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A Study to Determine the Optimal Dose of Tildrakizumab (SCH 900222/MK-3222) for the Treatment of Moderate-to-severe Chronic Plaque Psoriasis (P05495) (MK-3222-003)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT01225731

First received: October 7, 2010
Last updated: June 30, 2015
Last verified: June 2015
History of Changes

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Purpose

This is a response-driven study of tildrakuzumab for the treatment of moderate to severe chronic plaque psoriasis. The primary study hypothesis is that one or more doses of tildrakizumab will be superior to placebo for the treatment of psoriasis.

Condition	Intervention	Phase
Psoriasis	Biological: tildrakizumab Drug: Placebo	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: Randomized, Double-Blinded, Placebo-Controlled, Parallel-Design, Dose-Range Finding Study of Subcutaneous Tildrakizumab (SCH 900222/MK-3222) in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis (Study P05495)

Resource links provided by NLM:

MedlinePlus related topics: Psoriasis

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Percentage of Participants With a Psoriasis Area and Severity Index (PASI)75 Response at Week 16 [Time Frame: Week 16]

[Designated as safety issue: No]

The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease). PASI 75 response was defined as >=75% improvement in PASI score when compared to the baseline score.

- Number of Participants Experiencing Adverse Events [Time Frame: Up to 72 weeks] [Designated as safety issue: Yes]

  An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment.

- Number of Particpants Discontinuing Study Treatment Due to Adverse Events [Time Frame: Up to 52 weeks] [Designated as safety issue: Yes]

  An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment. Participants may be discontinued from study drug due to adverse events, but remain on the study.

Secondary Outcome Measures:

- Percentage of Participants With a PASI 75 Response at Week 12 [Time Frame: Week 12] [Designated as safety issue: No]

  The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease). PASI 75 response was defined as >=75% improvement in PASI score when compared to the baseline score.

- Percentage of Participants With Physician's Global Assessment (PGA) of "Cleared" or "Minimal" at Week 16 [Time Frame: Week 16] [Designated as safety issue: No]

  The PGA is used to determine the overall severity of a subject's psoriasis lesions at a given time point. Overall lesions will be graded for induration, erythema, and scaling on a scale from 0 to 5. The sum of the 3 scales will be divided by 3 to obtain the PGA score. PGA is assessed as: 0= Cleared, except for residual discoloration. 1= Minimal, majority of lesions have individual scores that average . 2 =Mild, majority of lesions have individual scores that average 2. 3= Modreate, majority of lesions have individual scores that average 3. 4= Marked, majority of lesions have individual scores that average 4. 5= Severe, majority of lesions have individual scores that average 5.

- Percentage of Participants With PASI 90 Response at Week 16 [Time Frame: Week 16] [Designated as safety issue: No]

  The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease). PASI 90 response was defined as >=90 % improvement in PASI score when compared to the baseline score.

- Percentage of Participants With PASI 100 Response at Week 16 [Time Frame: Week 16] [Designated as safety issue: No]

  The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease). PASI 100 response was defined as 100 % improvement in PASI score when compared to the baseline score.

- PASI 75 Response Rate by Time [Time Frame: Up to 16 Weeks] [Designated as safety issue: No]

  The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of

the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease).PASI 75 response was defined as >=75% improvement in PASI score when compared to the baseline score at Week 2, 4, 6, 8, 12, or 16.

- Mean Change From Baseline in PASI Score at Weeks 12 and 16 [Time Frame: Baseline and Weeks 12 and 16] [Designated as safety issue: No]

  The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease).

- Percentage of Participants With PASI 50 Response at Week 16 [Time Frame: Week 16] [Designated as safety issue: No]

  The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease). PASI 50 response was defined as >=50 % improvement in PASI score when compared to the baseline score.

- Mean Change From Baseline in Dermatology Life Quality Index (DLQI) at Week 16 [Time Frame: Week 16] [Designated as safety issue: No]

  The DLQI is a 10-item questionnaire that measures how much participant skin problems have affected their life. Responses range from 0=Not at all to 3=Very much. The DLQI is broken down into 6 subscales: Symptoms and feelings (range 0-6), Daily activities (range 0-6), Leisure (range 0-6), Work and school (range 0-3), Personal relationships (range 0-6), and Treatment (range 0-3). DLQI subscales were summed to yield the DLQI total score, which could range from 0 to 30. For both DLQI subscales and DLQI total score, a higher score indicated a greater negative impact on life.

- Percentage of Participants Achieving DLQI Score of 0 or 1 at Week 16 [Time Frame: Week 16] [Designated as safety issue: No]

  The DLQI is a 10-item questionnaire that measures how much participant skin problems have affected their life. Responses range from 0=Not at all to 3=Very much. The DLQI is broken down into 6 subscales: Symptoms and feelings (range 0-6), Daily activities (range 0-6), Leisure (range 0-6), Work and school (range 0-3), Personal relationships (range 0-6), and Treatment (range 0-3). DLQI subscales were summed to yield the DLQI total score, which could range from 0 to 30. For both DLQI subscales and DLQI total score, a higher score indicated a greater negative impact on life.

- Percentage of Participants Achieving a >=5 Point Reduction in DLQI at Week 16 [Time Frame: Week 16] [Designated as safety issue: No]

  The DLQI is a 10-item questionnaire that measures how much participant skin problems have affected their life. Responses range from 0=Not at all to 3=Very much. The DLQI is broken down into 6 subscales: Symptoms and feelings (range 0-6), Daily activities (range 0-6), Leisure (range 0-6), Work and school (range 0-3), Personal relationships (range 0-6), and Treatment (range 0-3). DLQI subscales were summed to yield the DLQI total score, which could range from 0 to 30. For both DLQI subscales and DLQI total score, a higher score indicated a greater negative impact on life.

Enrollment:	355
Study Start Date:	October 2010
Study Completion Date:	October 2012
Primary Completion Date:	November 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Part 1: Tildrakizumab 5 mg Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4	Biological: tildrakizumab SC administration of tildrakizumab at assigned dose Other Names: • SCH 900222 • MK-3222

