Online supplement to: Safety and Efficacy of Subcutaneous Golimumab in Patients with Active Rheumatoid Arthritis despite Methotrexate Therapy: Final 5-year Results of the GO-FORWARD Trial. doi:10.3899/jrheum.150712

Supplementary Table 1. Patient disposition through week 256

			Golimumab + MTX			
	Placebo + MTX	Golimumab 100 mg + Placebo	50 mg	100 mg	Combined	Total
Patients randomized, n	133	133	89	89	178	444
Patients treated, n	133	133	89	89	178	444
Treatment received						
Placebo + MTX	133 (100.0)	0	0	0	0	133 (30.0)
Placebo + MTX → golimumab 50 mg + MTX (early escaped at week 16)	42 (31.6)	0	0	0	0	42 (9.5)
Dose escalated to 100 mg + MTX (LTE)[a]	18 (13.5)	0	0	0	0	18 (4.1)
Dose decreased to 50 mg + MTX (LTE)[b]	3 (2.3)	0	0	0	0	3 (0.7)
Placebo + MTX → golimumab 50 mg + MTX (crossover at week 24)	82 (61.7)	0	0	0	0	82 (18.5)
Dose escalated to 100 mg + MTX (LTE)[a]	36 (27.1)	0	0	0	0	36 (8.1)
Dose decreased to 50 mg + MTX (LTE)[b]	13 (9.8)	0	0	0	0	13 (2.9)
Golimumab 100 mg + Placebo	0	133 (100.0)	0	0	0	133 (30.0)
Golimumab 100 mg + Placebo → golimumab 100 mg + MTX (early escaped at week 16)	0	36 (27.1)	0	0	0	36 (8.1)
Dose decreased to 50 mg + MTX (LTE)[b]	0	4 (3.0)	0	0	0	4 (0.9)
Golimumab 100mg + Placebo did not early escape at week 16	0	97 (72.9)	0	0	0	97 (21.8)
Dose decreased to 50 mg + Placebo (LTE)[b]	0	17 (12.8)	0	0	0	17 (3.8)
Golimumab 50 mg + MTX	0	0	89 (100.0)	0	89 (50.0)	89 (20.0)
Golimumab 50 mg + MTX did not early escape at week 16	0	0	74 (83.1)	0	74 (41.6)	74 (16.7)
Dose escalated to 100 mg + MTX (LTE)[a]	0	0	33 (37.1)	0	33 (18.5)	33 (7.4)
Dose decreased to 50 mg + MTX (LTE)[b]	0	0	8 (9.0)	0	8 (4.5)	8 (1.8)
Golimumab 50 mg + MTX → 100 mg + MTX (early escaped at week 16)	0	0	15 (16.9)	0	15 (8.4)	15 (3.4)
Dose decreased to 50 mg + MTX (LTE)[b]	0	0	3 (3.4)	0	3 (1.7)	3 (0.7)
Golimumab 100 mg + MTX	0	0	0	89 (100.0)	89 (50.0)	89 (20.0)
Dose decreased to 50 mg + MTX (LTE)[b]	0	0	0	13 (14.6)	13 (7.3)	13 (2.9)

Data presented as n (%). MTX, methotrexate; LTE, long-term extension

[a] Per protocol, after the week 52 database lock, the golimumab dose could be increased from 50 mg to 100 mg at the discretion of the investigator.

[b] Based on protocol amendment 3, the golimumab dose could be decreased from 100 mg to 50 mg at the discretion of the investigator.

Supplementary Table 2. Annual incidence per 100 patient-years of serious infections, total malignancies, lymphoma, and deaths.

	Placebo+MTX	50 mg + MTX only	50 and 100mg + Placebo or MTX	Golimumab 100 mg +/- MTX	Total Golimumab
Patients treated with golimumab, n	134	105	145	184	434
Serious infections					
Year 1					
Patients treated during year 1, n	134	105	145	184	434
Total patient-years of follow-up	55	76	122	174	372
Observed number of events	1	2	3	18	23
Incidence/100 patient-years (95% CI)	1.82 (0.05, 10.12)	2.65 (0.32, 9.57)	2.46 (0.51, 7.18)	10.33 (6.12, 16.32)	6.18 (3.92, 9.28)
Year 2					
Patients treated during year 2, n	0	98	145	158	401
Total patient-years of follow-up		88	145	145	378
Observed number of events		3	4	4	11
Incidence/100 patient-years (95% CI)		3.40 (0.70, 9.95)	2.77 (0.75, 7.08)	2.75 (0.75, 7.05)	2.91 (1.45, 5.21)
Year 3					
Patients treated during year 3, n	0	79	144	137	360
Total patient-years of follow-up		77	142	133	353
Observed number of events		1	2	3	6
Incidence/100 patient-years (95% CI)		1.29 (0.03, 7.21)	1.41 (0.17, 5.09)	2.25 (0.46, 6.58)	1.70 (0.62, 3.70)
Year 4					
Patients treated during year 4, n	0	76	138	130	344
Total patient-years of follow-up		74	137	127	338
Observed number of events		1	8	2	11
Incidence/100 patient-years (95% CI)		1.36 (0.03, 7.56)	5.83 (2.52, 11.49)	1.58 (0.19, 5.69)	3.26 (1.63, 5.83)
Year 5					
Patients treated during year 5, n	0	71	135	123	329
Total patient-years of follow-up		76	148	135	359
Observed number of events		3	5	3	11
Incidence/100 patient-years (95% CI)		3.93 (0.81, 11.49)	3.37 (1.10, 7.88)	2.23 (0.46, 6.52)	3.06 (1.53, 5.48)
Total Malignancies					
Year 1					
Patients treated during year 1, n	134	105	145	184	434
Total patient-years of follow-up	55	75	122	172	369
Observed number of events	2	2	1	5	8
Incidence/100 patient-years (95% CI)	3.65 (0.44, 13.18)	2.67 (0.32, 9.63)	0.82 (0.02, 4.57)	2.90 (0.94, 6.77)	2.17 (0.94, 4.27)
Year 2					
Patients treated during year 2, n	0	96	144	155	395
Total patient-years of follow-up		86	143	142	372

Supplementary Table 2. Annual incidence per 100 patient-years of serious infections, total malignancies, lymphoma, and deaths.

	Placebo+MTX	50 mg + MTX only	50 and 100mg + Placebo or MTX	Golimumab 100 mg +/- MTX	Total Golimumab
Observed number of events		2	1	3	6
Incidence/100 patient-years (95% CI)		2.31 (0.28, 8.35)	0.70 (0.02, 3.89)	2.11 (0.44, 6.18)	1.62 (0.59, 3.52)
Year 3					
Patients treated during year 3, n	0	79	142	133	354
Total patient-years of follow-up		77	139	129	346
Observed number of events		0	2	0	2
Incidence/100 patient-years (95% CI)		0.00 (0.00, 3.87)	1.43 (0.17, 5.18)	0.00 (0.00, 2.32)	0.58 (0.07, 2.09)
Year 4					
Patients treated during year 4, n	0	76	135	126	337
Total patient-years of follow-up		74	134	123	331
Observed number of events		0	0	2	2
Incidence/100 patient-years (95% CI)		0.00 (0.00, 4.06)	0.00 (0.00, 2.23)	1.63 (0.20, 5.88)	0.60 (0.07, 2.18)
Year 5					
Patients treated during year 5, n	0	71	132	120	323
Total patient-years of follow-up		75	144	130	349
Observed number of events		2	2	5	9
Incidence/100 patient-years (95% CI)		2.67 (0.32, 9.64)	1.39 (0.17, 5.01)	3.85 (1.25, 8.97)	2.58 (1.18, 4.89)
Lymphoma					
Year 1					
Patients treated during year 1, n	134	105	145	184	434
Total patient-years of follow-up	55	76	122	174	372
Observed number of events	0	0	0	0	0
Incidence/100 patient-years (95% CI)	0.00 (0.00, 5.44)	0.00 (0.00, 3.97)	0.00 (0.00, 2.45)	0.00 (0.00, 1.72)	0.00 (0.00, 0.81)
Year 2					
Patients treated during year 2, n	0	98	145	158	401
Total patient-years of follow-up		88	145	145	378
Observed number of events		0	0	1	1
Incidence/100 patient-years (95% CI)		0.00 (0.00, 3.40)	0.00 (0.00, 2.07)	0.69 (0.02, 3.84)	0.26 (0.01, 1.47)
Year 3					
Patients treated during year 3, n	0	79	144	137	360
Total patient-years of follow-up		77	142	133	353
Observed number of events		0	0	0	0
Incidence/100 patient-years (95% CI)		0.00 (0.00, 3.87)	0.00 (0.00, 2.11)	0.00 (0.00, 2.25)	0.00 (0.00, 0.85)
Year 4					
Patients treated during year 4, n	0	76	138	130	344
Total patient-years of follow-up		74	137	127	338

Supplementary Table 2. Annual incidence per 100 patient-years of serious infections, total malignancies, lymphoma, and deaths.

	Placebo+MTX	50 mg + MTX only	50 and 100mg + Placebo or MTX	Golimumab 100 mg +/- MTX	Total Golimumab
Observed number of events		0	0	1	1
Incidence/100 patient-years (95% CI)		0.00 (0.00, 4.06)	0.00 (0.00, 2.18)	0.79 (0.02, 4.40)	0.30 (0.01, 1.65)
Year 5					
Patients treated during year 5, n	0	71	135	123	329
Total patient-years of follow-up		76	148	135	359
Observed number of events		0	0	0	0
Incidence/100 patient-years (95% CI)		0.00 (0.00, 3.92)	0.00 (0.00, 2.02)	0.00 (0.00, 2.23)	0.00 (0.00, 0.83)
Deaths					
Year 1					
Patients treated during year 1, n	134	105	145	184	434
Total patient-years of follow-up	55	76	122	174	372
Observed number of events	0	0	0	2	2
Incidence/100 patient-years (95% CI)	0.00 (0.00, 5.44)	0.00 (0.00, 3.97)	0.00 (0.00, 2.45)	1.15 (0.14, 4.15)	0.54 (0.07, 1.94)
Year 2					
Patients treated during year 2, n	0	98	145	158	401
Total patient-years of follow-up		88	145	145	378
Observed number of events		0	0	2	2
Incidence/100 patient-years (95% CI)		0.00 (0.00, 3.40)	0.00 (0.00, 2.07)	1.38 (0.17, 4.97)	0.53 (0.06, 1.91)
Year 3					
Patients treated during year 3, n	0	79	144	137	360
Total patient-years of follow-up		77	142	133	353
Observed number of events		0	0	0	0
Incidence/100 patient-years (95% CI)		0.00 (0.00, 3.87)	0.00 (0.00, 2.11)	0.00 (0.00, 2.25)	0.00 (0.00, 0.85)
Year 4					
Patients treated during year 4, n	0	76	138	130	344
Total patient-years of follow-up		74	137	127	338
Observed number of events		0	1	0	1
Incidence/100 patient-years (95% CI)		0.00 (0.00, 4.06)	0.73 (0.02, 4.06)	0.00 (0.00, 2.36)	0.30 (0.01, 1.65)
Year 5					
Patients treated during year 5, n	0	71	135	123	329
Total patient-years of follow-up		76	148	135	359
Observed number of events		0	0	1	1
Incidence/100 patient-years (95% CI)		0.00 (0.00, 3.92)	0.00 (0.00, 2.02)	0.74 (0.02, 4.14)	0.28 (0.01, 1.55)

CI, confidence interval; MTX, methotrexate

Supplementary Table 3. Clinical efficacy and patient-reported outcomes at week 256 using observed data.

			Golimumab + MTX			
	Placebo + MTX	Golimumab 100 mg + Placebo	50 mg	100 mg	Combined	Total
Clinical efficacy						
ACR20	69 (75.8)	71 (76.3)	57 (77.0)	44 (74.6)	101 (75.9)	241 (76.0)
ACR50	43 (47.3)	48 (51.6)	40 (54.1)	28 (47.5)	68 (51.1)	159 (50.2)
ACR70	21 (23.1)	27 (29.0)	28 (37.8)	15 (25.4)	43 (32.3)	91 (28.7)
DAS28-CRP response[a]	81 (90.0)	83 (90.2)	65 (89.0)	52 (88.1)	117 (88.6)	281 (89.5)
DAS28-CRP remission[b]	38 (42.2)	41 (44.6)	35 (47.9)	27 (45.8)	62 (47.0)	141 (44.9)
DAS28-CRP ≤3.2	56 (62.2)	59 (64.1)	46 (63.0)	38 (63.3)	84 (63.2)	199 (63.2)
SDAI ≤3.3	25 (27.8)	21 (22.8)	20 (27.4)	17 (28.3)	37 (27.8)	83 (26.3)
CDAI ≤2.8	23 (25.3)	21 (22.6)	22 (29.7)	18 (29.5)	40 (29.6)	84 (26.3)
Improvement from baseline in HAQ-DI, mean ± SD	0.44 ± 0.68	0.50 ± 0.63	0.61 ± 0.66	0.47 ± 0.55	0.55 ± 0.62	0.50 ± 0.64)\
Patients with improvement in HAQ-DI ≥0.25	61 (67.0)	59 (63.4)	55 (74.3)	42 (71.2)	97 (72.9)	217 (68.5)

Data presented as n (%) unless otherwise noted. [a] Good or moderate response as defined by the European League Against Rheumatism. [b] DAS28-CRP score <2.6. MTX, methotrexate; ACR20/50/70, ≥20%/50%/70% improvement in American College of Rheumatology criteria; DAS28-CRP, 28-joint count disease activity score using C-reactive protein; SDAI, simplified disease activity index; CDAI, clinical disease activity index; HAQ-DI, Health Assessment Questionnaire-Disability Index; SD, standard deviation