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Janssen Biotech, Inc.
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SUPPLEMENTAL APPENDIX

Phase 2 Analysis

In Phase 2, 176 patients were randomized to a single IV infusion at week 0 with golimumab (132 subjects to golimumab [44 to each 1 mg/kg, 2 mg/kg, or 4 mg/kg group]) or placebo (44 patients; Supplemental Figure 1A).

Demographic characteristics were generally comparable across treatment groups, with the exception of CRP which was lower in the 4mg/kg golimumab group (Supplemental Table S1). At baseline, the golimumab and placebo groups had comparable median Mayo scores (8.0 in each treatment group).

The median changes from baseline in the Mayo score at week 6 were lower than anticipated, but greater for golimumab-treated (-2.0 in the 1 mg/kg and 2 mg/kg groups, -1.5 in the 4 mg/kg group) than for placebo-treated patients (-1.0) (Supplemental Table S2). While the proportions of patients in clinical response were greater for the 1- and 2-mg/kg groups, relative to placebo, in general golimumab did not differentiate from placebo with respect to remission and mucosal healing rates at week 6. (Supplemental Table S2).

Golimumab-treated patients in Phase 2 showed greater change in Mayo scores and numerically greater proportions of patients in clinical response at week 6 compared with placebo patients; however, no dose response was observed. The benefit of a single golimumab IV infusion was lower than expected across all efficacy measures (Supplemental Table S2) and lower than that observed in PURSUIT-SC.[11]

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SUPPLEMENTAL APPENDIX

Table S1. Summary of Baseline Demographics and Disease Characteristics; All Randomized Patients in Phase 2

		----------Golimumab----------				
	Placebo (N=44)	1 mg/kg (N=44)	2 mg/kg (N=44)	4 mg/kg (N=44)	All (N=132)	Total (N=176)
Male patients, n (%)	27 (61.4)	30 (68.2)	23 (52.3)	28 (63.6)	81 (61.4)	108 (61.4)
Race, n (%)						
Caucasian	33 (75.0)	33 (75.0)	35 (79.5)	34 (77.3)	102 (77.3)	135 (76.7)
Black	2 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.1)
Asian	7 (15.9)	9 (20.5)	9 (20.5)	10 (22.7)	28 (21.2)	35 (19.9)
Other	2 (4.5)	2 (4.5)	0 (0.0)	0 (0.0)	2 (1.5)	4 (2.3)
Age (years)						
Mean ± SD	41.0 ± 12.69	41.7 ± 17.11	41.1 ± 13.39	40.2 ± 14.84	41.0 ± 15.09	41.0 ± 14.49
Median (IQR)	41.0 (30.5, 49.0)	40.0 (26.0, 52.5)	42.5 (28.5, 52.0)	38.5 (27.0, 49.0)	40.0 (27.0, 51.5)	41.0 (28.0, 50.5)
UC disease duration(yrs)						
Mean ± SD	6.9 ± 7.44	5.8 ± 4.71	6.9 ± 6.71	6.4 ± 5.55	6.4 ± 5.69	6.5 ± 6.15
Median (IQR)	4.25 (1.98, 9.25)	4.99 (1.88, 8.28)	4.12 (2.69, 8.77)	4.77 (2.18, 9.08)	4.46 (2.26, 8.44)	64.28 (2.15, 8.78)
Extent of disease n (%)						
Limited to left side of colon	25 (56.8)	22 (50.0)	28 (63.6)	25 (56.8)	75 (56.8)	100 (56.8)
Extensive	19 (43.2)	22 (50.0)	16 (36.4)	19 (43.2)	57 (43.2)	76 (43.2)
Mayo score						
Mean ± SD	8.1 ± 1.56	8.3 ± 1.36	8.4 ± 1.47	8.0 ± 1.47	8.2 ± 1.43	8.2 ± 1.46
Median (IQR)	8.0 (7.0, 9.0)	8.0 (7.0, 9.0)	8.0 (7.0, 9.0)	8.0 (7.0, 9.0)	8.0 (7.0, 9.0)	8.0 (7.0, 9.0)
CRP (mg/L), n	42	42	43	40	125	167
Mean ± SD	11.4 ± 18.98	12.8 ± 19.20	13.9 ± 21.90	7.4 ± 11.07	11.5 ± 18.17	11.5 ± 18.32
Median (IQR)	5.4 (2.7, 11.2)	5.8 (3.0, 14.0)	5.4 (1.6, 14.2)	3.2 (0.7, 8.2)	5.0 (1.3, 12.1)	5.0 (1.5, 12.1)

