 (2.27%) 2	0 / 73 (0.00%) 0
Gastroesophageal Reflux Disease subjects affected / exposed occurrences (all)	1 / 72 (1.39%) 1	0 / 44 (0.00%) 0	1 / 73 (1.37%) 1
Nausea subjects affected / exposed occurrences (all)	1 / 72 (1.39%) 1	0 / 44 (0.00%) 0	3 / 73 (4.11%) 4
Vomiting			

subjects affected / exposed occurrences (all)	1 / 72 (1.39%) 1	0 / 44 (0.00%) 0	3 / 73 (4.11%) 4
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 72 (1.39%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 72 (0.00%)	1 / 44 (2.27%)	2 / 73 (2.74%)
occurrences (all)	0	1	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 72 (1.39%)	0 / 44 (0.00%)	1 / 73 (1.37%)
occurrences (all)	1	0	1
Back Pain			
subjects affected / exposed	0 / 72 (0.00%)	1 / 44 (2.27%)	1 / 73 (1.37%)
occurrences (all)	0	1	1
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 72 (1.39%)	1 / 44 (2.27%)	4 / 73 (5.48%)
occurrences (all)	1	1	4
Nasopharyngitis			
subjects affected / exposed	3 / 72 (4.17%)	2 / 44 (4.55%)	7 / 73 (9.59%)
occurrences (all)	3	2	8
Rhinitis			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 72 (1.39%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	0 / 72 (0.00%)	0 / 44 (0.00%)	0 / 73 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part II: Placebo	Part II: Placebo to JNJ-64304500 Middle Dose	Part II: JNJ-64304500 Low Dose
Total subjects affected by non-serious adverse events subjects affected / exposed	16 / 48 (33.33%)	6 / 31 (19.35%)	24 / 50 (48.00%)
Investigations			
Blood Alkaline Phosphatase Increased subjects affected / exposed	1 / 48 (2.08%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Lymphocyte Count Decreased subjects affected / exposed	1 / 48 (2.08%)	0 / 31 (0.00%)	2 / 50 (4.00%)
occurrences (all)	1	0	2
Neutrophil Count Decreased subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Platelet Count Increased subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Weight Decreased subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Decreased subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Tumour Inflammation subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache subjects affected / exposed	3 / 48 (6.25%)	0 / 31 (0.00%)	2 / 50 (4.00%)
occurrences (all)	3	0	2
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed	3 / 48 (6.25%)	0 / 31 (0.00%)	6 / 50 (12.00%)
occurrences (all)	4	0	7
Iron Deficiency Anaemia			

subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	1 / 31 (3.23%) 1	0 / 50 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0	1 / 50 (2.00%) 1
General disorders and administration site conditions			
Fatigue subjects affected / exposed occurrences (all)	2 / 48 (4.17%) 5	0 / 31 (0.00%) 0	1 / 50 (2.00%) 1
Pyrexia subjects affected / exposed occurrences (all)	3 / 48 (6.25%) 6	1 / 31 (3.23%) 1	0 / 50 (0.00%) 0
Ear and labyrinth disorders			
Vertigo subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0	1 / 50 (2.00%) 2
Gastrointestinal disorders			
Abdominal Pain subjects affected / exposed occurrences (all)	1 / 48 (2.08%) 2	1 / 31 (3.23%) 7	2 / 50 (4.00%) 2
Crohn's Disease subjects affected / exposed occurrences (all)	4 / 48 (8.33%) 5	0 / 31 (0.00%) 0	4 / 50 (8.00%) 4
Diarrhoea subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0	1 / 50 (2.00%) 2
Enterovesical Fistula subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0	0 / 50 (0.00%) 0
Gastric Ulcer subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0	0 / 50 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0	0 / 50 (0.00%) 0
Gastrooesophageal Reflux Disease			

