ONLINE SUPPLEMENT

Patients and Methods

In the GO-BEFORE, GO-FORWARD, and GO-AFTER studies, study participants were adults (≥18 years) who had active (i.e., at least 4 swollen and 4 tender joints) rheumatoid arthritis (RA) according to the revised 1987 American College of Rheumatology (ACR; formerly, the American Rheumatism Association) classification criteria[44] for ≥3 months before the initial administration of study agent. In GO-BEFORE, RA patients could not have received >3 weekly doses of oral methotrexate (MTX) for RA. In the Phase 2b and GO-FORWARD trials, RA patients must have been receiving methotrexate (≥10 or 15–25 mg/week, respectively) for ≥3 months, with the dose being stable for ≥4 weeks before the start of study treatment. In GO-AFTER, RA patients must have received ≥1 dose of an anti-TNF agent (etanercept, adalimumab, or infliximab), the last dose of which must have been given ≥8 weeks (adalimumab or etanercept) or ≥12 weeks (infliximab) before initiating study treatment.

Patients in the GO-REVEAL study were adults who had active psoriatic arthritis (PsA), defined by the presence of ≥3 swollen and ≥3 tender joints, despite treatment with disease-modifying antirheumatic drugs (DMARDs) or nonsteroidal anti-inflammatory drugs (NSAIDs); the absence of circulating rheumatoid factor; and the presence of a qualifying plaque psoriasis lesion ≥2 cm in diameter. Stable doses of MTX (≤25mg/week) were allowed but not required. Patients in the GO-RAISE study were adults who had ankylosing spondylitis AS (diagnosed according to the modified New York Criteria[45]), a Bath AS Disease Activity Index[46] score ≥4, a spinal pain assessment score ≥4, and an inadequate response to NSAIDs and/or DMARDs.

In all trials, eligible patients met the prespecified tuberculosis (TB) screening criteria. Patients with positive TB skin (per local criteria) and/or whole blood interferon-based QuantiFERON®-TB Gold-In-Tube (QFT; Cellestis; Valencia, CA) testing results could participate, but had to begin treatment for latent TB before or simultaneously with the first administration of study agent.

Data collection and analyses

In the Phase 3 studies, patients could cross over from placebo to golimumab 50 mg or increase the golimumab dose from 50 mg to 100 mg in cases of inadequate response. Thus, a single patient with ≥1 adverse event (AE) may contribute data to ≥1 treatment column; each AE is attributed to the dose that the patient was receiving at the time of the event. Serum samples from patients who developed injection-site reactions were tested for the presence of antibodies to golimumab.[47] Clinically significant abnormal laboratory values were recorded as AEs; criteria prespecified by the sponsor and consistent across the trials identified laboratory values considered markedly abnormal.

The occurrences of AEs, serious adverse events, study agent discontinuation due to AEs, infections, injection-site reactions, and predefined hepatobiliary AEs (i.e., alanine aminotransferase level ≥3 times the upper limit of normal [ULN] in combination with either bilirubin level ≥2 times ULN or an AE within the hepatobiliary system-organ class of the MedDRA dictionary that was classified as serious by the investigator in accordance with regulatory guidelines) are summarized for patients in the Phase 3 trials with ≥1 event. For the rare events of death, serious infection, tuberculosis, opportunistic infection, demyelinating disorder, and malignancy, incidence rates were calculated as the number of events per

100 patient-years (/pt-yrs) of follow up, along with the corresponding exact 95% confidence intervals (CIs); data from the aforementioned Phase 2b RA trial were also included. Each infection for an individual patient was counted separately. For malignancies, other than non-melanoma skin cancer, incidences were compared with those derived from an age-, gender- and race-matched population from the 2007 US National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) database.[48] Standardized incidence ratios with 95% CIs were calculated by dividing the observed number (of events in the golimumab trials) by the expected number (of events from the SEER database).

Table S1. Safety events through week 160 by indication: pooled data from Phase 2b and Phase 3 studies of SC golimumab in rheumatological indications (RA, PsA, AS).