CRP, C-reactive protein; IQR, interquartile range; SD, standard deviation; UC, ulcerative colitis; yrs, years

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SUPPLEMENTAL APPENDIX

Table S2. Efficacy Findings; All randomized patients in Phase 2 (excluding noncompliant site)

		----------Golimumab----------			
Variable	**Placebo**	**1 mg/kg**	**2 mg/kg**	**4 mg/kg**	**Combined**
	(N=41)	(N=43)	(N=44)	(N=44)	(N=131)
Mayo score change from baseline at week 6[a, b]					
Baseline					
Mean ± SD	8.0 ± 1.55	8.3 ± 1.37	8.4 ± 1.47	8.0 ± 1.47	8.2 ± 1.44
Median (IQR)	8.0 (7.0, 9.0)	8. 0(7.0, 9.0)	8.0 (7.0, 9.0)	8.0 (7.0, 9.0)	8.0 (7.0, 9.0)
week 6 change					
Mean ± SD	-1.3 ± 2.50	-2.0 ± 2.73	-2.3 ± 3.08	-1.8 ± 2.21	-2.0 ± 2.69
Median (IQR)	-1.0 (-3.0, 0.0)	-2.0 (-4.0, 0.0)	-2.0 (-4.5, 0.0)	-1.5 (-3.0, 0.0)	-2.0 (-4.0, 0.0)
P-value		0.241	0.099	0.479	0.152
Clinical response at week 6, n (%) [a,b]	10 (24.4)	18 (41.9)	18 (40.9)	13 (29.5)	49 (37.4)
P-value		0.090	0.105	0.593	0.126
Clinical remission at week 6, n (%)[a,b]	4 (9.8)	4 (9.3)	8 (18.2)	3 (6.8)	15 (11.5)
P-value		0.944	0.265	0.622	0.763
Mucosal healing at week 6, n (%)[a,b]	10 (24.4)	15 (34.9)	13 (29.5)	13 (29.5)	41 (31.3)
P-value		0.293	0.593	0.593	0.398
Partial Mayo score change from baseline					
Baseline					
Mean ± SD	5.6 ± 1.38	5.8 ± 1.17	5.9 ± 1.25	5.6 ± 1.21	5.8 ± 1.21
Median (IQR)	6.0 (5.0, 6.0)	6.0 (5.0, 6.0)	6.0 (5.0, 7.0)	6.0 (5.0, 6.0)	6.0 (5.0, 6.0)

SUPPLEMENTAL APPENDIX

Table S2. Efficacy Findings; All randomized patients in Phase 2 (excluding noncompliant site)