Experimental: Part 1: Tildrakizumab 25 mg Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4	Biological: tildrakizumab SC administration of tildrakizumab at assigned dose Other Names: • SCH 900222 • MK-3222
Experimental: Part 1: Tildrakizumab 100 mg Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4	Biological: tildrakizumab SC administration of tildrakizumab at assigned dose Other Names: • SCH 900222 • MK-3222
Experimental: Part 1: Tildrakizumab 200 mg Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4	Biological: tildrakizumab SC administration of tildrakizumab at assigned dose Other Names: • SCH 900222 • MK-3222
Placebo Comparator: Part 1: Placebo Participants receive placebo, SC, at Weeks 0 and 4	Drug: Placebo SC administration of Placebo
Experimental: Part 2: Tildrakizumab 5 mg Participants receive tildrakizumab 5 mg, SC, every 12 weeks for up to 36 weeks	Biological: tildrakizumab SC administration of tildrakizumab at assigned dose Other Names: • SCH 900222 • MK-3222
Experimental: Part 2: Tildrakizumab 25 mg Participants receive tildrakizumab 25 mg, SC, every 12 weeks for up to 36 weeks	Biological: tildrakizumab SC administration of tildrakizumab at assigned dose Other Names: • SCH 900222 • MK-3222
Experimental: Part 2: Tildrakizumab 100 mg Participants receive tildrakizumab 100 mg, SC, every 12 weeks for up to 36 weeks	Biological: tildrakizumab SC administration of tildrakizumab at assigned dose Other Names: • SCH 900222 • MK-3222
Experimental: Part 2: Tildrakizumab 200 mg Participants receive tildrakizumab 200 mg, SC, every 12 weeks for up to 36 weeks	Biological: tildrakizumab SC administration of tildrakizumab at assigned dose Other Names: • SCH 900222 • MK-3222
No Intervention: Part 3: Tildrakizumab 5 mg Follow-up Participants are followed for up to 20 weeks after the last dose of study drug.	
No Intervention: Part 3: Tildrakizumab 25 mg Follow-up Participants are followed for up to 20 weeks after the last dose of study drug.	
No Intervention: Part 3: Tildrakizumab 100 mg Follow-up Participants are followed for up to 20 weeks after the last dose of study drug.	

No Intervention: Part 3: Tildrakizumab 200 mg Follow-up Participants are followed for up to 20 weeks after the last dose of study drug.	
No Intervention: Part 3: Placebo Follow-up Participants are followed for up to 20 weeks after the last dose of study drug.	

Detailed Description:

Each participant will be enrolled in the trial for approximately 72-76 weeks. Each participant will receive assigned treatment at Weeks 0 and 4 in Part I. At Week 16, the dosage of treatment the patient is assigned to may be adjusted based on the Psoriasis Area and Severity Index (PASI) 75 response (responder vs non-responder). Participants will receive study medication once every 12 weeks during Part 2 (Weeks 16 to 52); no participants will receive placebo in Part 2. Part 3 is an observational period and each subject will continue to be monitored on a monthly basis through Week 72. Subjects will not receive any study medication during Part 3.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Adult participants (≥18 years of age) with a diagnosis of moderate-to-severe chronic plaque psoriasis (defined by ≥10% body surface area [BSA] involvement, "moderate" or greater score on the Physician's Global Assessment [PGA] scale, and PASI score ≥12 at Baseline)
- Participants must have a diagnosis of predominantly plaque psoriasis for ≥6 months (as determined by interview and confirmation of diagnosis through physical examination by investigator) and be considered candidates for phototherapy or systemic therapy. Participants with psoriatic arthritis may be included in the study

Exclusion Criteria:

- Nonplaque forms of psoriasis specifically erythrodermic psoriasis, predominantly pustular psoriasis, medication-induced or medication-exacerbated psoriasis, or new onset guttate psoriasis
- Participants who will require oral or injectable corticosteroids during the trial
- Presence of any infection requiring treatment with systemic antibiotics within 2 weeks prior to Screening, or serious infection (eg, pneumonia, cellulitis, bone or joint infections) requiring hospitalization or treatment with intravenous antibiotics within 8 weeks prior to Screening
- Participants with evidence of active or untreated latent tuberculosis (TB) according to Screening criteria specified in the protocol. (Prophylactic treatment for latent TB as per local guidelines must be initiated at least 4 weeks prior to treatment with study medication)
- Previous exposure to any agents targeting interleukin-12 (IL-12) and/or Interleukin-23 (IL-23)
- Participants with prior exposure to two or more tumor necrosis factor (TNF) antagonists with discontinuation due to lack of efficacy.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01225731

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Publications:

Papp K, Thaçi D, Reich K, Riedl E, Langley RG, Krueger JG, Gottlieb AB, Nakagawa H, Bowman EP, Mehta A, Li Q, Zhou Y, Shames R. Tildrakizumab (MK-3222), an anti-interleukin-23p19 monoclonal antibody, improves psoriasis in a phase IIb randomized placebo-controlled trial. Br

J Dermatol. 2015 Oct;173(4):930-9. doi: 10.1111/bjd.13932. Epub 2015 Oct 15.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01225731 History of Changes
Other Study ID Numbers:	P05495 2009-017272-24 MK-3222-003
Study First Received:	October 7, 2010
Results First Received:	March 18, 2015
Last Updated:	June 30, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:
Psoriasis
Skin Diseases
Skin Diseases, Papulosquamous

ClinicalTrials.gov processed this record on May 08, 2016

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A Study to Determine the Optimal Dose of Tildrakizumab (SCH 900222/MK-3222) for the Treatment of Moderate-to-severe Chronic Plaque Psoriasis (P05495) (MK-3222-003)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT01225731

First received: October 7, 2010
Last updated: June 30, 2015
Last verified: June 2015
History of Changes

Results First Received: March 18, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Psoriasis
Interventions:	Biological: tildrakizumab Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4
Part 2: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, every 12 weeks for up to 36

	weeks
Part 2: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, every 12 weeks for up to 36 weeks
Part 3: Tildrakizumab 5 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.
Part 3: Tildrakizumab 25 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.
Part 3: Tildrakizumab 100 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.
Part 3: Tildrakizumab 200 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.

Participant Flow for 3 periods

Period 1: Part 1

	Part 1: Tildrakizumab 5 mg	Part 1: Tildrakizumab 25 mg	Part 1: Tildrakizumab 100 mg	Part 1: Tildrakizumab 200 mg	Part 1: Placebo	Part 2: Tildrakizumab 5 mg	Part 2: Tildrakizumab 25 mg	Part 2: Tildrakizumab 100 mg	Part 2: Tildrakizumab 200 mg	Part 3: Tildrakizumab 5 mg Follow-up	Part 3: Tildrakizumab 25 mg Follow-up	Part 3: Tildrakizumab 100 mg Follow-up	Part 3: Tildrakizumab 200 mg Follow-up
STARTED	42	92	89	86	46	0	0	0	0	0	0	0	0
COMPLETED	40	87	88	84	40	0	0	0	0	0	0	0	0
NOT COMPLETED	2	5	1	2	6	0	0	0	0	0	0	0	0
Did not meet eligibility criteria	1	0	0	0	1	0	0	0	0	0	0	0	0
Adverse Event	1	2	1	1	1	0	0	0	0	0	0	0	0
Withdrawal by Subject	0	3	0	0	4	0	0	0	0	0	0	0	0
Protocol Violation	0	0	0	1	0	0	0	0	0	0	0	0	0

