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CONCISE REPORT

Clinical efficacy, radiographic and safety findings through 5 years of subcutaneous golimumab treatment in patients with active psoriatic arthritis: results from a long-term extension of a randomised, placebo-controlled trial (the GO-REVEAL study)

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Handling editor Tore K Kvien

► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/annrheumdis-2013-204902>).

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Received 11 November 2013
Revised 21 March 2014
Accepted 23 March 2014
Published Online First
19 April 2014



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To cite: Kavanaugh A, McInnes IB, Mease P, et al. *Ann Rheum Dis* 2014;**73**:1689–1694.

ABSTRACT

Objectives Assess golimumab's long-term efficacy/safety in psoriatic arthritis (PsA).

Methods Adults with active PsA (≥ 3 swollen and tender joints, active psoriasis) were randomly assigned to subcutaneous placebo, golimumab 50 mg, or golimumab 100 mg every 4 weeks (q4wks) through wk20. All patients received golimumab 50 mg or 100 mg q4wks from wk24 forward. Methotrexate was allowed and taken by approximately half the patients. Findings through 5 years are reported herein. Efficacy assessments included $\geq 20\%$ improvement in American College of Rheumatology (ACR20) response, C-reactive-protein-based, 28-joint-count Disease Activity Score (DAS28-CRP) response, $\geq 75\%$ improvement in Psoriasis Area and Severity Index (PASI75) scores, and PsA-modified Sharp/van der Heijde scores (SHSs).

Results 126/405 (31%) randomised patients discontinued treatment through wk252. Golimumab was effective in maintaining clinical improvement through year-5 (ACR20: 62.8–69.9%, DAS28-CRP: 75.2–84.9% for randomised patients; PASI75: 60.8–72.2% among randomised patients with $\geq 3\%$ body surface area involvement) and inhibiting radiographic progression (mean changes in PsA-modified SHS: 0.1–0.3) among patients with radiographic data. While concomitant methotrexate did not affect ACR20/PASI75, it appeared to reduce radiographic progression. No new safety signals were identified. Antibodies-to-golimumab occurred in 1.8%/10.0% of patients with/without methotrexate).

Conclusions Long-term golimumab safety/efficacy in PsA was demonstrated through 5 years.

Trial registration number NCT00265096.

Biologic anti-tumour necrosis factor- α (TNF) agents have demonstrated efficacy in psoriatic arthritis (PsA), in treating arthritic/dermatologic symptoms and inhibiting structural damage progression.^{1–5} The human anti-TNF monoclonal antibody golimumab (50/100 mg subcutaneously every 4 weeks (q4wks)) was evaluated in the GO-REVEAL Phase 3, randomised, double-blind, placebo-controlled trial in 405 patients with active PsA (NCT00265096). Study results through wk24 (placebo-controlled), wk52, and

wk104 have been published.^{6–8} We now provide a final report of efficacy and safety data in PsA patients receiving golimumab through 5 years.

PATIENTS AND METHODS

Details of patient eligibility criteria, study design, and study endpoints have been reported.^{6–8} Briefly, patients were naive to anti-TNF therapy, had active PsA (≥ 3 swollen, ≥ 3 tender joints), and had plaque psoriasis (qualifying lesion diameter ≥ 2 cm) despite therapy with disease-modifying antirheumatic or non-steroidal anti-inflammatory drugs. Concomitant methotrexate was allowed but not required. Study design and analytical details specific to the GO-REVEAL long-term extension (LTE) are provided online.

RESULTS

Patient disposition and baseline characteristics

Four hundred and five patients were randomised and treated. Consent was obtained for the first patient on 12 December 2005; the last patient completed wk268 (16 weeks after last study injection) on 13 January 2012. Patient disposition through wk24,⁶ wk52⁷ and wk104⁸ have been reported. Among the 405 randomised patients, 126 (31%) discontinued study treatment through wk252 (see online supplementary table S1). Radiographic images/scores were available for 304 patients at baseline and wk104 and for 267 patients at wk256. For details of baseline patient and disease characteristics and concomitant medications, see online tables S1, S2, S3, and supplemental material.