		----------Golimumab----------			
Variable	**Placebo**	**1 mg/kg**	**2 mg/kg**	**4 mg/kg**	**Combined**
	(N=41)	(N=43)	(N=44)	(N=44)	(N=131)
week 2 change					
Mean ± SD	-0.7 ± 1.48	-1.9 ± 1.90	-1.9 ± 1.97	-1.3 ± 1.29	-1.7 ± 1.75
Median (IQR)	-1.0 (-1.0, 0.0)	-2.0 (-3.0, 0.0)	-2.0 (-3.0, 0.0)	-1.0 (-2.0, -0.5)	-2.0 (-3.0, 0.0)
week 4 change					
Mean ± SD	-0.9 ± 1.68	-2.1 ± 2.14	-1.9 ± 1.97	-1.4 ± 1.51	-1.8 ± 1.90
Median (IQR)	-1.0 (-2.0, 0.0)	-2.0 (-4.0, 0.0)	-1.5 (-3.0, 0.0)	-1.0 (-2.0, 0.0)	-2.0 (-3.0, 0.0)
week 6 change					
Mean ± SD	-0.9 ± 2.02	-1.4 ± 2.24	-1.7 ± 2.39	-1.2 ± 1.73	-1.4 ± 2.13
Median (IQR)	-1.0 (-2.0, 0.0)	-1.0 (-3.0, 0.0)	-1.0 (-3.0, 0.0)	-1.0 (-2.0, 0.0)	-1.0 (-3.0, 0.0)
CRP (mg/L) change from baseline, n[a,b]					
Baseline	40	41	43	40	124
Mean ± SD	11.8 ± 19.40	12.4 ± 19.21	13.9 ± 21.87	7.4 ± 11.07	11.3 ± 18.16
Median (IQR)	6.1 (2.5, 11.7)	5.6 (3.0, 13.8)	5.4 (1.6, 14.2)	3.2 (0.7, 8.2)	5.0 (1.3, 12.0)
week 2 change					
Mean ± SD	-3.9 ± 16.83	-7.1 ± 17.02	-5.7 ± 13.22	-3.6 ± 9.64	-5.5 ± 13.62
Median (IQR)	-1.5 (-2.5, 0.2)	-2.7 (-6.5, -0.6)	-1.3 (-6.2, 0.0)	-0.9 (-4.4, -0.1)	-1.9 (-5.9, -0.3)
P-value		0.038	0.218	0.304	0.069
week 4 change					
Mean ± SD	-4.2 ± 15.10	-4.9 ± 20.01	-3.0 ± 16.23	-3.4 ± 10.61	-3.7 ± 16.02
Median (IQR)	-0.2 (-3.5, 1.1)	-1.5 (-5.9, 0.2)	-0.8 (-5.4, 0.0)	-0.6 (-4.2, 0.3)	-0.9 (-5.3, 0.1)
P-value		0.268	0.575	0.713	0.405
week 6 change					
Mean ± SD	-1.8 ± 25.63	-4.8 ± 17.34	-2.2 ± 15.48	-0.1 ± 13.57	-2.4 ± 15.55

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Table S2. Efficacy Findings; All randomized patients in Phase 2 (excluding noncompliant site)

		----------Golimumab----------			
Variable	**Placebo**	**1 mg/kg**	**2 mg/kg**	**4 mg/kg**	**Combined**
	(N=41)	(N=43)	(N=44)	(N=44)	(N=131)
Median (IQR)	-0.1 (-4.6, 1.8)	-2.6 (-8.8, 1.6)	-0.5 (-6.2, 0.2)	0.1 (-1.6, 3.4)	-0.5 (-3.7, 1.1)
P-value		0.567	0.733	0.162	0.880
IBDQ change from baseline [a,b]					
Baseline, n	39	43	42	43	128
Mean ± SD	137.2 ± 39.26	128.9 ± 33.17	123.6 ± 32.31	135.0 ± 32.97	129.2 ± 32.90
Median (IQR)	134.0 (113.0, 170.0)	126.0 (104.0, 158.0)	126.5 (102.0, 148.0)	138.0 (115.0, 154.0)	129.0 (108.5, 154.0)
week 6 change					
Mean ± SD	10.3 ± 26.49	24.7 ± 34.70	27.4 ± 33.22	15.1 ± 31.40	22.4 ± 33.29
Median (IQR)	7.0 (-6.0, 25.0)	18.0 (0.0, 43.0)	22.0 (0.0, 46.0)	8.0 (0.0, 31.0)	16.5 (0.0, 38.5)
P-value		0.057	0.010	0.461	0.034

a Patients who had a prohibited change in medication or had an ostomy or colectomy prior to the designated analysis timepoint were considered not to be in clinical response or clinical remission and not to have mucosal healing; for Mayo and partial Mayo scores, IBDQ score, and CRP, the respective baseline value was carried forward from the time of the event onward

b Patients who had all 4 mayo subscores missing at the designated analysis timepoint were considered not tobe in clinical response or clinical remission and had their last available Mayo subscores carried forward to impute the Missing Mayo score or partial Mayo scores. Patients who had a missing endoscopy subscore at the designated analysis timepoint were considered not to have mucosal healing. Patients who had a missing partial Mayo score, IBDQ score , and CRP at the designated analysis timepoint had the last available value carried forward.