subjects affected / exposed	1 / 48 (2.08%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	1 / 48 (2.08%)	0 / 31 (0.00%)	2 / 50 (4.00%)
occurrences (all)	1	0	2
Vomiting			
subjects affected / exposed	1 / 48 (2.08%)	0 / 31 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 48 (8.33%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences (all)	4	0	0
Back Pain			
subjects affected / exposed	0 / 48 (0.00%)	1 / 31 (3.23%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 31 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 48 (2.08%)	1 / 31 (3.23%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	2 / 48 (4.17%)	1 / 31 (3.23%)	3 / 50 (6.00%)
occurrences (all)	2	1	3
Rhinitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 31 (3.23%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Upper Respiratory Tract Infection			

subjects affected / exposed occurrences (all)	1 / 48 (2.08%) 1	0 / 31 (0.00%) 0	1 / 50 (2.00%) 1
Metabolism and nutrition disorders Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 48 (0.00%) 0	0 / 31 (0.00%) 0	1 / 50 (2.00%) 1

Non-serious adverse events	Part II: JNJ-64304500 Middle Dose	Part II: JNJ-64304500 High Dose	Part II: Ustekinumab
Total subjects affected by non-serious adverse events subjects affected / exposed	23 / 49 (46.94%)	26 / 49 (53.06%)	20 / 47 (42.55%)
Investigations Blood Alkaline Phosphatase Increased subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	0 / 49 (0.00%) 0	1 / 47 (2.13%) 1
Lymphocyte Count Decreased subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	1 / 49 (2.04%) 1	0 / 47 (0.00%) 0
Neutrophil Count Decreased subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	1 / 49 (2.04%) 2	1 / 47 (2.13%) 1
Platelet Count Increased subjects affected / exposed occurrences (all)	4 / 49 (8.16%) 5	0 / 49 (0.00%) 0	2 / 47 (4.26%) 2
Weight Decreased subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	0 / 49 (0.00%) 0	1 / 47 (2.13%) 1
White Blood Cell Count Decreased subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	1 / 49 (2.04%) 1	1 / 47 (2.13%) 1
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Tumour Inflammation subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	0 / 49 (0.00%) 0	0 / 47 (0.00%) 0
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	4 / 49 (8.16%) 5	4 / 49 (8.16%) 4	5 / 47 (10.64%) 5
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	7 / 49 (14.29%) 8	2 / 49 (4.08%) 2	1 / 47 (2.13%) 1
Iron Deficiency Anaemia subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	0 / 49 (0.00%) 0	0 / 47 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	1 / 49 (2.04%) 1	0 / 47 (0.00%) 0
General disorders and administration site conditions			
Fatigue subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	1 / 49 (2.04%) 1	0 / 47 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 5	1 / 49 (2.04%) 2	2 / 47 (4.26%) 2
Ear and labyrinth disorders			
Vertigo subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	1 / 49 (2.04%) 1	1 / 47 (2.13%) 1
Gastrointestinal disorders			
Abdominal Pain subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	3 / 49 (6.12%) 4	5 / 47 (10.64%) 8
Crohn's Disease subjects affected / exposed occurrences (all)	7 / 49 (14.29%) 7	2 / 49 (4.08%) 2	2 / 47 (4.26%) 2
Diarrhoea subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	1 / 49 (2.04%) 1	0 / 47 (0.00%) 0
Enterovesical Fistula			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastric Ulcer			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 49 (0.00%)	3 / 49 (6.12%)	0 / 47 (0.00%)
occurrences (all)	0	3	0
Nausea			
subjects affected / exposed	1 / 49 (2.04%)	3 / 49 (6.12%)	1 / 47 (2.13%)
occurrences (all)	1	4	1
Vomiting			
subjects affected / exposed	0 / 49 (0.00%)	4 / 49 (8.16%)	0 / 47 (0.00%)
occurrences (all)	0	5	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 49 (0.00%)	3 / 49 (6.12%)	0 / 47 (0.00%)
occurrences (all)	0	3	0
Rash			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 49 (0.00%)	2 / 49 (4.08%)	1 / 47 (2.13%)
occurrences (all)	0	2	1
Back Pain			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Influenza			

subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 2	0 / 49 (0.00%) 0	1 / 47 (2.13%) 1
Nasopharyngitis subjects affected / exposed occurrences (all)	3 / 49 (6.12%) 3	4 / 49 (8.16%) 4	4 / 47 (8.51%) 4
Rhinitis subjects affected / exposed occurrences (all)	1 / 49 (2.04%) 1	5 / 49 (10.20%) 5	0 / 47 (0.00%) 0
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	2 / 49 (4.08%) 3	4 / 49 (8.16%) 4	1 / 47 (2.13%) 1
Metabolism and nutrition disorders Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 49 (0.00%) 0	1 / 49 (2.04%) 1	0 / 47 (0.00%) 0

Non-serious adverse events	Part II LTE: Placebo	Part II LTE: Placebo to JNJ-64304500 Middle Dose	Part II LTE: JNJ- 64304500 Low Dose
Total subjects affected by non-serious adverse events subjects affected / exposed	5 / 10 (50.00%)	5 / 12 (41.67%)	6 / 21 (28.57%)
Investigations Blood Alkaline Phosphatase Increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0	1 / 21 (4.76%) 1
Lymphocyte Count Decreased subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 12 (0.00%) 0	1 / 21 (4.76%) 1
Neutrophil Count Decreased subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 12 (0.00%) 0	0 / 21 (0.00%) 0
Platelet Count Increased subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 12 (0.00%) 0	0 / 21 (0.00%) 0
Weight Decreased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0	0 / 21 (0.00%) 0
White Blood Cell Count Decreased			

subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 12 (0.00%) 0	0 / 21 (0.00%) 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Tumour Inflammation subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 12 (8.33%) 1	0 / 21 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	1 / 12 (8.33%) 1	0 / 21 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 12 (8.33%) 1	0 / 21 (0.00%) 0
Iron Deficiency Anaemia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0	0 / 21 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0	0 / 21 (0.00%) 0
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0	0 / 21 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 12 (0.00%) 0	0 / 21 (0.00%) 0
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0	0 / 21 (0.00%) 0
Gastrointestinal disorders Abdominal Pain subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 12 (0.00%) 0	1 / 21 (4.76%) 1
Crohn's Disease			

subjects affected / exposed	1 / 10 (10.00%)	1 / 12 (8.33%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
Diarrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Enterovesical Fistula			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Gastric Ulcer			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2
Vomiting			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Back Pain			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 12 (0.00%) 0	1 / 21 (4.76%) 2
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Rhinitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 21 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Part II LTE: JNJ-64304500 Middle Dose	Part II LTE: JNJ-64304500 High Dose	Part II LTE: Ustekinumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 27 (44.44%)	10 / 24 (41.67%)	9 / 28 (32.14%)
Investigations			
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 27 (0.00%)	1 / 24 (4.17%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Neutrophil Count Decreased			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0

Platelet Count Increased subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 2	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
Weight Decreased subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	2 / 28 (7.14%) 2
White Blood Cell Count Decreased subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Tumour Inflammation subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1	0 / 24 (0.00%) 0	2 / 28 (7.14%) 2
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	3 / 27 (11.11%) 3	1 / 24 (4.17%) 2	2 / 28 (7.14%) 2
Iron Deficiency Anaemia subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	2 / 28 (7.14%) 2
Lymphopenia subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 2	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 2	2 / 24 (8.33%) 2	0 / 28 (0.00%) 0
Ear and labyrinth disorders			