Efficacy results

Among randomised patients, wk256 response rates were 62.8–69.9%, 43.4–50.7% and 30.8–35.6% for American College of Rheumatology $\geq 20\%/50\%/70\%$ improvement criteria (American College of Rheumatology, ACR20, ACR50 and ACR70, respectively; [figure 1A](#)). No consistent differences in ACR response by baseline methotrexate use were observed ([figures 1B,C](#)). Mean C-reactive-protein-based, 28-joint-count Disease Activity Scores (DAS28-CRP) at wk256 were 2.8–3.0 versus

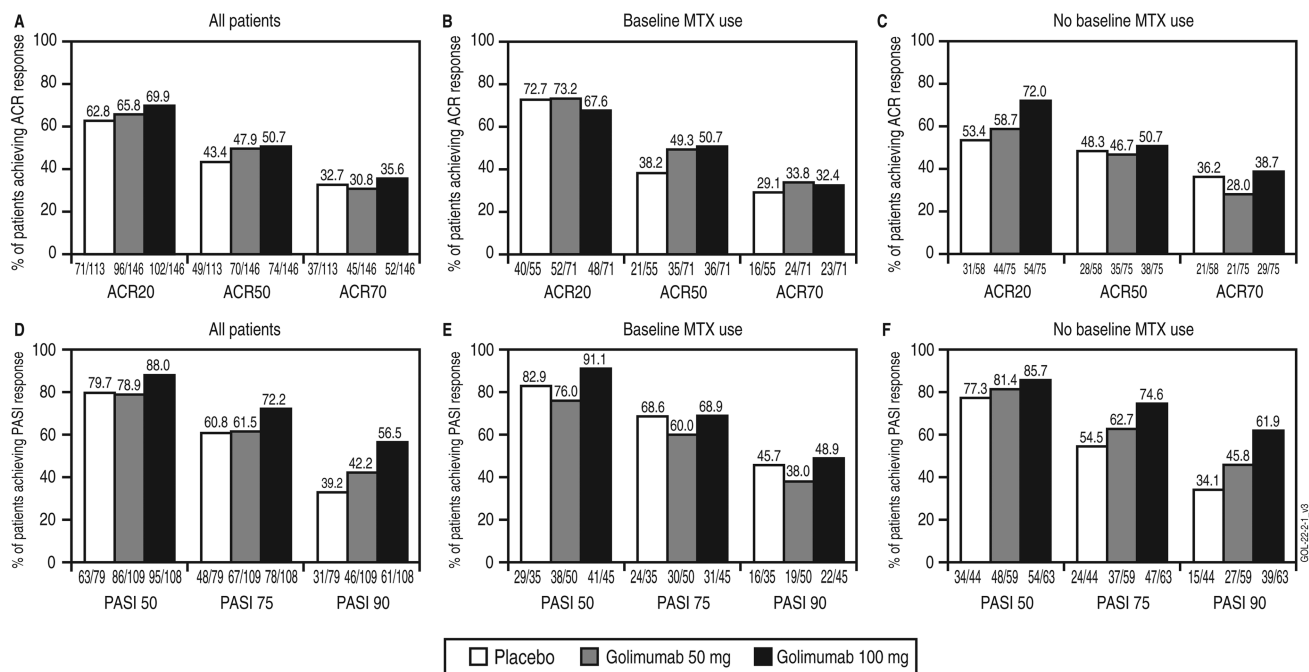


Figure 1 The proportions of patients achieving clinical improvement at week 256, defined by at least 20%, 50% and/or 70% improvement in the American College of Rheumatology response criteria (ACR20, ACR50 and ACR70, respectively; A–C) or at least 50%, 75% and/or 90% improvement in the Psoriasis Area and Severity Index response criteria (PASI50, PASI75 and PASI90, respectively) among randomised patients with baseline psoriasis involving $\geq 3\%$ body surface area (D–F) among all patients (A, D) patients with methotrexate (MTX) use at baseline (B, E), and patients with no MTX use at baseline (C, F). Analyses were based on intent-to-treat analyses by randomised group, irrespective of treatment changes during the study. The placebo group includes patients who were initially randomised to placebo and later early escaped/crossed over at week 16/24 to receive golimumab 50 mg, with the possibility to increase golimumab from 50 to 100 mg after the week-52 database lock. The golimumab 50 mg group includes patients who were initially randomised to golimumab 50 mg and later early escaped at week 16 or dose escalated after the week 52 database lock to receive golimumab 100 mg. All patients could decrease the golimumab dose from 100 to 50 mg after the week-52 database lock.

baseline scores of 4.9–5.0 (table 1). DAS28-CRP responses and improvements in dactylitis and enthesitis scores are also summarised in table 1.

At least 75% improvement in the Psoriasis Area and Severity Index (PASI75) (figure 1D) was achieved at wk256 in 60.8–72.2% of randomised patients with baseline psoriasis involving $\geq 3\%$ body surface area. No consistent differences in PASI responses by baseline methotrexate use were observed (figures 1E,F). Improvements in nail psoriasis severity were also evident (table 1).