	Rheumatoid arthritis			Psoriatic arthritis			Ankylosing spondylitis		
	Placebo ± MTX	**Golimumab 50 mg ± MTX**	**Golimumab 100 mg ± MTX**	**Placebo ±MTX**	**Golimumab 50 mg ± MTX**	**Golimumab 100 mg ± MTX**	**Placebo ±MTX**	**Golimumab 50 mg ± MTX**	**Golimumab 100 mg ± MTX**
Number of treated patients[1]	449	788	1062	113	248	248	77	213	191
Any adverse event, n (%)	341 (75.9)	671 (85.2)	933 (87.9)	69 (61.1)	198 (79.8)	195 (78.6)	60 (77.9)	200 (93.9)	174 (91.1)
Most common system-organ classes									
Infection	167 (37.2)	467 (59.3)	689 (64.9)	29 (25.7)	143 (57.7)	146 (58.9)	25 (32.5)	144 (67.6)	130 (68.1)
Musculoskeletal disorder	95 (21.2)	249 (31.6)	424 (39.9)	18 (15.9)	70 (28.2)	78 (31.5)	20 (26.0)	95 (44.6)	95 (49.7)
General disorder	71 (15.8)	161 (20.4)	299 (28.2)	14 (12.4)	56 (22.6)	46 (18.5)	10 (13.0)	78 (36.6)	76 (39.8)
Skin disorder	73 (16.3)	158 (20.1)	279 (26.3)	16 (14.2)	58 (23.4)	47 (19.0)	9 (11.7)	68 (31.9)	60 (31.4)
Gastrointestinal disorder	127 (28.3)	278 (35.3)	400 (37.7)	19 (6.8)	69 (27.8)	63 (25.4)	17 (22.1)	88 (41.3)	90 (47.1)
Injury	39 (8.7)	143 (18.1)	227 (21.4)	8 (7.1)	48 (19.4)	56 (22.6)	6 (7.8)	39 (18.3)	46 (24.1)
Nervous disorder	51 (11.4)	147 (18.7)	244 (23.0)	12 (10.6)	47 (19.0)	41 (16.5)	6 (7.8)	69 (32.4)	65 (34.0)
Any serious adverse event, n (%)	43 (9.6)	146 (18.5)	269 (25.3)	8 (7.1)	23 (9.3)	27 (10.9)	6 (7.8)	23 (10.8)	29 (15.2)
Most common system-organ classes									
Infection	11 (2.4)	39 (4.9)	101 (9.5)	5 (4.4)	3 (1.2)	5 (2.0)	1 (1.3)	6 (2.8)	11 (5.8)
Musculoskeletal disorder	9 (2.0)	24 (3.0)	62 (5.8)	0 (0.0)	0 (0.0)	6 (2.4)	0 (0.0)	5 (2.3)	6 (3.1)
Neoplasm	6 (1.3)	24 (3.0)	29 (2.7)	0 (0.0)	5 (2.0)	2 (0.8)	1 (1.3)	1 (0.5)	0 (0.0)
Injury	6 (1.3)	14 (1.8)	29 (2.7)	0 (0.0)	2 (0.8)	3 (1.2)	1 (1.3)	5 (2.3)	5 (2.6)
Cardiac disorder	3 (0.7)	12 (1.5)	19 (1.8)	1 (0.9)	2 (0.8)	4 (1.6)	0 (0.0)	1 (0.5)	2 (1.0)
Gastrointestinal disorder	3 (0.7)	12 (1.5)	26 (2.4)	0 (0.0)	3 (1.2)	3 (1.2)	3 (3.9)	8 (3.8)	2 (1.0)
Number of treated patients[2]	484	856	1132	113	248	248	77	213	191
Death, n (%)	1 (0.2)	5 (0.6)	14 (1.2)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Incidence per 100 pt-yrs (95% CI)	0.35 (0.01, 1.95)	0.37 (0.12, 0.86)	0.58 (0.32, 0.98)	0.00 (0.00, 7.04)	0.41 (0.05, 1.50)	0.00 (0.00, 0.53)	0.00 (0.00, 10.24)	0.00 (0.00, 0.63)	0.00 (0.00, 0.67)
Serious infection, n (%)	12 (2.5)	46 (5.4)	101 (8.9)	4 (3.5)	4 (1.6)	6 (2.4)	1 (1.3)	7 (3.3)	10 (5.2)
Incidence per 100 pt-yrs (95% CI)	4.90 (2.68, 8.22)	4.28 (3.25, 5.54)	6.35 (5.38, 7.44)	9.41 (2.56, 24.08)	0.83 (0.23, 2.12)	1.25 (0.50, 2.57)	3.42 (0.09, 19.05)	1.68 (0.73, 3.31)	3.14 (1.72, 5.27)
Tuberculosis, n (%)	0 (0.0)	4 (0.5)	11 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)
Incidence per 100 pt-yrs (95% CI)	0.00 (0.00, 1.05)	0.30 (0.08, 0.76)	0.46 (0.23, 0.82)	0.00 (0.00, 7.04)	0.00 (0.00, 0.62)	0.00 (0.00, 0.53)	0.00 (0.00, 10.24)	0.00 (0.00, 0.63)	0.22 (0.01, 1.25)
Opportunistic infection, n (%)	0 (0.0)	2 (0.2)	6 (0.5)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	1 (0.5)	0 (0.0)
Incidence per 100 pt-yrs (95% CI)	0.00 (0.00, 1.05)	0.15 (0.02, 0.53)	0.25 (0.09, 0.55)	0.00 (0.00, 7.04)	0.00 (0.00, 0.62)	0.36 (0.04, 1.29)	0.00 (0.00, 10.24)	0.21 (0.01, 1.17)	0.00 (0.00, 0.67)
Malignancy, n (%)	6 (1.2)	22 (2.6)	31 (2.7)	0 (0.0)	6 (2.4)	5 (2.0)	1 (1.3)	1 (0.5)	2 (1.0)
Incidence per 100 pt-yrs (95% CI)	2.11 (0.77, 4.59)	1.64 (1.03, 2.48)	1.31 (0.89, 1.86)	0.00 (0.00, 7.04)	1.25 (0.46, 2.72)	0.89 (0.29, 2.08)	3.44 (0.09, 19.14)	0.21 (0.01, 1.17)	0.45 (0.05, 1.63)
SIR (95% CI) versus SEER database[3]	1.09	1.64	1.15	0.00	1.30	0.64	0.00	0.70	0.00

	(0.13, 3.92)	(0.92, 2.71)	(0.68, 1.81)	(0.00, 14.57)	(0.27, 3.81)	(0.08, 2.32)	(0.00, 32.82)	(0.02, 3.89)	(0.00, 2.19)
Lymphoma, n (%)	0 (0.0)	0 (0.0)	6 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)
Incidence per 100 pt-yrs (95% CI)	0.00	0.00	0.25	0.00	0.00	0.00	0.00	0.21	0.00
	(0.00, 1.05)	(0.00, 0.22)	(0.09, 0.55)	(0.00, 7.04)	(0.00, 0.62)	(0.00, 0.53)	(0.00, 10.24)	(0.01, 1.17)	(0.00, 0.67)
SIR (95% CI) versus SEER database	0.00	0.00	8.98	0.00	0.00	0.00	0.00	11.97	0.00
	(0.00, 38.33)	(0.00, 7.81)	(3.30, 19.55)	(0.00, 291.44)	(0.00, 25.76)	(0.00, 19.68)	(0.00, 571.98)	(0.30, 66.71)	(0.00, 38.96)
Demyelinating disorder, n (%)	0 (0.0)	0 (0.0)	3 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Incidence per 100 pt-yrs (95% CI)	0.00	0.00	0.17	0.00	0.00	0.00	0.00	0.00	0.00
	(0.00, 1.05)	(0.00, 0.22)	(0.05, 0.43)	(0.00, 7.04)	(0.00, 0.62)	(0.00, 0.53)	(0.00, 10.24)	(0.00, 0.63)	(0.00, 0.67)

[1] Patients may appear in ≥1 treatment column. For 'Any adverse event' and 'Any serious adverse event', only the 5 Phase 3 trials are included.

[2] Patients may appear in ≥1 treatment column. For rare adverse events, the Phase 2b and Phase 3 trials are included.

[3] Excluding nonmelanoma skin cancer.

AS – ankylosing spondylitis, CI – confidence interval, MTX – methotrexate, PsA – psoriatic arthritis, pt-yrs – patient-years, RA – rheumatoid arthritis, SC – subcutaneous, SEER –Surveillance, Epidemiology and End Results, SIR – standardized incidence ratio

Table S2. Occurrence of infections through week 24 and through week 160 by use of oral corticosteroid use at baseline: pooled data from Phase 2b and Phase 3 studies of SC golimumab in rheumatological indications (RA, PsA, AS).

	Placebo ± MTX	Golimumab 50 mg ± MTX	Golimumab 100 mg ± MTX
INFECTIONS THROUGH WEEK 24			
Patients with oral corticosteroid use at baseline, n	306	567	432
-All infections - Incidence per 100 pt-yrs (95% CI)	92.55 (75.78, 111.94)	94.38 (78.06, 113.12)	82.81 (70.86, 96.19)
-Serious infections - Incidence per 100 pt-yrs (95% CI)	7.11 (3.41, 13.07)	4.52 (1.82, 9.31)	6.26 (3.58, 10.16)
-Opportunistic infections - Incidence per 100 pt-yrs (95% CI)	0.00 (0.00, 2.11)	0.00 (0.00, 1.92)	0.00 (0.00, 1.15)
Patients without oral corticosteroid use at baseline, n	364	742	853
-All infections - Incidence per 100 pt-yrs (95% CI)	100.54 (84.12, 119.23)	107.52 (92.10, 124.79)	120.81 (106.95, 135.96)
-Serious infections - Incidence per 100 pt-yrs (95% CI)	4.16 (1.67, 8.57)	2.41 (0.78, 5.61)	3.53 (1.76, 6.31)
-Opportunistic infections - Incidence per 100 pt-yrs (95% CI)	0.00 (0.00, 1.77)	0.00 (0.00, 1.44)	0.32 (0.01, 1.77)
INFECTIONS THROUGH WEEK 160			
Patients with oral corticosteroid use at baseline, n	306	567	432
-All infections - Incidence per 100 pt-yrs (95% CI)	116.88 (100.89, 134.68)	92.25 (86.26, 98.54)	87.00 (82.32, 91.87)
-Serious infections - Incidence per 100 pt-yrs (95% CI)	7.34 (3.79, 12.83)	4.29 (3.08, 5.82)	7.39 (6.07, 8.91)
-Opportunistic infections - Incidence per 100 pt-yrs (95% CI)	0.00 (0.00, 1.83)	0.10 (0.00, 0.58)	0.20 (0.04, 0.59)
Patients without oral corticosteroid use at baseline, n	364	742	853
-All infections - Incidence per 100 pt-yrs (95% CI)	123.06 (107.89, 139.77)	102.89 (97.54, 108.46)	102.31 (97.78, 107.00)
-Serious infections - Incidence per 100 pt-yrs (95% CI)	3.63 (1.46, 7.49)	2.16 (1.44, 3.10)	3.25 (2.49, 4.18)
-Opportunistic infections - Incidence per 100 pt-yrs (95% CI)	0.00 (0.00, 1.56)	0.15 (0.02, 0.54)	0.27 (0.09, 0.62)

AS – ankylosing spondylitis, CI – confidence interval, MTX – methotrexate, PsA – psoriatic arthritis, pt-yrs – patient-years, RA – rheumatoid arthritis, SC – subcutaneous