Period 2: Part 2

	Part 1: Tildrakizumab 5 mg	Part 1: Tildrakizumab 25 mg	Part 1: Tildrakizumab 100 mg	Part 1: Tildrakizumab 200 mg	Part 1: Placebo	Part 2: Tildrakizumab 5 mg	Part 2: Tildrakizumab 25 mg	Part 2: Tildrakizumab 100 mg	Part 2: Tildrakizumab 200 mg	Part 3: Tildrakizumab 5 mg Follow-up	Part 3: Tildrakizumab 25 mg Follow-up	Part 3: Tildrakizumab 100 mg Follow-up	Part 3: Tildrakizumab 200 mg Follow-up
STARTED	0 [1]	0 [1]	0 [1]	0 [1]	0 [2]	13 [3]	94 [3]	153 [3]	79 [3]	0	0	0	0
COMPLETED	0	0	0	0	0	10	86	128	68	0	0	0	0
NOT COMPLETED	0	0	0	0	0	3	8	25	11	0	0	0	0
Protocol Violation	0	0	0	0	0	1	0	0	1	0	0	0	0
Adverse Event	0	0	0	0	0	0	4	4	2	0	0	0	0
Lack of Efficacy	0	0	0	0	0	1	0	12	3	0	0	0	0
Pregnancy	0	0	0	0	0	0	1	0	1	0	0	0	0
Lost to Follow-up	0	0	0	0	0	0	0	3	1	0	0	0	0
Physician Decision	0	0	0	0	0	0	0	2	2	0	0	0	0
Withdrawal by Subject	0	0	0	0	0	1	3	4	1	0	0	0	0

[1] Participants could progress into Part 2
[2] Participants could progress into Part 2; no placebo was given in Part 2
[3] Participants were reassigned based on PASI score at Week 16

Period 3: Part 3

	Part 1: Tildrakizumab 5 mg	Part 1: Tildrakizumab 25 mg	Part 1: Tildrakizumab 100 mg	Part 1: Tildrakizumab 200 mg	Part 1: Placebo	Part 2: Tildrakizumab 5 mg	Part 2: Tildrakizumab 25 mg	Part 2: Tildrakizumab 100 mg	Part 2: Tildrakizumab 200 mg	Part 3: Tildrakizumab 5 mg Follow-up	Part 3: Tildrakizumab 25 mg Follow-up	Part 3: Tildrakizumab 100 mg Follow-up	Part 3: Tildrakizumab 200 mg Follow-up
STARTED	0	0	0	0	0	0 [1]	0 [1]	0 [1]	0 [1]	10 [2]	86 [2]	126 [2]	67 [2]
COMPLETED	0	0	0	0	0	0	0	0	0	10	80	116	60
NOT COMPLETED	0	0	0	0	0	0	0	0	0	0	6	10	7
Adverse Event	0	0	0	0	0	0	0	0	0	0	1	1	0
Lost to Follow-up	0	0	0	0	0	0	0	0	0	0	1	2	1
Physician Decision	0	0	0	0	0	0	0	0	0	0	0	1	2
Withdrawal by Subject	0	0	0	0	0	0	0	0	0	0	4	6	4

[1] Participants could enter the follow-up period
[2] Not all participants entered follow-up

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4
Total	Total of all reporting groups

Baseline Measures

	Part 1: Tildrakizumab 5 mg	Part 1: Tildrakizumab 25 mg	Part 1: Tildrakizumab 100 mg	Part 1: Tildrakizumab 200 mg	Part 1: Placebo	Total
Number of Participants [units: participants]	42	92	89	86	46	355
Age [units: years] Mean (Standard Deviation)	43.2 (12.9)	46.3 (13.7)	45.5 (12.8)	43.2 (12.6)	45.9 (11.7)	44.9 (12.9)
Gender [units: participants]						
Female	11	32	13	21	8	85

Male	**31**	**60**	**76**	**65**	**38**	**270**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With a Psoriasis Area and Severity Index (PASI)75 Response at Week 16 [Time Frame: Week 16]

Measure Type	Primary
Measure Title	Percentage of Participants With a Psoriasis Area and Severity Index (PASI)75 Response at Week 16
Measure Description	The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease). PASI 75 response was defined as >=75% improvement in PASI score when compared to the baseline score.
Time Frame	Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS), all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement. The last non-missing post-baseline PASI score was carried forward (LOCF) unless the participant discontinued drug due to lack of efficacy, loss of response, or use of prohibited medications.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	**Part 1: Tildrakizumab 25 mg**	**Part 1: Tildrakizumab 100 mg**	**Part 1: Tildrakizumab 200 mg**	**Part 1: Placebo**
Number of Participants Analyzed [units: participants]	**42**	**90**	**89**	**86**	**45**
Percentage of Participants With a Psoriasis Area and Severity Index (PASI)75 Response at Week 16 [units: Percentage of participants]	**33.33**	**64.44**	**66.29**	**74.42**	**4.44**

Statistical Analysis 1 for Percentage of Participants With a Psoriasis Area and Severity Index (PASI)75 Response at Week 16

Groups [1]	Part 1: Tildrakizumab 5 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.001
% Difference in Response Rate [4]	28.89
95% Confidence Interval	13.41 to 44.36

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants With a Psoriasis Area and Severity Index (PASI)75 Response at Week 16

Groups [1]	Part 1: Tildrakizumab 25 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
% Difference in Response Rate [4]	60.00
95% Confidence Interval	48.42 to 71.58

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Percentage of Participants With a Psoriasis Area and Severity Index (PASI)75 Response at Week 16

Groups [1]	Part 1: Tildrakizumab 100 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
% Difference in Response Rate [4]	61.85
95% Confidence Interval	50.33 to 73.37

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Percentage of Participants With a Psoriasis Area and Severity Index (PASI)75 Response at Week 16

Groups [1]	Part 1: Tildrakizumab 200 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
% Difference in Response Rate [4]	69.97
95% Confidence Interval	58.96 to 80.99

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Primary: Number of Participants Experiencing Adverse Events [Time Frame: Up to 72 weeks]

Measure Type	Primary
Measure Title	Number of Participants Experiencing Adverse Events
Measure Description	An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment.
Time Frame	Up to 72 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants receiving at least one dose of study drug.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4
Part 2: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, every 12 weeks for up to 36 weeks
Part 3: Tildrakizumab 5 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug
Part 3: Tildrakizumab 25 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug
Part 3: Tildrakizumab 100 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug
Part 3: Tildrakizumab 200 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug

Measured Values

	Part 1: Tildrakizumab 5 mg	**Part 1: Tildrakizumab 25 mg**	**Part 1: Tildrakizumab 100 mg**	**Part 1: Tildrakizumab 200 mg**	**Part 1: Placebo**	**Part 2: Tildrakizumab 5 mg**	**Part 2: Tildrakizumab 25 mg**	**Part 2: Tildrakizumab 100 mg**	**Part 2: Tildrakizumab 200 mg**	**Part 3: Tildrakizumab 5 mg Follow-up**	**Part 3: Tildrakizumab 25 mg Follow-up**	**Part 3: Tildrakizumab 100 mg Follow-up**	**Part 3: Tildrakizumab 200 mg Follow-up**
Number of Participants Analyzed [units: participants]	**42**	**91**	**89**	**86**	**45**	**13**	**94**	**153**	**79**	**10**	**86**	**126**	**67**
Number of Participants Experiencing Adverse Events [units: Participants]	**30**	**56**	**58**	**54**	**31**	**7**	**60**	**105**	**52**	**3**	**32**	**53**	**28**

No statistical analysis provided for Number of Participants Experiencing Adverse Events

3. Primary: Number of Particpants Discontinuing Study Treatment Due to Adverse Events [Time Frame: Up to 52 weeks]

Measure Type	Primary
Measure Title	Number of Particpants Discontinuing Study Treatment Due to Adverse Events
Measure Description	An adverse event is any unfavorable and unintended change in the structure, function, or chemistry of the body whether or not considered related to the study treatment. Participants may be discontinued from study drug due to adverse events, but remain on the study.
Time Frame	Up to 52 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All particpants receiving at least one dose of study drug during the treatment period.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4
Part 2: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, every 12 weeks for up to 36 weeks

Measured Values

	Part 1: Tildrakizumab 5 mg	**Part 1: Tildrakizumab 25 mg**	**Part 1: Tildrakizumab 100 mg**	**Part 1: Tildrakizumab 200 mg**	**Part 1: Placebo**	**Part 2: Tildrakizumab 5 mg**	**Part 2: Tildrakizumab 25 mg**	**Part 2: Tildrakizumab 100 mg**	**Part 2: Tildrakizumab 200 mg**
Number of Participants Analyzed [units: participants]	**42**	**91**	**89**	**86**	**45**	**13**	**94**	**153**	**79**
Number of Particpants Discontinuing Study Treatment Due to Adverse Events [units: Participants]	**1**	**2**	**1**	**1**	**1**	**0**	**5**	**5**	**3**

No statistical analysis provided for Number of Particpants Discontinuing Study Treatment Due to Adverse Events

4. Secondary: Percentage of Participants With a PASI 75 Response at Week 12 [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Percentage of Participants With a PASI 75 Response at Week 12
Measure Description	The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease). PASI 75 response was defined as >=75% improvement in PASI score when compared to the baseline score.
Time Frame	Week 12

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The FAS, all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement. The last non-missing post-baseline PASI score was carried forward (LOCF) unless the participant discontinued drug due to lack of efficacy, loss of response, or use of prohibited medications.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	**Part 1: Tildrakizumab 25 mg**	**Part 1: Tildrakizumab 100 mg**	**Part 1: Tildrakizumab 200 mg**	**Part 1: Placebo**
Number of Participants Analyzed [units: participants]	**42**	**90**	**89**	**86**	**45**
Percentage of Participants With a PASI 75 Response at Week 12 [units: Percentage of participants]	**23.81**	**58.89**	**60.67**	**72.09**	**4.44**

Statistical Analysis 1 for Percentage of Participants With a PASI 75 Response at Week 12

Groups [1]	Part 1: Tildrakizumab 5 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.009
% Difference in Response Rate [4]	19.37
95% Confidence Interval	5.15 to 33.58

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants With a PASI 75 Response at Week 12

Groups [1]	Part 1: Tildrakizumab 25 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
% Difference in Response Rate [4]	54.55
95% Confidence Interval	42.63 to 66.26

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Percentage of Participants With a PASI 75 Response at Week 12

Groups [1]	Part 1: Tildrakizumab 100 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
% Difference in Response Rate [4]	56.23
95% Confidence Interval	44.43 to 68.03

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Percentage of Participants With a PASI 75 Response at Week 12

Groups [1]	Part 1: Tildrakizumab 200 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
% Difference in Response Rate [4]	67.65
95% Confidence Interval	56.42 to 78.88

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

5. Secondary: Percentage of Participants With Physician's Global Assessment (PGA) of "Cleared" or "Minimal" at Week 16 [Time Frame: Week 16]

Measure Type	Secondary
Measure Title	Percentage of Participants With Physician's Global Assessment (PGA) of "Cleared" or "Minimal" at Week 16
Measure Description	The PGA is used to determine the overall severity of a subject's psoriasis lesions at a given time point. Overall lesions will be graded for induration, erythema, and scaling on a scale from 0 to 5. The sum of the 3 scales will be divided by 3 to obtain the PGA score. PGA is assessed as: 0= Cleared, except for residual discoloration. 1= Minimal, majority of lesions have individual scores that average . 2 =Mild, majority of lesions have

	individual scores that average 2. 3= Modreate, majority of lesions have individual scores that average 3. 4= Marked, majority of lesions have individual scores that average 4. 5= Severe, majority of lesions have individual scores that average 5.
Time Frame	Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS), all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement. The last non-missing post-baseline PGA value was carried forward (LOCF) unless the participant discontinued drug due to lack of efficacy, loss of response, or use of prohibited medications.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	**Part 1: Tildrakizumab 25 mg**	**Part 1: Tildrakizumab 100 mg**	**Part 1: Tildrakizumab 200 mg**	**Part 1: Placebo**
Number of Participants Analyzed [units: participants]	**42**	**90**	**89**	**86**	**45**
Percentage of Participants With Physician's Global Assessment (PGA) of "Cleared" or "Minimal" at Week 16 [units: Percentage of participants]	**33.33**	**57.78**	**61.80**	**74.42**	**2.22**

Statistical Analysis 1 for Percentage of Participants With Physician's Global Assessment (PGA) of "Cleared" or "Minimal" at Week 16

Groups [1]	Part 1: Tildrakizumab 5 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
% Difference in Response Rate [4]	31.11
95% Confidence Interval	16.22 to 46.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants With Physician's Global Assessment (PGA) of "Cleared" or "Minimal" at Week 16

Groups [1]	Part 1: Tildrakizumab 25 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
% Difference in Response Rate [4]	55.56

95% Confidence Interval	44.48 to 66.63

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Percentage of Participants With Physician's Global Assessment (PGA) of "Cleared" or "Minimal" at Week 16

Groups [1]	Part 1: Tildrakizumab 100 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
% Difference in Response Rate [4]	59.58
95% Confidence Interval	48.60 to 70.55

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Percentage of Participants With Physician's Global Assessment (PGA) of "Cleared" or "Minimal" at Week 16

Groups [1]	Part 1: Tildrakizumab 200 mg vs. Part 1: Placebo
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001
% Difference in Response Rate [4]	72.20
95% Confidence Interval	62.02 to 82.37

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Stratified by baseline weight (≤90 kg or >90 kg) and prior use of biologics for psoriasis (Yes/No).
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

6. Secondary: Percentage of Participants With PASI 90 Response at Week 16 [Time Frame: Week 16]

Measure Type	

	Secondary
Measure Title	Percentage of Participants With PASI 90 Response at Week 16
Measure Description	The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease). PASI 90 response was defined as >=90 % improvement in PASI score when compared to the baseline score.
Time Frame	Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The FAS, all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement, and data for this endpoint.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	**Part 1: Tildrakizumab 25 mg**	**Part 1: Tildrakizumab 100 mg**	**Part 1: Tildrakizumab 200 mg**	**Part 1: Placebo**
Number of Participants Analyzed [units: participants]	**40**	**87**	**88**	**84**	**41**
Percentage of Participants With PASI 90 Response at Week 16 [units: Percentage of participants]	**12.50**	**25.29**	**38.64**	**52.38**	**2.44**

No statistical analysis provided for Percentage of Participants With PASI 90 Response at Week 16

7. Secondary: Percentage of Participants With PASI 100 Response at Week 16 [Time Frame: Week 16]

Measure Type	Secondary
Measure Title	Percentage of Participants With PASI 100 Response at Week 16
Measure Description	The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease). PASI 100 response was defined as 100 % improvement in PASI score when compared to the baseline score.
Time Frame	Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The FAS, all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement, and data fior this endpoint

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4

Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	Part 1: Tildrakizumab 25 mg	Part 1: Tildrakizumab 100 mg	Part 1: Tildrakizumab 200 mg	Part 1: Placebo
Number of Participants Analyzed [units: participants]	**40**	**87**	**88**	**84**	**41**
Percentage of Participants With PASI 100 Response at Week 16 [units: Percentage of participants]	**5.0**	**9.20**	**14.77**	**16.67**	**0.00**

No statistical analysis provided for Percentage of Participants With PASI 100 Response at Week 16

8. Secondary: PASI 75 Response Rate by Time [Time Frame: Up to 16 Weeks]

Measure Type	Secondary
Measure Title	PASI 75 Response Rate by Time
Measure Description	The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease).PASI 75 response was defined as >=75% improvement in PASI score when compared to the baseline score at Week 2, 4, 6, 8, 12, or 16.
Time Frame	Up to 16 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The FAS, all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement. and data for the specific Week.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	Part 1: Tildrakizumab 25 mg	Part 1: Tildrakizumab 100 mg	Part 1: Tildrakizumab 200 mg	Part 1: Placebo
Number of Participants Analyzed [units: participants]	**42**	**90**	**89**	**86**	**45**
PASI 75 Response Rate by Time [units: Percentage of participants]					
Week 2 (n=42, 89, 89, 85, 45)	**0.00**	**1.12**	**1.12**	**0.00**	**0.00**
Week 4 (n=42, 89, 89, 85, 45)	**0.00**	**11.24**	**11.24**	**3.53**	**0.00**
Week 6 (n=40, 86, 88, 84,44)	**12.50**	**20.93**	**25.00**	**30.95**	**2.27**

Week 8 (n=40, 88, 87, 83, 43)	**12.50**	**35.23**	**47.13**	**61.45**	**4.65**
Week 12 (n=40, 87, 88, 83, 42)	**25.00**	**59.77**	**61.36**	**73.49**	**4.76**
Week 16 (n=40, 87, 88, 84, 41)	**35.00**	**65.52**	**67.05**	**76.19**	**4.88**

No statistical analysis provided for PASI 75 Response Rate by Time

9. Secondary: Mean Change From Baseline in PASI Score at Weeks 12 and 16 [Time Frame: Baseline and Weeks 12 and 16]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in PASI Score at Weeks 12 and 16
Measure Description	The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3, arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease).
Time Frame	Baseline and Weeks 12 and 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The FAS, all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement, and data for Week 12 and Week 16.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	**Part 1: Tildrakizumab 25 mg**	**Part 1: Tildrakizumab 100 mg**	**Part 1: Tildrakizumab 200 mg**	**Part 1: Placebo**
Number of Participants Analyzed [units: participants]	**42**	**90**	**89**	**86**	**45**
Mean Change From Baseline in PASI Score at Weeks 12 and 16 [units: Score on a scale] Mean (95% Confidence Interval)					
Week 12	**-10.2 (-12.5 to -7.9)**	**-14.4 (-16.0 to -12.9)**	**-14.1 (-15.7 to -12.5)**	**-14.9 (-16.5 to -13.3)**	**-2.2 (-4.4 to 0.00)**
Week 16	**-10.0 (-12.3 to -7.6)**	**-14.6 (-16.2 to -13.0)**	**-14.9 (-16.5 to -13.3)**	**-15.6 (-17.2 to -14.0)**	**-2.4 (-4.7 to -0.2)**

No statistical analysis provided for Mean Change From Baseline in PASI Score at Weeks 12 and 16

10. Secondary: Percentage of Participants With PASI 50 Response at Week 16 [Time Frame: Week 16]

Measure Type	Secondary
Measure Title	Percentage of Participants With PASI 50 Response at Week 16
Measure Description	The PASI score measures the severity and extent of psoriasis. Using a scale of 0=none to 4= very severe, each body region (head, trunk, arms, and legs) is rated for redness, thickness, and scaling of the largest psoriatic area in that region producing a Lesion Score. The percentage of the area affected by disease is then estimated, ranging from 0 = no lesions to 6 = 90-100% of the region is covered providing an Area Score. Then, the Lesion Score and Area Score for each region are multiplied, producing 4 subtotals. The 4 region subtotals are multiplied by a standardized percentage of body surface area for that region (head = 0.1, trunk = 0.3,

	arms=0.2, and legs = 0.4); these four region calculations are added to provide the final PASI score, ranging from 0 = no disease to 72 = maximal disease). PASI 50 response was defined as >=50 % improvement in PASI score when compared to the baseline score.
Time Frame	Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The FAS, all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement. The last non-missing post-baseline PASI score was carried forward (LOCF) unless the participant discontinued drug due to lack of efficacy, loss of response, or use of prohibited medications.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	**Part 1: Tildrakizumab 25 mg**	**Part 1: Tildrakizumab 100 mg**	**Part 1: Tildrakizumab 200 mg**	**Part 1: Placebo**
Number of Participants Analyzed [units: participants]	**42**	**90**	**89**	**86**	**45**
Percentage of Participants With PASI 50 Response at Week 16 [units: Percentage of participants]	**57.14**	**82.22**	**82.02**	**91.86**	**8.89**

No statistical analysis provided for Percentage of Participants With PASI 50 Response at Week 16

11. Secondary: Mean Change From Baseline in Dermatology Life Quality Index (DLQI) at Week 16 [Time Frame: Week 16]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Dermatology Life Quality Index (DLQI) at Week 16
Measure Description	The DLQI is a 10-item questionnaire that measures how much participant skin problems have affected their life. Responses range from 0=Not at all to 3=Very much. The DLQI is broken down into 6 subscales: Symptoms and feelings (range 0-6), Daily activities (range 0-6), Leisure (range 0-6), Work and school (range 0-3), Personal relationships (range 0-6), and Treatment (range 0-3). DLQI subscales were summed to yield the DLQI total score, which could range from 0 to 30. For both DLQI subscales and DLQI total score, a higher score indicated a greater negative impact on life.
Time Frame	Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The FAS, all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement, and had data for this endpoint.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	Part 1: Tildrakizumab 25 mg	Part 1: Tildrakizumab 100 mg	Part 1: Tildrakizumab 200 mg	Part 1: Placebo
Number of Participants Analyzed [units: participants]	40	87	88	83	42
Mean Change From Baseline in Dermatology Life Quality Index (DLQI) at Week 16 [units: Score on a scale] Mean (95% Confidence Interval)	-4.9 (-7.0 to -2.8)	-9.2 (-10.6 to -7.7)	-8.5 (-9.9 to -7.1)	-8.8 (-10.3 to -7.4)	1.0 (-1.1 to 3.0)

No statistical analysis provided for Mean Change From Baseline in Dermatology Life Quality Index (DLQI) at Week 16

12. Secondary: Percentage of Participants Achieving DLQI Score of 0 or 1 at Week 16 [Time Frame: Week 16]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving DLQI Score of 0 or 1 at Week 16
Measure Description	The DLQI is a 10-item questionnaire that measures how much participant skin problems have affected their life. Responses range from 0=Not at all to 3=Very much. The DLQI is broken down into 6 subscales: Symptoms and feelings (range 0-6), Daily activities (range 0-6), Leisure (range 0-6), Work and school (range 0-3), Personal relationships (range 0-6), and Treatment (range 0-3). DLQI subscales were summed to yield the DLQI total score, which could range from 0 to 30. For both DLQI subscales and DLQI total score, a higher score indicated a greater negative impact on life.
Time Frame	Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The FAS, all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement, and data for this endpoint, excluding all participants on the placebo arm.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	Part 1: Tildrakizumab 25 mg	Part 1: Tildrakizumab 100 mg	Part 1: Tildrakizumab 200 mg
Number of Participants Analyzed [units: participants]	40	87	88	83
Percentage of Participants Achieving DLQI Score of 0 or 1 at Week 16 [units: Percentage of participants]	32.5	57.47	52.27	57.83

No statistical analysis provided for Percentage of Participants Achieving DLQI Score of 0 or 1 at Week 16

13. Secondary: Percentage of Participants Achieving a >=5 Point Reduction in DLQI at Week 16 [Time Frame: Week 16]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving a >=5 Point Reduction in DLQI at Week 16
Measure Description	The DLQI is a 10-item questionnaire that measures how much participant skin problems have affected their life. Responses range from 0=Not at all to 3=Very much. The DLQI is broken down into 6 subscales: Symptoms and feelings (range 0-6), Daily activities (range 0-6), Leisure (range 0-6), Work and school (range 0-3), Personal relationships (range 0-6), and Treatment (range 0-3). DLQI subscales were summed to yield the DLQI total score, which could range from 0 to 30. For both DLQI subscales and DLQI total score, a higher score indicated a greater negative impact on life.
Time Frame	Week 16

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The FAS, all randomized participants who received >=1 dose of study drug and had a baseline and >=1 post-treatment efficacy measurement, and had data for this endpoint.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4

Measured Values

	Part 1: Tildrakizumab 5 mg	**Part 1: Tildrakizumab 25 mg**	**Part 1: Tildrakizumab 100 mg**	**Part 1: Tildrakizumab 200 mg**	**Part 1: Placebo**
Number of Participants Analyzed [units: participants]	**40**	**87**	**88**	**83**	**42**
Percentage of Participants Achieving a >=5 Point Reduction in DLQI at Week 16 [units: Percentage of participants]	**52.50**	**70.11**	**64.77**	**73.49**	**19.05**

No statistical analysis provided for Percentage of Participants Achieving a >=5 Point Reduction in DLQI at Week 16

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 72 weeks
Additional Description	All participants who received at least one dose of tildrakizumab or placebo.

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4
Part 2: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, every 12 weeks for up to 36 weeks
Part 3: Tildrakizumab 5 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.
Part 3: Tildrakizumab 25 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.
Part 3: Tildrakizumab 100 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.

Part 3: Tildrakizumab 200 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.
Placebo Follow-up	Participants who received placebo in Part 1 and did not receive additional therapy.

Serious Adverse Events

	Part 1: Tildrakizumab 5 mg	Part 1: Tildrakizumab 25 mg	Part 1: Tildrakizumab 100 mg	Part 1: Tildrakizumab 200 mg	Part 1: Placebo	Part 2: Tildrakizumab 5 mg	Part 2: Tildrakizumab 25 mg	Part 2: Tildrakizumab 100 mg	Part 2: Tildrakizumab 200 mg	Part 3: Tildrakizumab 5 mg Follow-up	Part 3: Tildrakizumab 25 mg Follow-up	Part 3: Tildrakizumab 100 mg Follow-up	Part 3: Tildrakizumab 200 mg Follow-up	Placebo Follow-up
Total, serious adverse events														
# participants affected / at risk	0/42 (0.00%)	1/91 (1.10%)	1/89 (1.12%)	2/86 (2.33%)	0/45 (0.00%)	0/13 (0.00%)	5/94 (5.32%)	6/153 (3.92%)	3/79 (3.80%)	0/12 (0.00%)	1/87 (1.15%)	2/137 (1.46%)	2/75 (2.67%)	1/2 (50.00%)
General disorders														
Death [†1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	1/89 (1.12%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Hernia [†1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	1/87 (1.15%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Infections and infestations														
Arthritis bacterial [†1]														
# participants affected / at risk	0/42 (0.00%)	1/91 (1.10%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Appendicitis [†1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	1/153 (0.65%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Cellulitis [†1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	1/79 (1.27%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Epiglottitis [†1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	1/153 (0.65%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Sinusitis [†1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	1/94 (1.06%)	1/153 (0.65%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	1	1	0	0	0	0	0	0

Soft tissue infection † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	1/75 (1.33%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Injury, poisoning and procedural complications														
Contusion † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	1/153 (0.65%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	2	0	0	0	0	0	0
Lower limb fracture † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	1/79 (1.27%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Tendonn rupture † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	1/153 (0.65%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders														
Arthralgia † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	1/94 (1.06%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Back pain † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	1/79 (1.27%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Bursitis † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	1/79 (1.27%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Psoriatic arthropathy † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	1/94 (1.06%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	1/75 (1.33%)	0/2 (0.00%)
# events	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Arthropathy † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	1/137 (0.73%)	0/75 (0.00%)	0/2 (0.00%)

# events	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)														
Malignant melanoma † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	1/94 (1.06%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Malignant melanoma in situ † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	1/153 (0.65%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	2	0	0	0	0	0	0
Rectal cancer † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	1/153 (0.65%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Nervous system disorders														
Ischaemic stroke † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	1/94 (1.06%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Thrombotic cerebral infarction † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	1/137 (0.73%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	0	0	0	0	0	1	0	0
Reproductive system and breast disorders														
Ovarian cyst † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	1/86 (1.16%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders														
Psoriasis † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	1/2 (50.00%)
# events	0	0	0	0	0	0	0	0	0	0	0	0	0	1

Vascular disorders														
Lymphoedema †1														
# participants affected / at risk	**0/42 (0.00%)**	**0/91 (0.00%)**	**0/89 (0.00%)**	**1/86 (1.16%)**	**0/45 (0.00%)**	**0/13 (0.00%)**	**0/94 (0.00%)**	**0/153 (0.00%)**	**0/79 (0.00%)**	**0/12 (0.00%)**	**0/87 (0.00%)**	**0/137 (0.00%)**	**0/75 (0.00%)**	**0/2 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 15.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 72 weeks
Additional Description	All participants who received at least one dose of tildrakizumab or placebo.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Part 1: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, subcutaneously (SC) at Weeks 0 and 4
Part 1: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, at Weeks 0 and 4
Part 1: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, at Weeks 0 and 4
Part 1: Placebo	Participants receive placebo, SC, at Weeks 0 and 4
Part 2: Tildrakizumab 5 mg	Participants receive tildrakizumab 5 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 25 mg	Participants receive tildrakizumab 25 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 100 mg	Participants receive tildrakizumab 100 mg, SC, every 12 weeks for up to 36 weeks
Part 2: Tildrakizumab 200 mg	Participants receive tildrakizumab 200 mg, SC, every 12 weeks for up to 36 weeks
Part 3: Tildrakizumab 5 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.
Part 3: Tildrakizumab 25 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.
Part 3: Tildrakizumab 100 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.
Part 3: Tildrakizumab 200 mg Follow-up	Participants are followed for up to 20 weeks after the last dose of study drug.
Placebo Follow-up	Participants who received placebo in Part 1 and did not receive additional therapy.

Other Adverse Events

	Part 1: Tildrakizumab 5 mg	**Part 1: Tildrakizumab 25 mg**	**Part 1: Tildrakizumab 100 mg**	**Part 1: Tildrakizumab 200 mg**	**Part 1: Placebo**	**Part 2: Tildrakizumab 5 mg**	**Part 2: Tildrakizumab 25 mg**	**Part 2: Tildrakizumab 100 mg**	**Part 2: Tildrakizumab 200 mg**	**Part 3: Tildrakizumab 5 mg Follow-up**	**Part 3: Tildrakizumab 25 mg Follow-up**	**Part 3: Tildrakizumab 100 mg Follow-up**	**Part 3: Tildrakizumab 200 mg Follow-up**	**Placebo Follow-up**
Total, other (not including serious) adverse events														
# participants affected / at risk	**20/42 (47.62%)**	**35/91 (38.46%)**	**33/89 (37.08%)**	**30/86 (34.88%)**	**21/45 (46.67%)**	**7/13 (53.85%)**	**38/94 (40.43%)**	**64/153 (41.83%)**	**32/79 (40.51%)**	**3/12 (25.00%)**	**14/87 (16.09%)**	**29/137 (21.17%)**	**17/75 (22.67%)**	**1/2 (50.00%)**

Congenital, familial and genetic disorders														
Odontogenic cyst † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	1/13 (7.69%)	1/94 (1.06%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	1	1	0	0	0	0	0	0	0
Gastrointestinal disorders														
Abdominal pain upper † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	0/13 (0.00%)	1/94 (1.06%)	1/153 (0.65%)	1/79 (1.27%)	1/12 (8.33%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	0	1	1	1	1	0	0	0	0
Diarrhoea † 1														
# participants affected / at risk	1/42 (2.38%)	5/91 (5.49%)	6/89 (6.74%)	3/86 (3.49%)	3/45 (6.67%)	0/13 (0.00%)	0/94 (0.00%)	5/153 (3.27%)	3/79 (3.80%)	0/12 (0.00%)	1/87 (1.15%)	1/137 (0.73%)	1/75 (1.33%)	0/2 (0.00%)
# events	1	5	7	4	3	0	0	6	4	0	1	1	1	0
Gastric ulcer † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	1/13 (7.69%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Gastrooesophageal reflux disease † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	1/89 (1.12%)	0/86 (0.00%)	0/45 (0.00%)	1/13 (7.69%)	3/94 (3.19%)	2/153 (1.31%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	1/137 (0.73%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	1	0	0	1	3	2	0	0	0	1	0	0
Hiatus hernia † 1														
# participants affected / at risk	1/42 (2.38%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	1/13 (7.69%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	1	0	0	0	0	1	0	0	0	0	0	0	0	0
General disorders														
Pyrexia † 1														
# participants affected / at risk	0/42 (0.00%)	1/91 (1.10%)	3/89 (3.37%)	0/86 (0.00%)	1/45 (2.22%)	0/13 (0.00%)	0/94 (0.00%)	3/153 (1.96%)	2/79 (2.53%)	0/12 (0.00%)	0/87 (0.00%)	1/137 (0.73%)	0/75 (0.00%)	1/2 (50.00%)
# events	0	1	4	0	1	0	0	4	2	0	0	1	0	1
Infections and infestations														
Acute tonsilitis † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	1/13 (7.69%)	1/94 (1.06%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	1	1	0	0	0	0	0	0	0
Bronchiitis † 1														
# participants affected / at risk	3/42 (7.14%)	3/91 (3.30%)	1/89 (1.12%)	0/86 (0.00%)	2/45 (4.44%)	1/13 (7.69%)	0/94 (0.00%)	3/153 (1.96%)	2/79 (2.53%)	0/12 (0.00%)	2/87 (2.30%)	0/137 (0.00%)	2/75 (2.67%)	0/2 (0.00%)
# events	3	3	1	0	2	2	0	6	3	0	2	0	2	0
Diverticulitis † 1														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	1/13 (7.69%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Ear infection † 1														
# participants affected / at risk	0/42 (0.00%)	1/91 (1.10%)	0/89 (0.00%)	1/86 (1.16%)	0/45 (0.00%)	1/13 (7.69%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	1/87 (1.15%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	1	0	1	0	1	0	0	0	0	1	0	0	0
Folliculitis † 1														
# participants affected / at risk	0/42 (0.00%)	1/91 (1.10%)	1/89 (1.12%)	2/86 (2.33%)	1/45 (2.22%)	1/13 (7.69%)	0/94 (0.00%)	1/153 (0.65%)	1/79 (1.27%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	2/75 (2.67%)	0/2 (0.00%)
# events	0	1	1	4	1	1	0	1	1	0	0	0	2	0
Gastroenteritis † 1														

# participants affected / at risk	2/42 (4.76%)	0/91 (0.00%)	3/89 (3.37%)	3/86 (3.49%)	1/45 (2.22%)	1/13 (7.69%)	5/94 (5.32%)	4/153 (2.61%)	5/79 (6.33%)	0/12 (0.00%)	1/87 (1.15%)	1/137 (0.73%)	1/75 (1.33%)	0/2 (0.00%)
# events	2	0	3	3	1	1	5	5	5	0	1	1	1	0
Nasopharyngitis † [1]														
# participants affected / at risk	7/42 (16.67%)	12/91 (13.19%)	13/89 (14.61%)	11/86 (12.79%)	9/45 (20.00%)	3/13 (23.08%)	24/94 (25.53%)	34/153 (22.22%)	13/79 (16.46%)	0/12 (0.00%)	6/87 (6.90%)	12/137 (8.76%)	5/75 (6.67%)	0/2 (0.00%)
# events	9	14	15	11	10	4	32	42	21	0	9	13	6	0
Rhinitis † [1]														
# participants affected / at risk	1/42 (2.38%)	1/91 (1.10%)	2/89 (2.25%)	2/86 (2.33%)	0/45 (0.00%)	1/13 (7.69%)	0/94 (0.00%)	2/153 (1.31%)	3/79 (3.80%)	0/12 (0.00%)	1/87 (1.15%)	1/137 (0.73%)	2/75 (2.67%)	0/2 (0.00%)
# events	1	1	2	2	0	1	0	2	3	0	1	1	2	0
Upper Respiratory Tract Infection † [1]														
# participants affected / at risk	2/42 (4.76%)	0/91 (0.00%)	3/89 (3.37%)	2/86 (2.33%)	0/45 (0.00%)	0/13 (0.00%)	3/94 (3.19%)	6/153 (3.92%)	4/79 (5.06%)	0/12 (0.00%)	2/87 (2.30%)	3/137 (2.19%)	3/75 (4.00%)	0/2 (0.00%)
# events	3	0	3	2	0	0	5	7	5	0	2	3	3	0
Injury, poisoning and procedural complications														
Contusion † [1]														
# participants affected / at risk	0/42 (0.00%)	2/91 (2.20%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	1/13 (7.69%)	1/94 (1.06%)	0/153 (0.00%)	2/79 (2.53%)	0/12 (0.00%)	0/87 (0.00%)	1/137 (0.73%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	2	0	0	0	1	1	0	2	0	0	1	0	0
Injury † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	1/13 (7.69%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Investigations														
Blood pressure systolic increased † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	1/13 (7.69%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Hypercholesterolaemia † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	1/86 (1.16%)	0/45 (0.00%)	1/13 (7.69%)	1/94 (1.06%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	1	0	1	1	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders														
Back pain † [1]														
# participants affected / at risk	1/42 (2.38%)	4/91 (4.40%)	3/89 (3.37%)	3/86 (3.49%)	0/45 (0.00%)	0/13 (0.00%)	4/94 (4.26%)	8/153 (5.23%)	3/79 (3.80%)	1/12 (8.33%)	3/87 (3.45%)	5/137 (3.65%)	1/75 (1.33%)	0/2 (0.00%)
# events	1	4	4	4	0	0	5	8	3	1	4	5	1	0
Nervous system disorders														
Headache † [1]														
# participants affected / at risk	3/42 (7.14%)	5/91 (5.49%)	6/89 (6.74%)	7/86 (8.14%)	4/45 (8.89%)	0/13 (0.00%)	3/94 (3.19%)	13/153 (8.50%)	3/79 (3.80%)	0/12 (0.00%)	1/87 (1.15%)	5/137 (3.65%)	2/75 (2.67%)	0/2 (0.00%)
# events	3	8	8	8	6	0	3	17	6	0	1	7	3	0
Psychiatric disorders														
Sleep disorder † [1]														
# participants affected / at risk	0/42 (0.00%)	0/91 (0.00%)	0/89 (0.00%)	0/86 (0.00%)	0/45 (0.00%)	1/13 (7.69%)	0/94 (0.00%)	0/153 (0.00%)	0/79 (0.00%)	0/12 (0.00%)	0/87 (0.00%)	0/137 (0.00%)	0/75 (0.00%)	0/2 (0.00%)
# events	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders														

Cough † 1														
# participants affected / at risk	**3/42 (7.14%)**	**2/91 (2.20%)**	**2/89 (2.25%)**	**1/86 (1.16%)**	**2/45 (4.44%)**	**0/13 (0.00%)**	**2/94 (2.13%)**	**5/153 (3.27%)**	**0/79 (0.00%)**	**0/12 (0.00%)**	**1/87 (1.15%)**	**1/137 (0.73%)**	**0/75 (0.00%)**	**0/2 (0.00%)**
# events	**3**	**2**	**2**	**1**	**2**	**0**	**2**	**5**	**0**	**0**	**1**	**1**	**0**	**0**
Dyspnoea † 1														
# participants affected / at risk	**0/42 (0.00%)**	**0/91 (0.00%)**	**0/89 (0.00%)**	**0/86 (0.00%)**	**0/45 (0.00%)**	**0/13 (0.00%)**	**0/94 (0.00%)**	**2/153 (1.31%)**	**0/79 (0.00%)**	**1/12 (8.33%)**	**0/87 (0.00%)**	**0/137 (0.00%)**	**0/75 (0.00%)**	**0/2 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**0**	**1**	**0**	**0**	**0**	**0**
Skin and subcutaneous tissue disorders														
Pruritus † 1														
# participants affected / at risk	**1/42 (2.38%)**	**4/91 (4.40%)**	**0/89 (0.00%)**	**4/86 (4.65%)**	**4/45 (8.89%)**	**0/13 (0.00%)**	**1/94 (1.06%)**	**2/153 (1.31%)**	**3/79 (3.80%)**	**0/12 (0.00%)**	**0/87 (0.00%)**	**1/137 (0.73%)**	**1/75 (1.33%)**	**0/2 (0.00%)**
# events	**1**	**5**	**0**	**6**	**4**	**0**	**1**	**2**	**3**	**0**	**0**	**1**	**1**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 15.1

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

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

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

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

Restriction Description: The Investigator agrees not to publish or publicly present any interim results of the trial without the prior written consent of the Sponsor. The investigator further agrees to provide to the Sponsor 45 days prior to submission for publication or presentation, review copies of abstracts or manuscripts for publication in any media that report any results of the trial. The Sponsor shall have the right to review and comment on the data analysis and presentation.

Results Point of Contact:

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Publications of Results:

Papp K, Thaçi D, Reich K, Riedl E, Langley RG, Krueger JG, Gottlieb AB, Nakagawa H, Bowman EP, Mehta A, Li Q, Zhou Y, Shames R. Tildrakizumab (MK-3222), an anti-interleukin-23p19 monoclonal antibody, improves psoriasis in a phase IIb randomized placebo-controlled trial. Br J Dermatol. 2015 Oct;173(4):930-9. doi: 10.1111/bjd.13932. Epub 2015 Oct 15.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT01225731 History of Changes
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