Clinically meaningful improvements in physical function (Health Assessment Questionnaire Disability Index (HAQ-DI) decrease ≥ 0.3)⁹ were observed at wk256 for 52–58% of randomised patients. Mean wk256 HAQ-DI scores were 0.6–0.7 versus baseline scores of 1.0–1.1. Patients also experienced improvement in health-related quality of life (table 1).

The two radiographic readers demonstrated good agreement in radiographic image scoring (see online supplementary material). At wk256, observed changes (mean \pm SD) from baseline in PsA-modified radiographic scores were 0.3 \pm 3.8, 0.3 \pm 4.2, and 0.1 \pm 2.7 in the placebo, 50 mg and 100 mg groups, respectively (table 1, see online supplementary figure S1A). Patients receiving methotrexate at baseline demonstrated numerically less progression at wk256 than patients not receiving methotrexate based on mean changes in Sharp/van der Heijde score (SHS) (table 1, see online supplementary figures S1B,C). Estimated annual radiographic progression, calculated as baseline total score divided by baseline PsA duration, was markedly reduced over 5 years (see online supplementary figure S2).

The effect of golimumab dose escalation from 50 mg q4wks to 100 mg q4wks was evaluated for patients who had not achieved DAS28-CRP <2.6 or PASI75 response before dose

escalation. Increasing the golimumab dose yielded approximately 18% and 44% improvement in DAS28-CRP and PASI scores, respectively (table 1).

For details of golimumab pharmacokinetic and antibody assessments, please see online supplementary materials. Antibodies-to-golimumab developed in 6% (20/335), including 1.8% (3/165) and 10.0% (17/170), respectively, of patients receiving and not receiving methotrexate at baseline.

Safety results

Per protocol, no patient received placebo beyond wk24. In general, no differences in the types of adverse events (AE) were observed between golimumab doses (table 2). See online supplementary material for summaries of AEs reported after initiation of commercial drug, injection-site reactions, and clinical laboratory findings.

AEs leading to discontinuation observed in >1 golimumab-treated patient overall included basal cell carcinoma (basal cell carcinoma (BCC), 3–50 mg, 2–50+100 mg, 3–100 mg patients), increased alanine aminotransferase (5–50 mg, 1–50+100 mg), increased aspartate aminotransferase (3–50 mg, 1–50+100 mg), psoriatic arthropathy (1–50 mg, 2–50+100 mg), breast cancer (2–50 mg), and accidental death (1–50 mg, 1–100 mg).

Five patients died through wk268 (50 mg-climbing accident, 50 mg-small-cell lung cancer, 100 mg motor bike accident, 100 mg oesophageal cancer, 100 mg unknown cause).

Serious AEs observed in >1 golimumab-treated patient included 10 patients with BCC; five patients with myocardial infarction; three patients with cholelithiasis; and two patients each with breast cancer, abscess, cellulitis, pneumonia, arthritis, intervertebral disc degeneration, upper abdominal pain,

Table 1 Summary of efficacy and concomitant medication use at week 256 by randomised treatment group

	Placebo*	Golimumab	
		50 mg†	100 mg‡
Number of randomised patients	113	146	146
Radiographic efficacy at week 256 (among patients with SHS at weeks 0, 104, and 256)			
CHANGE in modified SHS			
Total score, N=	73	93	101
	0.3±3.8	0.3±4.2	0.1±2.7
	0.0 (−0.5, 0.5)	0.0 (−0.5, 1.0)	0.0 (0.0, 1.0)
MTX use at baseline, N=	43	48	52
	0.0±2.2	−0.3±4.8	−0.3±3.4
	0.0 (−1.0, 1.0)	0.0 (−1.5, 0.5)	0.0 (−0.5, 0.5)
No MTX use at baseline, N=	30	45	49
	0.7±5.4	0.9±3.3	0.4±1.8
	0.0 (0.0, 0.5)	0.0 (0.0, 1.5)	0.0 (0.0, 1.0)
Erosion score, N=	73	93	101
	−0.1±3.1	−0.03±2.8	−0.3±1.9
	0.0 (−0.5, 0.0)	0.0 (−0.5, 0.5)	0.0 (0.0, 0.5)
Joint space narrowing score, N=	73	94	101
	0.4±1.4	0.3±1.9	0.4±1.4
	0.0 (0.0, 0.5)	0.0 (0.0, 0.5)	0.0 (0.0, 0.5)
Pts with change in total PsA-modified SHS ≤0 (%)	46/73 (63.0)	58/93 (62.4)	66/101 (65.3)
Clinical efficacy at week 256 (intent-to-treat analysis by randomised treatment group)			
DAS28-CRP, N =	113	146	146
Baseline score	4.9±1.0	5.0±1.1	4.9±1.1
Week 256 score	3.0±1.4	2.8±1.2	2.8±1.2
DAS28-CRP responder (good/moderate) (%)	85 (75.2)	122 (83.6)	124 (84.9)
% improvement in DAS28-CRP score 12 weeks after DE among pts who had not achieved a DAS28-CRP score < 2.6 before DE§	–	–	N=47 18.0±21.2%
Enthesitis, ¶ N =	88	109	115
Baseline score	5.0±4.1	5.7±4.0	6.1±4.1
Week 256 score	2.4±4.0	1.9±3.3	2.0±3.4
Dactylitis,** N =	38	50	49
Baseline score	3.1±2.1	6.3±6.1	5.4±6.7
Week 256 score	1.2±2.3	1.3±4.9	0.8±2.1
HAQ-DI, N=	113	146	146
Baseline score	1.0±0.5	1.0±0.6	1.1±0.6
Week 256 score	0.7±0.6	0.6±0.6	0.6±0.6
Pts with HAQ-DI improvement ≥0.3 units	59 (52.2%)	79 (54.1%)	85 (58.2%)
PASI,†† N=	79	109	108
Baseline score	8.4±7.4	9.8±8.6	11.1±9.5
Week 256 score	3.0±5.8	2.7±4.5	2.2±3.9
% improvement in PASI score 12 weeks after DE among pts without PASI75 response before DE§	–	–	n=16 44.3±35.4%
NAPSI,‡‡ N=	83	95	109
Baseline score	4.4±2.2	4.7±2.2	4.6±2.1
Week 256 score	1.1±1.9	1.7±2.5	1.1±1.8
SF-36 PCS score, N=	113	146	146
Score	40.1±11.4	41.8±11.6	41.0±11.1
Improvement from baseline	8.1±10.9	8.8±11.1	8.2±11.0
SF-36 MCS score, N=	113	146	146
Score	50.9±10.1	49.5±10.4	49.6±10.6
Improvement from baseline	3.3±11.1	4.2±11.8	4.5±11.2
Concomitant medication use at wk256			
MTX (%)	46 (40.7)	59 (40.4)	73 (50.0)
Dose (prednisone equivalent mg/week)	15.2±4.6	13.6±4.6	14.2±4.5
Oral corticosteroids (%)	16 (14.2)	17 (11.6)	21 (14.4)
Prednisone-equivalent dose (mg/day)	6.1±2.1	7.5±2.9	7.5±8.2
NSAIDs (%)	68 (60.2)	93 (63.7)	98 (67.1)

Data shown are mean±SD, median (IQR) or number (%) of patients at week 256, unless otherwise specified.

*Includes patients who were initially randomised to placebo and later early escaped at week 16 or crossed over at week 24 to receive golimumab 50 mg, with the possibility after the week-52 database lock to increase the golimumab dose to 100 mg and also to decrease the golimumab dose from 100 mg to 50 mg.

†Includes patients who were initially randomised to golimumab 50 mg and later early escaped at week 16 or dose escalated after the week-52 database lock to receive golimumab 100 mg, with the possibility to decrease the dose from 100 mg to 50 mg after the week-52 database lock.

‡Includes patients randomised to receive golimumab 100 mg at week 0, with the possibility to decrease the golimumab dose from 100 mg to 50 mg after the week-52 database lock.

§Dose-escalation analyses used data from week 0 to 256, that is, from blinded and open-label portions of the study, from patients who had ≥12 weeks of follow-up after dose escalation.

¶Among patients with enthesitis at baseline.

**Among patients with dactylitis at baseline.

††Among patients with ≥3% BSA involvement at baseline.

‡‡Among patients with nail involvement at baseline.

BSA, body surface area; DAS28-CRP, C-reactive protein-based, 28-joint-count Disease Activity Score; HAQ-DI, Health Assessment Questionnaire Disability Index; DE, dose escalation from golimumab 50 mg q4w to golimumab 100 mg q4w; MCS, mental component summary; MTX, methotrexate; NAPSI, Nail Psoriasis Activity Index; NSAIDs, nonsteroidal anti-inflammatory drugs; PASI, Psoriasis Area and Severity Index; PCS, physical component summary; PsA, psoriatic arthritis; SF-36, 36-item short-form health survey, SHS, Sharp/van der Heijde score.

Table 2 Summary of safety through week 268

	Golimumab*			
	50 mg only	50 and 100 mg	100 mg only	Total
Number of golimumab-treated pts	139	146	109	394
Mean weeks of follow-up	190.0	242.1	217.3	216.9
Mean number of administrations	44.3	56.9	51.1	50.9
Pts with ≥1 AE (%)	121 (87.1)	126 (86.3)	100 (91.7)	347 (88.1)
Pts with ≥1 serious AE (%)	29 (20.9)	29 (19.9)	25 (22.9)	83 (21.1)
Pts who discontinued study (%) agent because of AE	21 (15.1)	9 (6.2)	19 (17.4)	49 (12.4)
Pts with ≥1 infection (%)	94 (67.6)	100 (68.5)	87 (79.8)	281 (71.3)
Death				
Pts with event (%)	2 (1.4)	0	3 (2.8)	5 (1.3)
Incidence/100 pt-yrs (95% CI)	0.39 (0.05 to 1.42)	0.00 (0.00 to 0.44)	0.66 (0.14 to 1.92)	0.30 (0.10 to 0.71)
Serious infection				
Pts with event (%)	5 (3.6)	4 (2.7)	6 (5.5)	15 (3.8)
Number of serious infections	5	7	7	19
Incidence/100 pt-yrs (95% CI)	0.98 (0.32 to 2.30)	1.03 (0.41 to 2.12)	1.54 (0.62 to 3.17)	1.16 (0.70 to 1.81)
MACE†				
Pts with event (%)	4 (2.9)	4 (2.7)	3 (2.8)	11 (2.8)
Number of MACE	5	4	4	13
Incidence/100 pt-yrs (95% CI)	0.98 (0.32 to 2.30)	0.59 (0.16 to 1.51)	0.88 (0.24 to 2.25)	0.79 (0.42 to 1.35)
All malignancies				
Pts with event	8	5	8	21
Incidence/100 pt-yrs (95% CI)	1.58 (0.68 to 3.12)	0.74 (0.24 to 1.72)	1.77 (0.77 to 3.49)	1.28 (0.80 to 1.96)
SIR (95% CI) relative to SEER (excluding NMSC)	1.85 (0.60 to 4.32)	0.57 (0.07 to 2.05)	1.42 (0.39 to 3.64)	1.22 (0.61 to 2.18)
Type of malignancies				
Pts with lymphoma	0	0	0	0
Pts with NMSC	3	3	4	10
Incidence/100 pt-yrs (95% CI)	0.59 (0.12 to 1.73)	0.44 (0.09 to 1.29)	0.88 (0.24 to 2.25)	0.61 (0.29 to 1.12)
Pts with other malignancies (excluding NMSC)	5	2	4	11
Incidence/100 pt-yrs (95% CI)	0.99 (0.32 to 2.30)	0.29 (0.04 to 1.06)	0.88 (0.24 to 2.26)	0.67 (0.34 to 1.20)
SIR (95% CI) relative to SEER	1.94 (0.63 to 4.52)	0.60 (0.07 to 2.16)	1.49 (0.41 to 3.81)	1.28 (0.64 to 2.28)
Golimumab injection-site reactions				
Pts with reactions (%)	14 (10.1)	8 (5.5)	15 (13.8)	37 (9.4)
Injections with reactions (%)	51/6158 (0.8)	11/8314 (0.1)	31/5572 (0.6)	93/20044 (0.5)
Number of pts with >1 markedly abnormal postbaseline value for most commonly observed abnormalities through wk256				
Elevated eosinophil count‡ (%)	3 (2.2)	3 (2.1)	2 (1.8)	8 (2.0)
Elevated total bilirubin§ (%)	5 (3.6)	5 (3.4)	1 (0.9)	11 (2.8)

Data shown are number (%) of patients, unless otherwise specified.

*With or without methotrexate.

†MACE were defined as cardiovascular deaths or cardio/cerebrovascular serious AEs and included acute myocardial infarction/ischemia, aphasia, carotid artery stenosis/disease/occlusion, death.

‡Markedly increased eosinophil count defined as ≥100% increase and value >0.8×10³/μL.

§Markedly elevated total bilirubin value defined as ≥100% increase and value >1.5 mg/dL.

AE, adverse event; MACE, major adverse cardiovascular event; NMSC, non-melanoma skin cancer; pt(s), patient(s); pt-yrs, patient-years; SEER, Surveillance, Epidemiology and End Results database; SIR, standardised incidence ratio (observed/expected based on the SEER database (2004)), adjusted for age, gender, and race).

vomiting, tibia fracture, accidental death, chest pain and superficial thrombophlebitis. Fifteen patients developed serious infections through wk268, with similar incidences across treatment groups. Few patients developed opportunistic infections, including one patient each with pulmonary tuberculosis plus legionella pneumonia, histoplasmosis and eye toxoplasmosis, all while receiving golimumab 100 mg. A patient receiving golimumab 100 mg developed non-serious herpes zoster involving the eye.

The incidence of major adverse cardiovascular events (MACE) through wk268 was similar across all treatment groups (table 2). Beyond MACE events, two golimumab patients (1–50 mg+100 mg, 1–100 mg only) had congestive heart/ventricular failure through wk268.

Malignancies were documented for 21 patients through wk268, including 10 patients with non-melanoma skin cancer

(NMSC, 1 squamous cell+basal cell, 9 basal cell) and 11 with other non-lymphoma malignancies that included breast (2–50 mg), bladder (1–50+100 mg, 1–100 mg), colon (2–50 mg, 1–100 mg), oesophageal (1–100 mg), prostate (1–100 mg), and small-cell lung (1–50 mg, 1–100 mg) cancers. The incidences of malignancies per 100 patient-years are presented in table 2. In an analysis comparing incidences of malignancies (excluding NMSC) observed in GO-REVEAL and expected rates in the general US population,¹⁰ the standard incidence ratios ranged from 0.57 to 1.85 (table 2).

DISCUSSION

We previously reported golimumab (subcutaneous 50 and 100 mg q4wks) efficacy/safety in patients with active PsA. Golimumab-treated patients displayed significant and/or

clinically meaningful improvements in all aspects of PsA versus placebo.^{6,7} Despite no control arm, findings through wk104 of the LTE also supported golimumab's clinical and radiographic benefits.⁸ The current report extends the golimumab experience by 3 years, representing the longest available clinical trial data of chronic anti-TNF treatment of PsA patients.

The GO-REVEAL trial retained more than two-thirds of randomised patients through 5 years, and although lacking a control after wk24, data through 5 years provide further insight into golimumab efficacy and safety. At the last efficacy evaluation (wk256; assessed with intent-to-treat (ITT) methodology), 63–70% and 43–51% of patients across randomised groups were ACR20 and ACR50 responders, respectively, and mean baseline DAS28-CRP scores decreased from 4.9–5.0 to <3.2 across treatment groups. Meaningful improvements were also noted in physical function, enthesitis, dactylitis, and skin manifestations, including >60% of patients achieving PASI75 improvement at wk256. Importantly, minimal changes in radiographic scores occurred from baseline to wk256 (mean change in total SHS ≤ 0.3), suggesting a long-term effect of golimumab on inhibiting radiographic progression.

No meaningful differences in efficacy outcomes were observed between the 50 mg and 100 mg doses of golimumab administered q4wks; however, analyses were limited by allowed dose changes. Similarly, analyses of clinical response in arthritis and psoriasis after dose escalation from 50 to 100 mg q4wks suggesting improved efficacy, especially in PASI scores, were limited by lack of a control arm. Golimumab dose escalation occurred in approximately one-quarter of randomised patients and, given low discontinuation rates due to lack of golimumab efficacy, likely reflects a treat-to-target therapeutic approach in patients with residual disease activity.

Golimumab safety through 5 years was also consistent with those observed previously in this PsA patient population.^{6–8} Serious infections occurred in 15 patients; a limited number of patients had opportunistic infections, all while receiving golimumab 100 mg. The incidence of antibodies to golimumab was low across the golimumab treatment groups and did not appear to affect injection-site-reaction development. Consistent with earlier observations,^{6–8} fewer methotrexate-treated than untreated patients developed antibodies to golimumab. The incidences of all malignancies excluding NMSC observed in GO-REVEAL did not differ from those expected in the general US population. No meaningful differences in safety outcomes were observed between patients receiving golimumab 50 mg, 100 mg, or both doses, except opportunistic infections (all reported for golimumab 100 mg).

Limitations of long-term data presented herein include the lack of a long-term control arm and golimumab dose changes, restricting the ability to compare golimumab 50 mg with 100 mg. To compensate for such limitations, clinical efficacy data were evaluated on an ITT basis (randomised patients with imputation for missing data). However, to avoid imputation of radiographic data, radiographic analyses were based on patients who had available images at baseline/wk104/wk256, comprising ~66% of randomised patients. Although radiographic analyses including patients with available data are possibly biased by including responders only, the alternative analyses employing all patients and imputation methodologies rely on assumptions made for patients with missing data, also possibly leading to biased estimates of radiographic progression. Baseline disease characteristics were similar between the radiographic patient subset and all randomised patients, indicating findings may be applicable to the overall study population.

Despite discussed limitations, the safety and efficacy of golimumab 50 mg and 100 mg administered subcutaneously q4wks to patients with active PsA were demonstrated through 5 years, as evidenced by sustained clinical and radiographic efficacy and a safety profile consistent with other anti-TNF agents used for PsA.¹¹

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Correction notice This article has been corrected since it was published Online First. A minor change has been made to the title.

Acknowledgements The authors thank Michelle Perate, MS and Mary Whitman, PhD (Janssen Scientific Affairs, LLC) for writing and editorial support. A complete list of study investigators was previously reported.¹⁰

Contributors DG participated in the trial design and conduct and manuscript preparation. AK participated in the trial design and conduct and manuscript preparation. GGK participated in the trial design and conduct and manuscript preparation. PM participated in the trial design and conduct and manuscript preparation. IM participated in the trial design and conduct and manuscript preparation. DvdH participated in the trial design and manuscript preparation. YZ, JL, JHL all contributed to data analysis and interpretation and manuscript preparation, and NG and AB contributed to study design/conduct, data interpretation, and manuscript preparation.

Funding The study was supported by Janssen Research & Development, LLC, Spring House, PA and Merck/Schering-Plough Corporation, Kenilworth, NJ.

Competing interests DG has received grant support, consultation fees and/or honoraria from Abbott, Amgen, Bristol-Myers Squibb, Genentech, Janssen, Merck/Schering-Plough and Wyeth. AK has received funding for clinical research sponsored by Abbott, Amgen, Janssen, and UCB. GGK has received fees as a consultant and/or advisory board member for Abbott, Almirall, Alza, Amgen, Anacor, Astellas, Barrier Therapeutics, Boehringer Ingelheim, Bristol-Myers Squibb, CombinatoRx, Exelixis, Genentech, Genzyme, Isis, Janssen, L'Oreal, Lupin Limited, Magen Biosciences, MedaCorp, Medicis, Merck/Schering-Plough, Novartis, Novo-Nordisk, Somagenics, theDerm.org, Synviva, Warner Chilcot, UCB, USANA Health Sciences and ZARS. GGK has received lecture fees from Abbott, Amgen, Astellas, Boehringer Ingelheim, Connetics, Janssen, National Psoriasis Foundation, The Foundation for Better Health Care and Warner Chilcot. PM has received research grant support, consultation fees, and speaker honoraria from Abbott, Amgen, Biogen-IDEC, Bristol-Myers Squibb, Genentech, Janssen, Pfizer, and UCB, and grant support and consultation fees from Celgene and Novartis. IM has received grant funding and honoraria from Abbott, Janssen, Roche, Merck/Schering-Plough, and Wyeth. DvdH has received consulting fees and/or research grants from AbbVie, Amgen, AstraZeneca, Augurex, BMS, Celgene, Chugai, Covagen, Daiichi, Eli-Lilly, GSK, Janssen Biologics, Merck, Novartis, Novo-Nordisk, Otsuka, Pfizer, Roche, Sanofi-Aventis, Schering-Plough, UCB, Vertex. YZ, JL, JHL, NG and AB are employees of Janssen Research & Development, LLC.

Ethics approval The study was conducted according to the Declaration of Helsinki and International Committee on Harmonisation good clinical practices. The protocol was reviewed and approved by each site's governing institutional review board or ethics committee, reflecting national requirements for study conduct approval. All patients provided written informed consent.

Provenance and peer review Not commissioned; externally peer reviewed.

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