Vertigo subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 2	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
Gastrointestinal disorders			
Abdominal Pain subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	2 / 28 (7.14%) 2
Crohn's Disease subjects affected / exposed occurrences (all)	4 / 27 (14.81%) 5	2 / 24 (8.33%) 3	2 / 28 (7.14%) 2
Diarrhoea subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	2 / 28 (7.14%) 2
Enterovesical Fistula subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
Gastric Ulcer subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
Gastritis subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
Gastrooesophageal Reflux Disease subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	1 / 24 (4.17%) 1	0 / 28 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	0 / 28 (0.00%) 0
Skin and subcutaneous tissue disorders			
Pruritus subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	1 / 24 (4.17%) 1	0 / 28 (0.00%) 0
Rash			

subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 24 (0.00%) 0	1 / 28 (3.57%) 1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Back Pain			
subjects affected / exposed	1 / 27 (3.70%)	2 / 24 (8.33%)	0 / 28 (0.00%)
occurrences (all)	1	2	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	0	2
Influenza			
subjects affected / exposed	0 / 27 (0.00%)	1 / 24 (4.17%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	3 / 27 (11.11%)	1 / 24 (4.17%)	1 / 28 (3.57%)
occurrences (all)	3	1	1
Rhinitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 27 (0.00%)	1 / 24 (4.17%)	1 / 28 (3.57%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 June 2016	<ul style="list-style-type: none">-To add the collection of stool consistency data using the Bristol Stool Form Scale and assessment of abdominal pain based on the numerical rating scale, as well as exploratory analyses of these data.-To include an additional sample for anti-drug antibody analysis at Week 2 and to increase the frequency of efficacy and clinical laboratory assessments to all visits of the Main Study phase.-Text was revised to clarify that the sample size for Part II was based on the power to detect a dose-response signal and the sample size/power considerations for the pairwise comparisons of the JNJ-64304500 groups with placebo were based on the comparison of the high dose group with placebo.
09 November 2016	<ul style="list-style-type: none">-To change the 12-week follow-up period after the last administration of study agent to a 16-week follow-up period.-To add the PGIS of Crohn's disease and the PGIC of severity of Crohn's disease as efficacy assessments in Part II of the study.-To add exploratory histologic assessments.-To add instructions regarding injection-site location to accurately assess potential injection-site reactions.-To update an inclusion criterion related to contraception to be in-line with the core safety information.-To update the inclusion criteria related to prior or current medications for Crohn's disease to clarify the requirements for Part II.
12 December 2017	<ul style="list-style-type: none">-To evaluate the efficacy and safety of JNJ-64304500 in a broader population, the subject population in Part II was changed to include both biologic intolerant or refractory (Bio-IR) and biologic nonfailure, that is, inadequate response to or failed to tolerate corticosteroids or immunomodulators, but not a biologic (Bio-NF) subjects.-To increase the sample size in Part II to 275 subjects to have sufficient power based on the amended Part II population.
24 April 2018	<ul style="list-style-type: none">-To revise the study drug concentrations for the JNJ-64304500 low and middle doses in Part II of the study to correspond to the Investigational Product Preparation Instructions dilution regimen.
17 January 2019	<ul style="list-style-type: none">-To reduce the sample size for Part II from 275 to 250 subjects.-To change the primary endpoint timing for Part II from Week 8 to Week 12, based on the results from the previous Part 1 Week 12 analysis.-To add a Part II LTE to provide longer term study drug access to eligible subjects for up to 52 weeks.-To clarify the exclusion and discontinuation criteria.
04 February 2020	<ul style="list-style-type: none">-To adjust the maximum proportion of Bio-NF subjects to 60 percent (%) (from 50%), which allowed for additional enrollment flexibility, based upon observed enrollment patterns in Part II. The maximum proportion of Bio-IR subjects remained at 60%. The proposed change did not pose a risk to statistical power for Part II, as the power was based on overall population.

04 June 2021	<p>-Part II of the study was unblinded due to lack of sufficient efficacy of JNJ-64304500 based on the Part II Week 12 analysis. The unblinding occurred after all Part II subjects completed their Week 24 assessments.</p> <p>-Subjects who were receiving JNJ-64304500 or placebo in the Part II LTE were discontinued.</p> <p>-Subjects receiving ustekinumab in countries where ustekinumab is not commercially available were continued in the LTE. To reduce the burden of the ustekinumab subjects who continue in the LTE, the laboratory assessments (including pharmacokinetic and immunogenicity) were removed, and the 16-week safety follow-up was removed due to the well-known safety profile of ustekinumab.</p>
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported