SUPPLEMENTAL INFORMATION

Efficacy and safety of tildrakizumab in patients with active psoriatic arthritis: 52-week results of a randomised, double-blind, placebo-controlled, multiple-dose, phase 2b study

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Supplemental Methods

Discontinuation

Patients who discontinued (apart from withdrawal of informed consent) completed the end of trial assessment ≥4 weeks after the last dose of study drug and entered the 20-week washout period.

Allowed and prohibited concomitant medications

Permitted comedications were nonsteroidal anti-inflammatory drugs (NSAIDs; including as needed use, and on a stable dose for ≥4 weeks prior to start of study treatment), methotrexate (≤25 mg/week, ≥3 months of use and on a stable dose for ≥8 weeks prior to start of study treatment), leflunomide (≤20 mg/day, ≥3 months of use and on a stable dose for ≥8 weeks prior to start of study treatment), and oral corticosteroids (equivalent of prednisone ≤10 mg/day and on a stable dose for ≥4 weeks prior to start of study treatment). Patients were required to maintain a stable dose of concomitant medication for the first 24 weeks of the study unless toxicity developed. Prohibited therapies for psoriasis and/or PsA were prior use of >1 biologic treatment; anti-TNFα therapy (etanercept <4 weeks, infliximab <8 weeks, all others <3 months before study drug treatment); B-cell and T-cell depleting agents (<12 months before screening); biologic therapies within the longer of 5 half-lives or 3 months before study drug treatment; apremilast, Janus kinase inhibitors, or other approved or investigational medications for treatment of PsA within the longer of 5 half-lives or 30 days of initiating study drug; and prior anti–IL-17, IL-23, or IL-12/IL-23 p40 biologic therapies for psoriasis/PsA.

Key exclusion criteria

Patients were excluded if they had major chronic inflammatory or connective tissue disease other than psoriatic arthritis (PsA) (eg, rheumatoid arthritis), concurrent uncontrolled systemic disease, history of hepatitis B/C or human immunodeficiency virus infections, history of malignancies within past 5 years,

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abnormal laboratory parameters at screening, or prior use of nonpermitted drugs (including high potency opioid analgesics, parenteral corticosteroids, or live vaccines) within 28 days of start of treatment.

Exploratory and post hoc efficacy assessments

Very low disease activity (VLDA) was defined as achieving all 7/7 Minimal Disease Activity (MDA) criteria. Nonresponse imputation (NRI) was used for patients who withdrew from the study early or had incomplete data at week 52 for DAPSA, PASDAS, and VLDA.

Assessments

The ACR components and DAS28-CRP were assessed at baseline and every 4 weeks thereafter. PASI was assessed at baseline and weeks 1, 4, 12, 16, 24, 28, 36, 40, 48, and 52/end of treatment (EoT). PsAID, LDI, and LEI were assessed at baseline and weeks 4, 12, 24, 28, 36, and 52/EoT. The TJC, SJC, LDI/LEI, and PASI assessments were performed by an independent assessor trained by the investigator—who did not have access to other patient data—after completion of patient-rated questionnaires and before other efficacy assessments by the investigator.

Interim analysis

Following the last patient's visit at week 24 (or end of trial prior to week 24) an interim analysis was conducted to evaluate the primary efficacy endpoint and selected secondary endpoints up to week 24.

Adverse event definitions

Severe infections were defined as any infection meeting the regulatory definition of a serious adverse event, or any infection requiring intravenous antibiotics. MACE included nonfatal stroke, nonfatal myocardial infarction, and cardiovascular death; MACE were evaluated and adjudicated by a Clinical Adjudication Committee. Adverse events of clinical interest included an overdose of the sponsor's product, even if not associated with clinical symptoms or abnormal laboratory results; elevated

aspartate aminotransferase or alanine aminotransferase level ≥3X the upper limit of normal (ULN) and an elevated total bilirubin level ≥2X ULN at the same time as an alkaline phosphatase level <2X ULN; infections that require intravenous antibiotics but do not meet the definition of a serious adverse event; and depression and suicidal ideation and behaviour events.

Statistical analysis

For the primary endpoint analysis (ACR20 response at week 24), the Simes testing procedure was used to protect the Type I error rate at the 2-sided level of 0.05. The P-values from Cochran-Mantel-Haenszel tests of the four comparisons of each tildrakizumab dose vs placebo were ordered from lowest to highest; the lowest P-value was compared with 0.0125, the second-lowest with 0.025, the third lowest with 0.0375, and the highest with 0.05. If any P-value was less than the specified value, the corresponding test was declared significant.

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Supplemental tables and figures

Table S1. Efficacy outcomes at week 52

	TIL 200 mg Q4W (n = 78)	TIL 200 mg Q12W (n = 79)	TIL 100 mg Q12W (n = 77)	TIL 20 mg→200 mg Q12W (n = 78)	PBO Q4W→ TIL 200 mg Q12W (n = 79)
ACR20	79.5 ± 4.6	72.2 ± 5.0	67.5 ± 5.3	78.2 ± 4.7	77.2 ± 4.7
ACR50	68.0 ± 5.3	60.8 ± 5.5	57.1 ± 5.6	65.4 ± 5.4	59.5 ± 5.5
ACR70	50.0 ± 5.7	39.2 ± 5.5	31.2 ± 5.3	38.5 ± 5.5	35.4 ± 5.4
MDA	47.4 ± 5.7	48.1 ± 5.6	35.1 ± 5.4	41.0 ± 5.6	36.7 ± 5.4
VLDA	29.5 ± 5.2	29.1 ± 5.1	18.2 ± 4.4	15.4 ± 4.1	24.1 ± 4.8
Tender joint counts ≤1	47.4 ± 5.7	41.8 ± 5.6	33.8 ± 5.4	39.7 ± 5.5	35.4 ± 5.4
Swollen joint counts ≤1	62.8 ± 5.5	62.0 ± 5.5	55.8 ± 5.7	62.8 ± 5.5	50.6 ± 5.6
PtGA, mean change from baseline ± SD	–36.2 ± 25.7	–35.5 ± 27.7	–30.4 ± 29.3	–36.9 ± 25.1	–38.5 ± 28.8
PGA, mean change from baseline ± SD	–34.4 ± 21.3	–35.9 ± 24.9	–35.3 ± 25.7	–41.6 ± 20.1	–39.8 ± 21.9
Pain, mean change from baseline ± SD	−35.0 ± 24.6	−34.6 ± 28.6	−30.1 ± 30.3	−36.1 ± 27.1	−38.9 ± 30.4
HAQ-DI, mean change from baseline ± SD	–0.4 ± 0.5	–0.4 ± 0.6	–0.4 ± 0.5	–0.4 ± 0.5	–0.4 ± 0.5
HAQ-DI improvement ≥0.35[a]	5.1 ± 2.5	3.8 ± 2.2	1.3 ± 1.3	3.9 ± 2.2	5.1 ± 2.5
LDI, mean change from baseline ± SD[b]	−21.4 ± 37.1	−42.1 ± 76.7	−41.6 ± 89.3	−56.5 ± 123.4	−81.5 ± 173.0
LDI, median (Q1, Q3)[b]	7.4 (0, 17.1)	3.2 (0, 22.4)	20 (0, 30.4)	0 (0, 27.5)	5.6 (0, 17.6)
LEI, mean change from baseline ± SD[c]	−1.7 ± 2.0	−1.6 ± 1.6	−2.0 ± 2.1	−1.7 ± 1.8	−2.1 ± 1.9
LEI, median (Q1, Q3)[c]	0 (0, 2.5)	0 (0, 2.0)	0 (0, 2.0)	0 (0, 2.0)	0 (0, 1.0)
LDI/LEI = 0[d]	-	11.1 ± 10.5	7.1 ± 6.9	18.8 ± 9.8	17.7 ± 9.3
DAPSA, mean change from baseline ± SD	–25.5 ± 21.0	–24.5 ± 21.6	–26.1 ± 23.3	–28.7 ± 16.4	–30.1 ± 22.5
PASDAS, mean change from baseline ± SD	–1.8 ± 1.1	–1.7 ± 1.2	–1.6 ± 1.3	–1.9 ± 1.1	–1.9 ± 1.2
PsAID, LS mean change from baseline ± SE	–2.7 ± 0.2	–2.6 ± 0.2	–2.3 ± 0.2	–2.9 ± 0.2	–2.8 ± 0.2
PsAID decrease by ≥3	48.7 ± 5.7	44.3 ± 5.6	45.5 ± 5.7	51.3 ± 5.7	48.1 ± 5.6

Data are response rate ± SE unless otherwise noted.

[a]Calculated as a percent of all patients.

[b]LDI is reported in patients with LDI ≥1 at baseline; tildrakizumab 200 mg Q4W, n = 27; tildrakizumab 200 mg Q12W, n = 21; tildrakizumab 100 mg Q12W, n = 21; tildrakizumab 20 mg Q12W, n = 19; placebo Q4W, n = 25.

[c]LEI is reported in patients with LEI ≥1 at baseline; tildrakizumab 200 mg Q4W, n = 48; tildrakizumab 200 mg Q12W, n = 43; tildrakizumab 100 mg Q12W, n = 51; tildrakizumab 20 mg Q12W, n = 55; placebo Q4W, n = 43.

[d]Complete resolution for both LDI and LEI is reported in patients with both LDI and LEI ≥1 at baseline; tildrakizumab 200 mg Q4W, n = 0; tildrakizumab 200 mg Q12W, n = 9; tildrakizumab 100 mg Q12W, n = 14; tildrakizumab 20 mg Q12W, n = 16; placebo Q4W, n = 17.

Missing responses were imputed as nonresponses.

ACR, American College of Rheumatology response criteria; DAPSA, disease activity in psoriatic arthritis; HAQ-DI, Health Assessment Questionnaire-Disability Index; LDI, Leeds Dactylitis Index; LEI, Leeds Enthesitis Index; LS, least squares; MDA, minimal disease activity; PASDAS, psoriatic arthritis disease activity score; PBO, placebo; PGA, physician's global assessment; PsAID, psoriatic arthritis impact of disease; PtGA, patient's general assessment; Q1, 25th percentile; Q3, 75th percentile; Q4W, every 4 weeks; Q12W, every 12 weeks; SD, standard deviation; SE, standard error; TIL, tildrakizumab; VLDA, very low disease activity.

Table S2. Week 24 ACR20 response rates by country of enrolment

Country	TIL 200 mg Q4W (n = 78)	TIL 200 mg Q12W (n = 79)	TIL 100 mg Q12W (n = 77)	TIL 20 mg Q12W (n = 78)	PBO Q4W (n = 79)
Argentina	1/1 (100)	1/1 (100)	1/1 (100)	1/1 (100)	0
Spain	4/6 (66.7)	5/7 (71.4)	7/8 (87.5)	6/9 (66.7)	2/6 (33.3)
Hungary	2/2 (100)	2/2 (100)	1/2 (50.0)	2/4 (50.0)	1/2 (50.0)
Mexico	8/8 (100)	12/13 (92.3)	3/5 (60.0)	6/8 (75.0)	6/8 (75.0)
Poland	24/25 (96.0)	26/30 (86.7)	19/22 (86.4)	18/21 (85.7)	16/29 (55.2)
Russia	6/8 (75.0)	3/5 (60.0)	9/10 (90.0)	11/13 (84.6)	5/7 (71.4)
Ukraine	11/12 (91.7)	5/6 (83.3)	6/9 (66.7)	3/4 (75.0)	5/8 (62.5)
US	6/9 (66.7)	7/12 (58.3)	9/16 (56.3)	10/11 (90.9)	5/14 (35.7)

Data are shown as number of patients with ACR20 response/number of patients observed (%) at week 24.

Missing data were not imputed.

ACR20 response, 20% improvement from baseline by American College of Rheumatology criteria; PBO, placebo; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab.

Table S3. Response rates for ACR20, ACR50, and ACR70 through week 52

Week	TIL 200 mg Q4W (n = 78)	TIL 200 mg Q12W (n = 79)	TIL 100 mg Q12W (n = 77)	TIL 20 mg Q12W → 200 mg Q12W (n = 78)	PBO Q4W → TIL 200 mg Q12W (n = 79)
ACR20					
1	10.3	11.4	6.5	6.4	5.1
4	21.8	20.3	29.9	18.0	19.0
8	44.9	38.0	48.1	37.2	27.9
12	52.6	49.4	46.8	41.0	32.9
16	69.2	57.0	54.6	46.2	34.2
20	73.1	68.4	59.7	53.9	35.4
24	79.5	77.2	71.4	73.1	50.6
28	73.1	74.7	66.2	66.7	60.8
32	71.8	73.4	64.9	71.8	65.8
36	75.6	72.2	61.0	68.0	65.8
40	74.4	69.6	66.2	68.0	70.9
44	75.6	69.6	63.6	69.2	69.6
48	75.6	72.2	64.9	70.5	73.4
52	79.5	72.2	67.5	78.2	77.2
ACR50					
1	0.0	2.5	1.3	1.3	0.0
4	2.6	5.1	9.1	3.9	2.5
8	16.7	7.6	13.0	14.1	7.6
12	18.0	17.7	20.8	19.2	6.3
16	30.8	27.9	27.3	20.5	5.1
20	44.9	41.8	28.6	23.1	16.5
24	52.6	50.6	45.5	39.7	24.1
28	55.1	48.1	48.1	41.0	32.9
32	56.4	50.6	49.4	42.3	39.2
36	57.7	50.6	45.5	39.7	39.2
40	55.1	49.4	46.8	47.4	39.2
44	57.7	53.2	50.7	50.0	43.0
48	65.4	57.0	53.3	51.3	57.0
52	68.0	60.8	57.1	65.4	59.5
ACR70					
1	0.0	1.3	0.0	0.0	0.0
4	1.3	1.3	0.0	1.3	1.3
8	2.6	3.8	2.6	2.6	3.8
12	10.3	3.8	6.5	10.3	1.3
16	14.1	12.7	11.7	9.0	2.5
20	20.5	26.6	14.3	12.8	3.8
24	28.2	29.1	22.1	16.7	10.1
28	29.5	29.1	23.4	20.5	12.7

32	32.1	34.2	28.6	19.2	21.5
36	37.2	29.1	23.4	23.1	21.5
40	33.3	30.4	29.9	23.1	20.3
44	44.9	29.1	27.3	25.6	29.1
48	47.4	40.5	31.2	28.2	38.0
52	50.0	39.2	31.2	38.5	35.4

Data are proportion of patients. Missing responses were imputed as nonresponses. Shown for randomised patients who received ≥1 dose of study drug.

ACR, American College of Rheumatology; PBO, placebo; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab.

Table S4. MDA and VLDA responders over time and responders for each MDA subcomponent at week 24

Week	TIL 200 mg Q4W (n = 78[a])	TIL 200 mg Q12W (n = 79)	TIL 100 mg Q12W (n = 77[b])	TIL 20 mg Q12W → 200 mg Q12W (n = 78)	PBO Q4W → TIL 200 mg Q12W (n = 79[c])
MDA					
1	0.0	1.3	0.0	0.0	0.0
4	3.9	1.3	1.3	2.6	1.3
8	3.9	2.5	2.6	0.0	2.5
12	12.8	8.9	7.8	9.0	2.5
16	12.8	6.3	7.8	9.0	1.3
20	18.0	15.2	9.1	9.0	2.5
24	33.3	34.2	28.6	19.2	6.3
28	39.7	38.0	26.0	20.5	15.2
32	25.6	20.3	16.9	14.1	3.8
36	37.2	35.4	29.9	24.4	20.3
40	25.6	21.5	19.5	19.2	10.1
44	21.8	21.5	18.2	15.4	10.1
48	39.7	31.7	26.0	21.8	20.3
52	47.4	48.1	35.1	41.0	36.7
VLDA					
1	0.0	1.3	0.0	0.0	0.0
8	0.0	1.3	1.3	0.0	1.3
12	2.6	1.3	3.9	5.1	0.0
16	7.7	1.3	3.9	5.1	0.0
20	5.1	5.1	2.6	5.1	0.0
24	15.4	16.5	6.5	6.4	1.3
28	20.5	24.1	11.7	9.0	1.3
32	6.4	6.3	3.9	6.4	1.3
36	21.8	21.5	10.4	11.5	5.1
40	18.0	12.7	13.0	11.5	3.8
44	2.6	7.6	3.9	6.4	2.5
48	24.4	21.5	10.4	12.8	11.4
52	29.5	29.1	18.2	15.4	24.1
MDA subcomponents at week 24					
Tender joint count ≤1	30.8	30.4	18.2	20.5	13.9
Swollen joint count ≤1	53.9	55.7	57.1	50.0	26.6
PASI ≤1 or BSA ≤3	80.8	88.6	74.0	74.4	65.8
Pain VAS ≤15	43.6	41.8	32.5	24.4	21.5

PtGA disease activity VAS ≤20	46.2	50.6	45.5	33.3	24.1
HAQ-DI ≤0.5	39.7	54.4	48.1	37.2	26.6
Tender entheseal points ≤1	80.3	79.8	75.0	71.8	74.4

Data are proportion of patients. Shown for randomised patients who received ≥1 dose of study drug.

Missing responses were imputed as nonresponses.

[a]n = 76 for tender entheseal points ≤1 at week 24.

[b]n = 76 for tender entheseal points ≤1 at week 24.

[c]n = 78 for tender entheseal points ≤1 at week 24.

BSA, body surface area; HAQ-DI, Health Assessment Questionnaire-Disability Index; MDA, minimum disease activity; PASI, Psoriasis Area and Severity Index; PBO, placebo; PtGA, Patient's Global Assessment; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab; VAS, visual analogue scale; VLDA, very low disease activity.

Table S5. Proportion of patients in remission based on DAPSA and with PASDAS scores <3.2, and change from baseline DAPSA and PASDAS

Week	TIL 200 mg Q4W (n = 78)	TIL 200 mg Q12W (n = 79)	TIL 100 mg Q12W (n = 77)	TIL 20 mg Q12W → 200 mg Q12W (n = 78)	PBO Q4W → TIL 200 mg Q12W (n = 79)
DAPSA remission, %[a]					
1	0	1.3	0	0	0
4	1.3	1.3	0	0	0
8	5.1	3.8	2.6	0	1.3
12	7.7	7.6	3.9	3.8	1.3
16	11.5	8.9	5.2	6.4	1.3
20	17.9	17.7	7.8	9	3.8
24	21.8	19	11.7	9	3.8
28	26.9	25.3	16.9	11.5	6.3
32	26.9	25.3	19.5	16.7	11.4
36	24.4	22.8	16.9	15.4	16.5
40	24.4	22.8	19.5	21.8	11.4
44	29.5	25.3	19.5	19.2	16.5
48	34.6	30.4	24.7	23.1	25.3
52	41	32.9	23.4	21.8	29.1
PASDAS <3.2, %					
1	1.3	2.5	1.3	0.0	0.0
4	6.4	5.1	2.6	3.9	0.0
8	10.3	6.3	3.9	9.0	2.5
12	14.1	19.0	10.4	16.7	2.5
16	15.4	19.0	9.1	14.1	2.5
20	28.2	26.6	13.0	14.1	3.8
24	29.5	38.0	26.0	30.8	13.9
28	37.2	38.0	26.0	25.6	15.2
32	30.8	26.6	23.4	24.4	12.7
36	44.9	38.0	36.4	30.8	26.6
40	33.3	29.1	22.1	30.8	20.3
44	33.3	30.4	23.4	28.2	17.7
48	39.7	32.9	27.3	26.9	26.6
52	56.4	57.0	39.0	51.3	40.5
Change from baseline DAPSA, LSM					
1	−4.2	−6.03	−5.25	−6.41	−3.6
4	−9.84	−11.11	−11.42	−8.03	−8.64
8	−15.4	−16.35	−17.35	−13.78	−13.41
12	−18.1	−20.44	−18.41	−14.07	−14.48
16	−21.68	−22.84	−21.77	−17.98	−15.82
20	−23.5	−23.8	−22.98	−20.31	−18.31

24	−25.12	−25.54	−26.98	−23.05	−19.26
Change from baseline PASDAS, LSM[b]					
1	−0.16	−0.24	−0.2	−0.2	−0.14
4	−0.42	−0.54	−0.55	−0.45	−0.34
8	−0.63	−0.68	−0.68	−0.58	−0.46
12	−0.96	−1.13	−1.05	−0.81	−0.67
16	−0.95	−1.02	−0.94	−0.85	−0.56
20	−1.13	−1.19	−0.99	−0.94	−0.66
24	−1.46	−1.51	−1.54	−1.39	−1.04

Missing responses were imputed as nonresponses.

[a]DAPSA remission was defined as a score between 0–4.

[b]n = 77 for TIL 200 mg Q12W, n = 76 for TIL 100 mg Q12W, n = 77 for PBO Q4W → TIL 200 mg Q12W.

DAPSA, Disease Activity in Psoriatic Arthritis; LSM, least squares mean; PASDAS, Psoriatic Arthritis Disease Activity Score; PBO, placebo; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab.

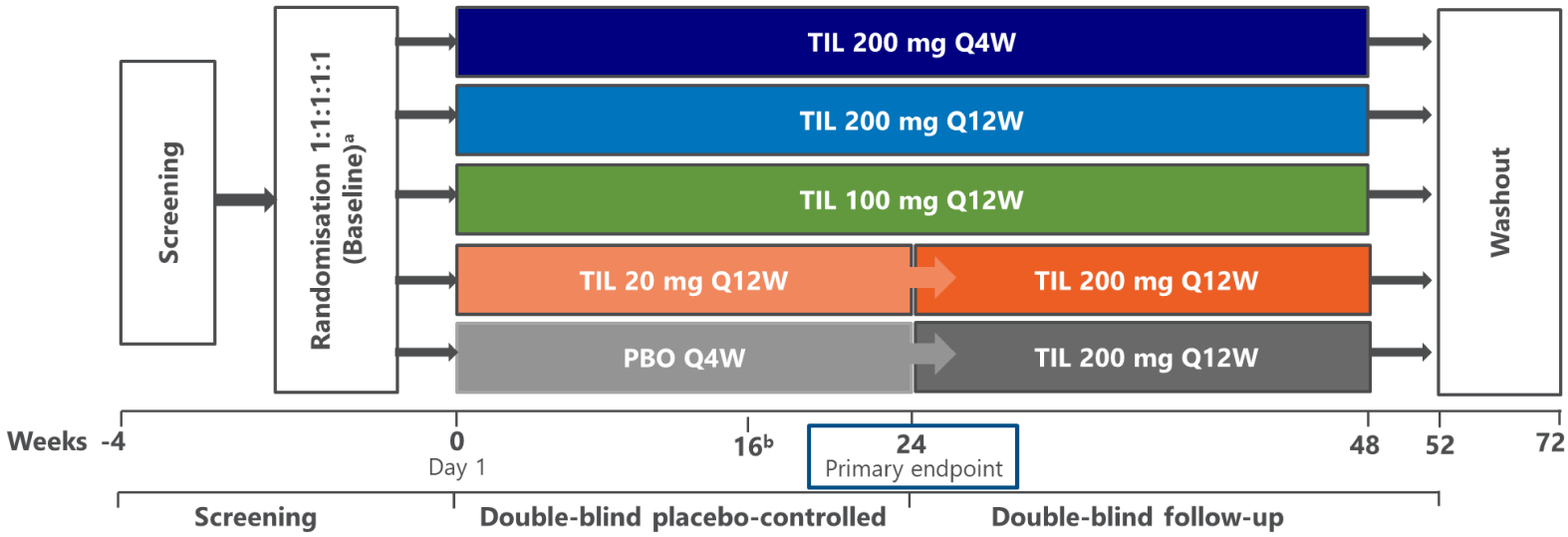
Table S6. Response rates for PASI 75, PASI 90, and PASI 100 through week 52

Week	TIL 200 mg Q4W (n = 53)	TIL 200 mg Q12W (n = 44)	TIL 100 mg Q12W (n = 55)	TIL 20 mg Q12W → 200 mg Q12W (n = 41)	PBO Q4W → TIL 200 mg Q12W (n = 42)
PASI 75					
1	0.0	0.0	0.0	0.0	2.4
4	11.3	22.7	7.3	2.4	7.1
12	37.7	43.2	34.6	26.8	14.3
16	58.5	68.2	43.6	41.5	16.7
24	64.2	79.6	56.4	46.3	16.7
28	69.8	68.2	50.9	56.1	26.2
36	75.5	70.5	60.0	61.0	47.6
40	73.6	70.5	60.0	68.3	57.1
48	79.3	70.5	54.6	70.7	61.9
52	77.4	77.3	61.8	73.2	64.3
PASI 90					
1	0.0	0.0	0.0	0.0	2.4
4	1.9	9.1	1.8	0.0	7.1
12	15.1	25.0	14.6	14.6	14.3
16	35.9	40.9	25.5	31.7	9.5
24	47.2	50.0	40.0	36.6	7.1
28	52.8	54.6	40.0	43.9	16.7
36	56.6	54.6	38.2	48.8	40.5
40	64.2	59.1	47.3	51.2	40.5
48	64.2	59.1	45.5	53.7	50.0
52	67.9	65.9	43.6	53.7	47.6
PASI 100					
1	0.0	0.0	0.0	0.0	2.4
4	1.9	4.6	0.0	0.0	4.8
12	9.4	6.8	7.3	7.3	9.5
16	17.0	18.2	10.9	14.6	7.1
24	30.2	25.0	27.3	22.0	4.8
28	35.9	31.8	27.3	29.3	11.9
36	39.6	31.8	23.6	36.6	28.6
40	43.4	38.6	29.1	39.0	28.6
48	47.2	36.4	29.1	41.5	38.1
52	50.9	36.4	32.7	46.3	33.3

Response rates were calculated in randomised patients who received ≥1 dose of study drug with BSA ≥3% at baseline. Missing responses were imputed as nonresponses.

BSA, body surface area; PASI, Psoriasis Area and Severity Index; PBO, placebo; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab.

Supplemental Figure 1. Study design

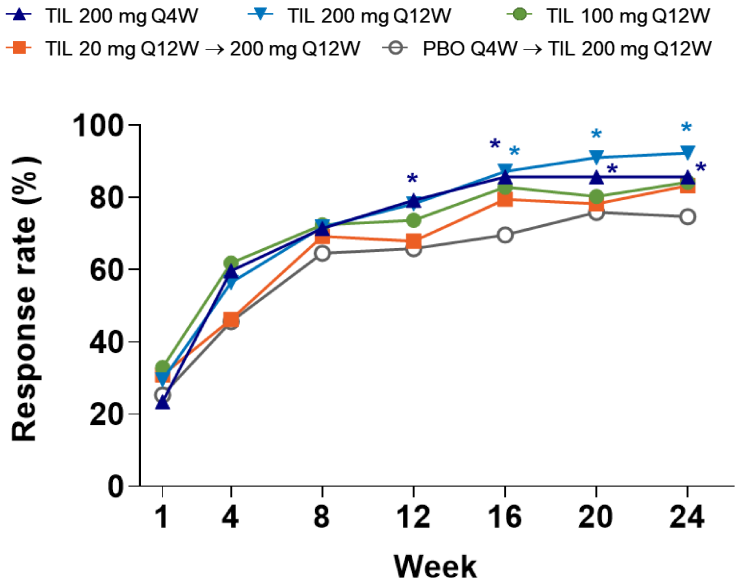


[a]Randomisation stratified by prior anti-TNFα use (prior use capped at 30% of total patients) and baseline body weight (≤90 kg/>90kg). [b]Patients who failed to show minimal response to treatment (<10% improvement from baseline in swollen and tender joint counts) at week 16 could have background medications (MTX, leflunomide, or oral corticosteroids) adjusted according to the maximum permitted daily dose and continue in the study as a nonresponder.

MTX, methotrexate; PBO, placebo; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab; TNF, tumour necrosis factor.

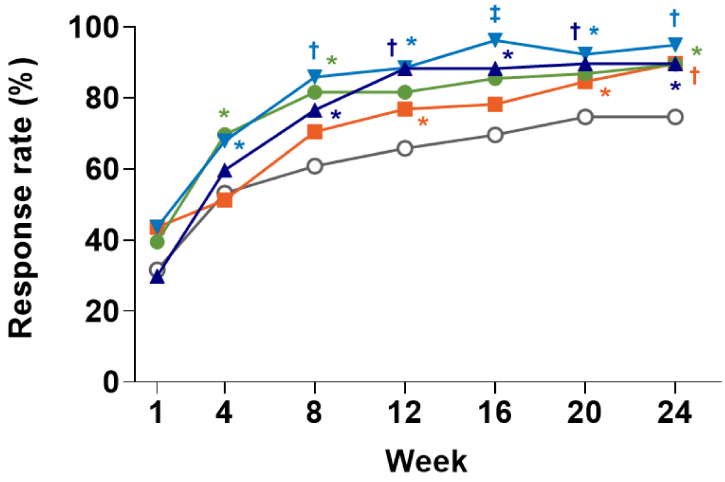
Supplemental Figure 2. Proportion of patients with ≥20% improvement in the following individual components of ACR20: (**A**) Tender joints; (**B**) swollen joints; (**C**) physician global disease assessment; (**D**) patient's global disease assessment; (**E**) patient-rated pain; and (**F**) proportion with ≥50% improvement in acute-phase high-sensitivity C-reactive protein at week 24

A)



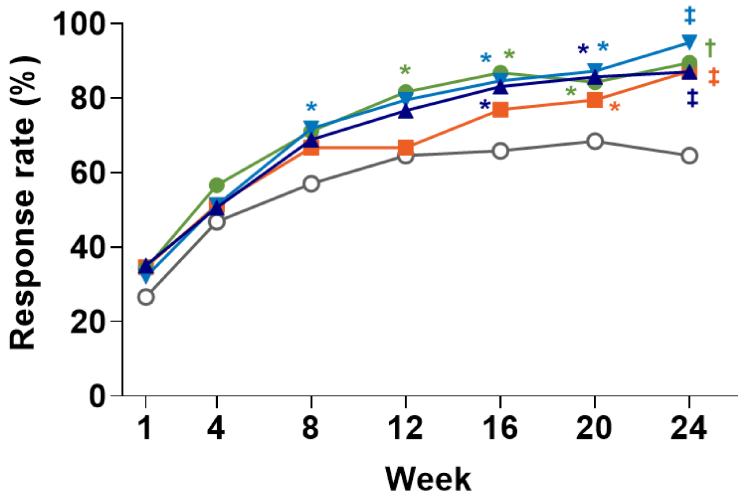
Week	Response rate (%)				
	TIL 200 mg Q4W (n = 77)	TIL 200 mg Q12W (n = 78)	TIL 100 mg Q12W (n = 76)	TIL 20→200 mg Q12W (n = 78)	PBO Q4W→ TIL 200 mg Q12W (n = 79)
1	23.4	29.5	32.9	30.8	25.3
4	59.7	56.4	61.8	46.2	45.6
8	71.4	71.8	72.4	69.2	64.6
12	79.2	78.2	73.7	67.9	65.8
16	85.7	87.2	82.9	79.5	69.6
20	85.7	91.0	80.3	78.2	75.9
24	85.7	92.3	84.2	83.3	74.7

B)



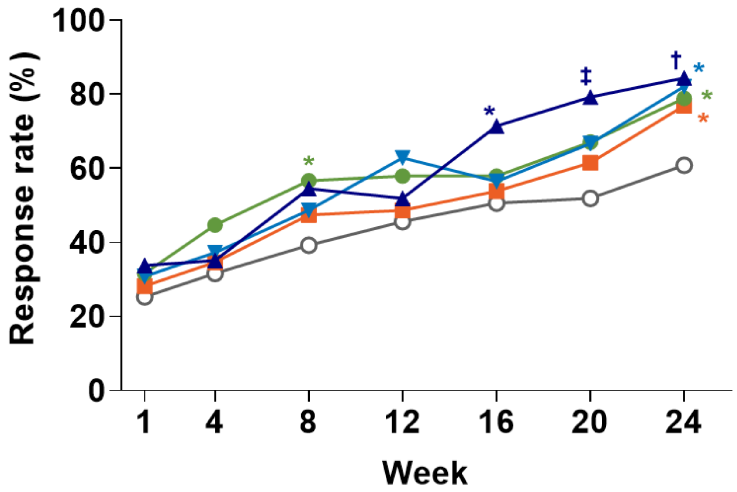
Week	Response rate (%)				
	TIL 200 mg Q4W (n = 77)	TIL 200 mg Q12W (n = 78)	TIL 100 mg Q12W (n = 76)	TIL 20→200 mg Q12W (n = 78)	PBO Q4W→ TIL 200 mg Q12W (n = 79)
1	29.9	43.6	39.5	43.6	31.6
4	59.7	67.9	69.7	51.3	53.2
8	76.6	85.9	81.6	70.5	60.8
12	88.3	88.5	81.6	76.9	65.8
16	88.3	96.2	85.5	78.2	69.6
20	89.6	92.3	86.8	84.6	74.7
24	89.6	94.9	89.5	89.7	74.7

C)



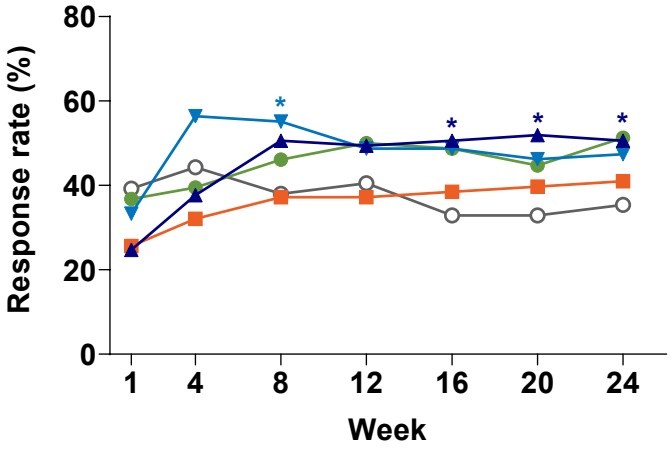
Week	Response rate (%)				
	TIL 200 mg Q4W (n = 77)	TIL 200 mg Q12W (n = 78)	TIL 100 mg Q12W (n = 76)	TIL 20→200 mg Q12W (n = 78)	PBO Q4W→ TIL 200 mg Q12W (n = 79)
1	35.1	32.1	34.2	34.6	26.6
4	50.6	51.3	56.6	51.3	46.8
8	68.8	71.8	71.1	66.7	57.0
12	76.6	79.5	81.6	66.7	64.6
16	83.1	84.6	86.8	76.9	65.8
20	85.7	87.2	84.2	79.5	68.4
24	87.0	94.9	89.5	87.2	64.6

D)



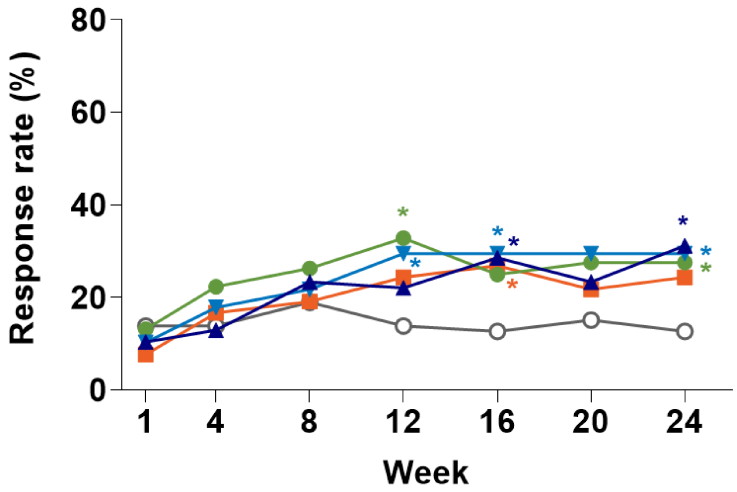
	Response rate (%)				
Week	TIL 200 mg Q4W (n = 77)	TIL 200 mg Q12W (n = 78)	TIL 100 mg Q12W (n = 76)	TIL 20→200 mg Q12W (n = 78)	PBO Q4W→ TIL 200 mg Q12W (n = 79)
1	33.8	30.8	31.6	28.2	25.3
4	35.1	37.2	44.7	34.6	31.6
8	54.5	48.7	56.6	47.4	39.2
12	51.9	62.8	57.9	48.7	45.6
16	71.4	56.4	57.9	53.8	50.6
20	79.2	66.7	67.1	61.5	51.9
24	84.4	82.1	78.9	76.9	60.8

E)



Week	Response rate (%)				
	TIL 200 mg Q4W (n = 77)	TIL 200 mg Q12W (n = 78)	TIL 100 mg Q12W (n = 76)	TIL 20→200 mg Q12W (n = 78)	PBO Q4W→ TIL 200 mg Q12W (n = 79)
1	24.7	33.3	36.8	25.6	39.2
4	37.7	56.4	39.5	32.1	44.3
8	50.6	55.1	46.1	37.2	38.0
12	49.4	48.7	50.0	37.2	40.5
16	50.6	48.7	48.7	38.5	32.9
20	51.9	46.2	44.7	39.7	32.9
24	50.6	47.4	51.3	41.0	35.4

F)



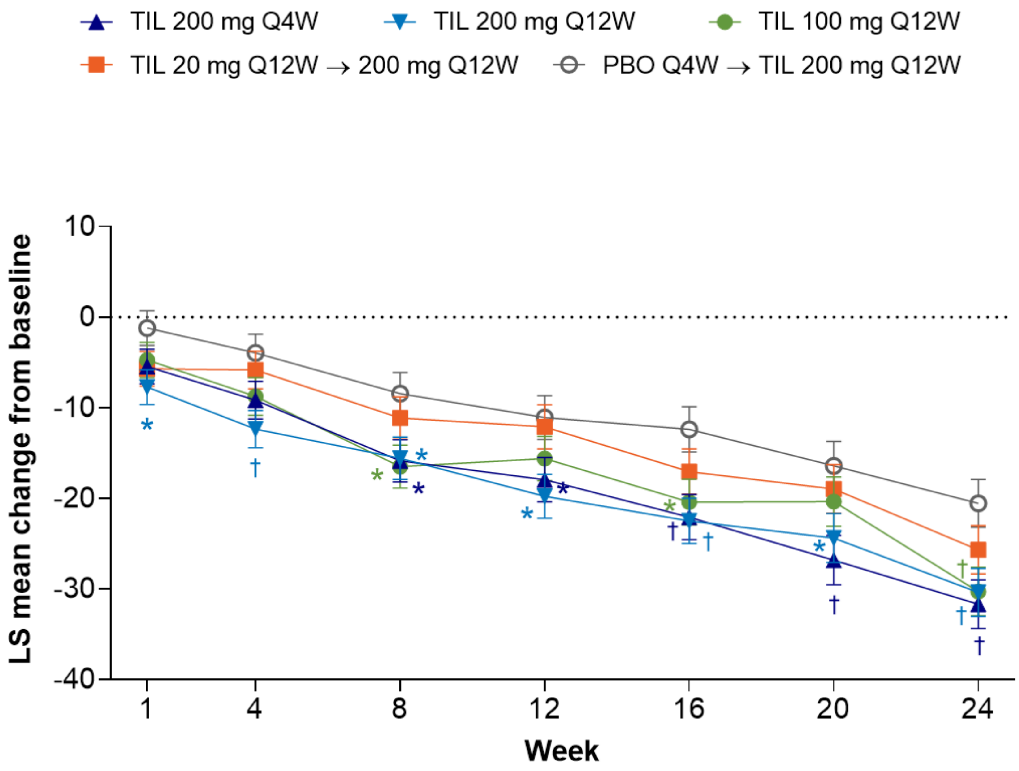
Week	Response rate (%)				
	TIL 200 mg Q4W (n = 77)	TIL 200 mg Q12W (n = 78)	TIL 100 mg Q12W (n = 76)	TIL 20→200 mg Q12W (n = 78)	PBO Q4W→ TIL 200 mg Q12W (n = 79)
1	10.4	10.3	13.2	7.7	13.9
4	13.0	17.9	22.4	16.7	13.9
8	23.4	21.8	26.3	19.2	19.0
12	22.1	29.5	32.9	24.4	13.9
16	28.6	29.5	25.0	26.9	12.7
20	23.4	29.5	27.6	21.8	15.2
24	31.2	29.5	27.6	24.4	12.7

Shown for randomised patients who received ≥1 dose of study drug.

*P <0.05; †P <0.001; ‡P <0.0001 vs PBO, not adjusted for multiplicity. PGA and PtGA of disease activity and patient-rated pain were measured using a visual analogue scale.

ACR, American College of Rheumatology; PBO, placebo; PGA, physician's global assessment; PtGA, patient's global assessment; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab.

Supplemental Figure 3. Least squares mean change in patient pain by treatment and time point through week 24



Week	TIL 200 mg Q4W (n = 78)	TIL 200 mg Q12W (n = 79)	TIL 100 mg Q12W (n = 77)	TIL 20→200 mg Q12W (n = 78)	PBO Q4W→ TIL 200 mg Q12W (n = 79)
1	−5.4	−7.7	−4.7	−5.7	−1.2
4	−9.1	−12.4	−8.8	−5.8	−3.9
8	−15.8	−15.6	−16.5	−11.1	−8.4
12	−17.9	−19.8	−15.6	−12.1	−11.1
16	−22.1	−22.5	−20.4	−17.1	−12.4
20	−26.8	−24.4	−20.4	−19.0	−16.4
24	−31.7	−30.4	−30.3	−25.7	−20.6

Data shown as LS mean change from baseline. Error bars represent standard error.

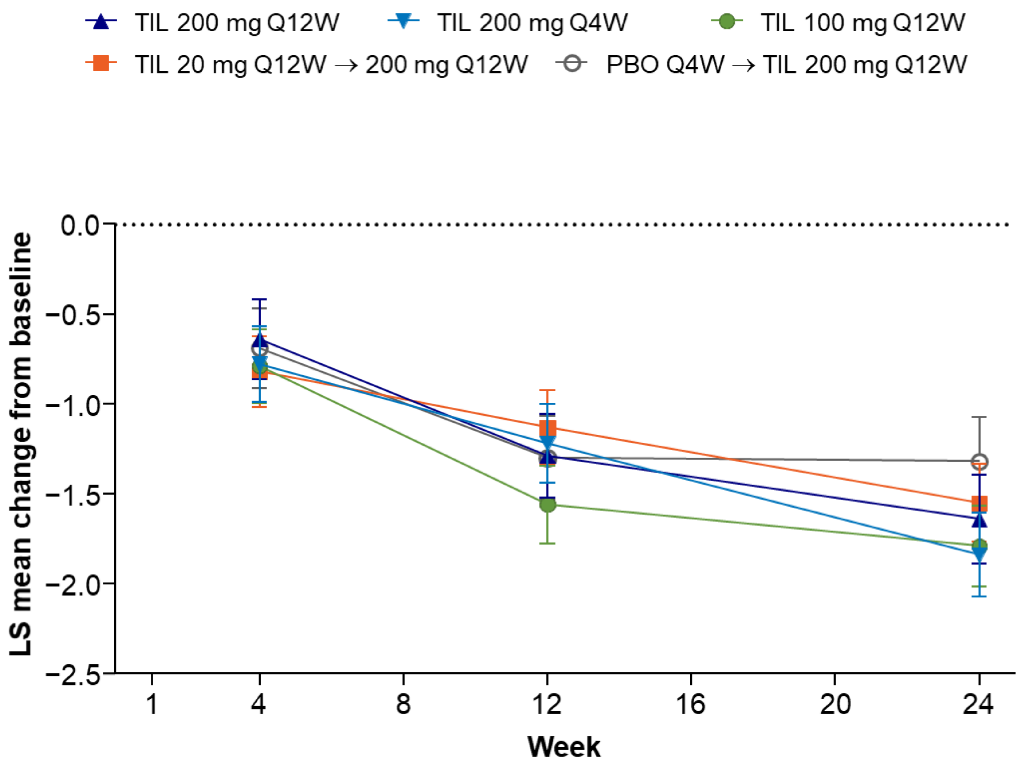
Missing data were imputed as nonresponse.

*P <0.05; †P <0.001; ‡P <0.0001 vs PBO, not adjusted for multiplicity.

LS, least squares; PBO, placebo; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab.

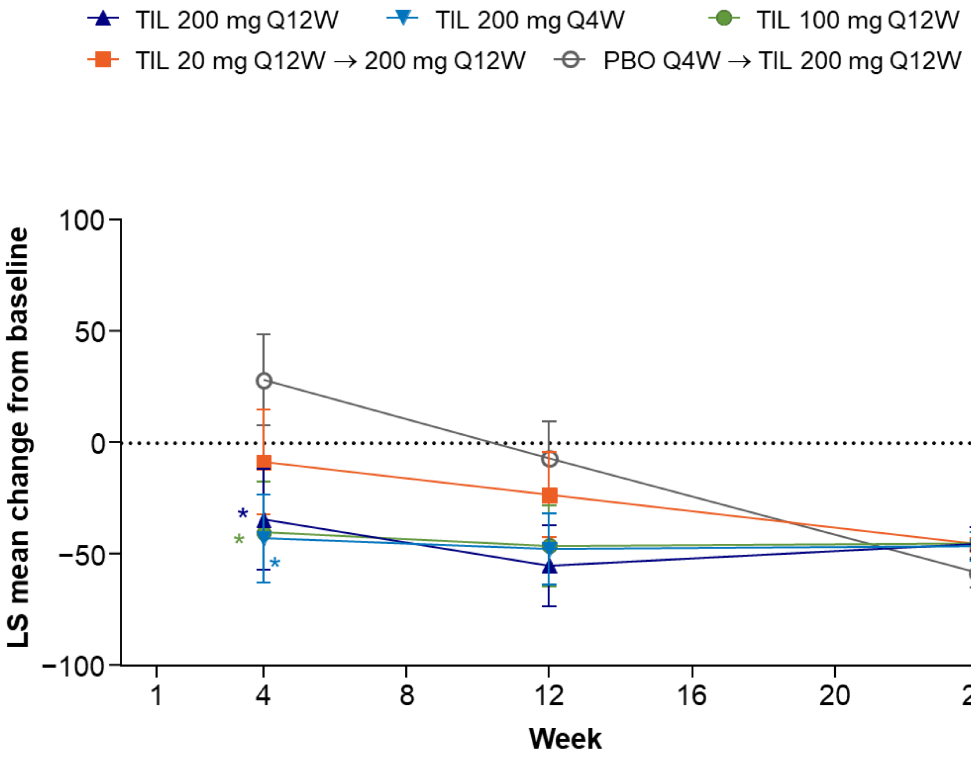
Supplemental Figure 4. Change from baseline in (**A**) Leeds Enthesitis Index and (**B**) Leeds Dactylitis Index to week 24

A)



Week	TIL 200 mg Q4W (n = 48)	TIL 200 mg Q12W (n = 43)	TIL 100 mg Q12W (n = 51)	TIL 20→200 mg Q12W (n = 55)	PBO Q4W→ TIL 200 mg Q12W (n = 43)
4	−0.78	−0.64	−0.79	−0.82	−0.69
12	−1.2	−1.3	−1.6	−1.1	−1.3
24	−1.8	−1.6	−1.8	−1.6	−1.3

B)



Week	TIL 200 mg Q4W (n = 27)	TIL 200 mg Q12W (n = 21)	TIL 100 mg Q12W (n = 21)	TIL 20→200 mg Q12W (n = 19)	PBO Q4W→ TIL 200 mg Q12W (n = 25)
4	−43.1	−34.5	−40.2	−8.8	28.0
12	−48.0	−55.3	−46.4	−23.5	−7.3
24	−46.7	−45.4	−45.2	−45.6	−58.5

Analysis in patients with baseline LEI/LDI ≥1 for A/B, respectively.

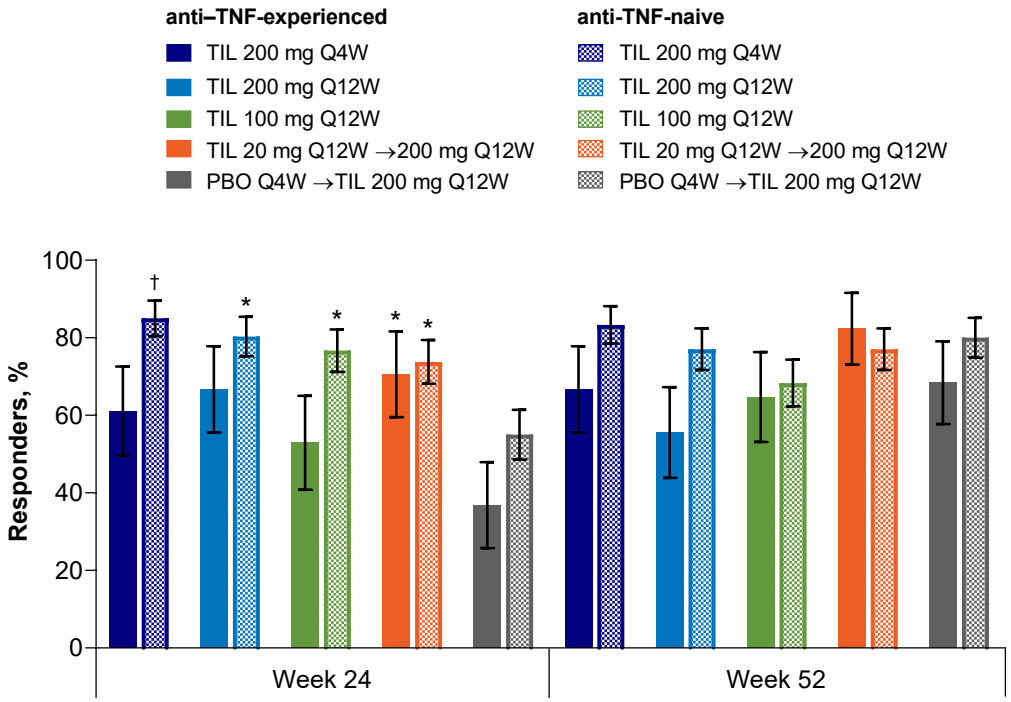
Data shown as LS mean change from baseline. Error bars represent standard error.

*P <0.05, not adjusted for multiplicity.

LDI, Leeds Dactylitis Index; LEI, Leeds Enthesitis Index; LS, least squares; PBO, placebo; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab.

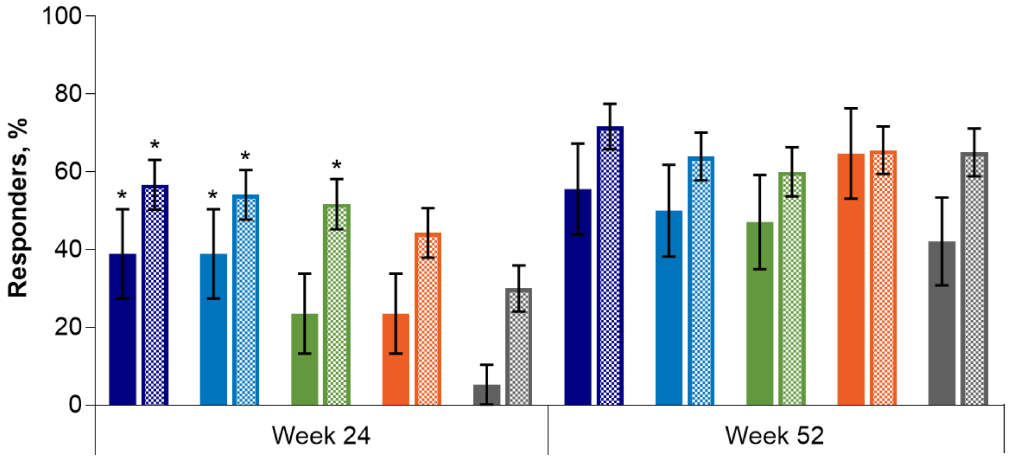
Supplemental Figure 5. Response rates for (**A**) ACR20, (**B**) ACR50, and (**C**) ACR70 at weeks 24 and 52 by presence vs absence of prior anti-TNFα therapy

A)



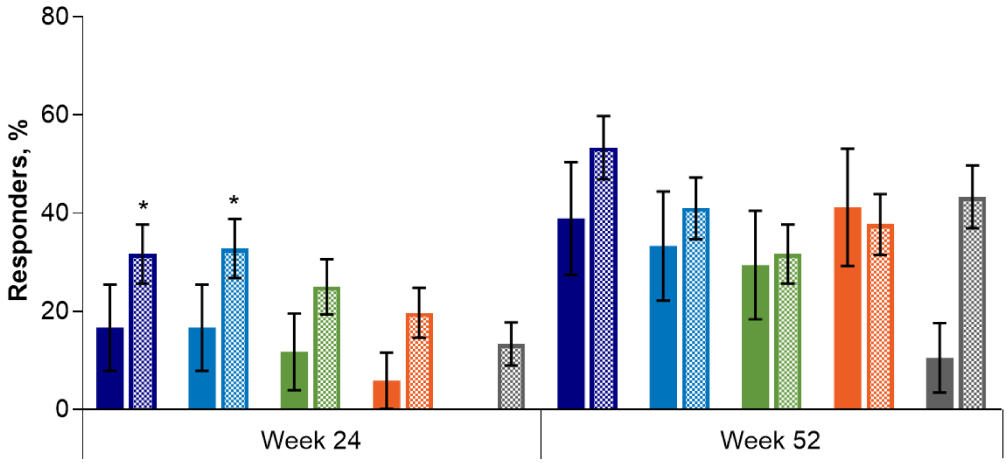
	Responders, %									
	TIL 200 mg Q4W (n = 78)		TIL 200 mg Q12W (n = 79)		TIL 100 mg Q12W (n = 77)		TIL 20→200 mg Q12W (n = 78)		PBO Q4W→ TIL 200 mg Q12W (n = 79)	
Prior anti-TNFα	**Naive**	**Exp.**	**Naive**	**Exp.**	**Naive**	**Exp.**	**Naive**	**Exp.**	**Naive**	**Exp.**
n	60	18	61	18	60	17	61	17	60	19
Week 24	85.0	61.1	80.3	66.7	76.7	52.9	73.8	70.6	55.0	36.8
Week 52	83.3	66.7	77.1	55.6	68.3	64.7	77.1	82.4	80.0	68.4

B)



	Responders, %									
	TIL 200 mg Q4W (n = 78)		TIL 200 mg Q12W (n = 79)		TIL 100 mg Q12W (n = 77)		TIL 20→200 mg Q12W (n = 78)		PBO Q4W→ TIL 200 mg Q12W (n = 79)	
Prior anti-TNFα	**Naive**	**Exp.**	**Naive**	**Exp.**	**Naive**	**Exp.**	**Naive**	**Exp.**	**Naive**	**Exp.**
n	60	18	61	18	60	17	61	17	60	19
Week 24	56.7	38.9	54.1	38.9	51.7	23.5	44.3	23.5	30.0	5.3
Week 52	71.7	55.6	63.9	50.0	60.0	47.1	65.6	64.7	65.0	42.1

C)



	Responders, %									
	TIL 200 mg Q4W (n = 78)		TIL 200 mg Q12W (n = 79)		TIL 100 mg Q12W (n = 77)		TIL 20→200 mg Q12W (n = 78)		PBO Q4W→ TIL 200 mg Q12W (n = 79)	
Prior anti-TNFα	**Naive**	**Exp.**	**Naive**	**Exp.**	**Naive**	**Exp.**	**Naive**	**Exp.**	**Naive**	**Exp.**
n	60	18	61	18	60	17	61	17	60	19
Week 24	31.7	16.7	32.8	16.7	25.0	11.8	19.7	5.9	13.3	0
Week 52	53.3	38.9	41.0	33.3	31.7	29.4	37.7	41.2	43.3	10.5

Shown for randomised patients who received ≥1 dose of study drug. Error bars represent standard error of the mean.

For both time points in **A**), **B**), and **C**), in the prior anti-TNFα + group, the total patients analysed (N) = 18, 18, 17, 17, and 19 for TIL 200 mg Q4W, TIL 200 mg Q12W, TIL 100 mg, TIL 20 mg, and PBO, respectively; in the prior anti-TNFα − group, N = 60, 61, 60, 61, and 60, respectively.

*P <0.05; †P <0.001 tildrakizumab arms vs placebo, not adjusted for multiplicity. P-values were not analysed beyond week 24.

ACR, American College of Rheumatology response criteria; PBO, placebo; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, tildrakizumab; TNFα, tumour necrosis factor alpha.