CRP, C-reactive protein; IBDQ, Inflammatory Bowel Disease Questionnaire; IQR, interquartile range; SD, standard deviation; UC, ulcerative colitis

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Figure S1. Patient disposition through Week 6 among patients randomized (A) in Phase 2, (B) while Phase 2 data were being analyzed, (C) in Phase 3, and (D) all randomized patients.

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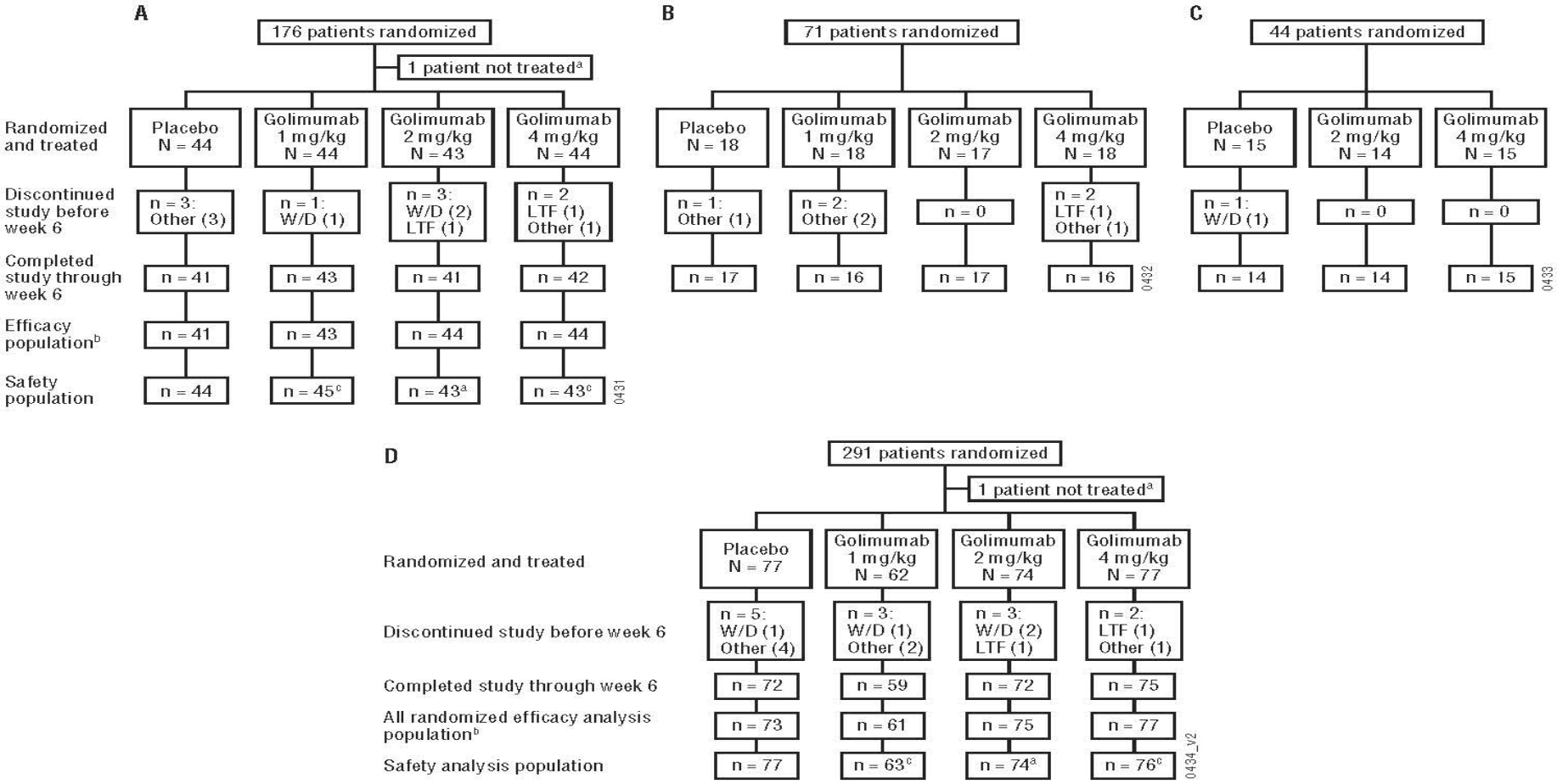
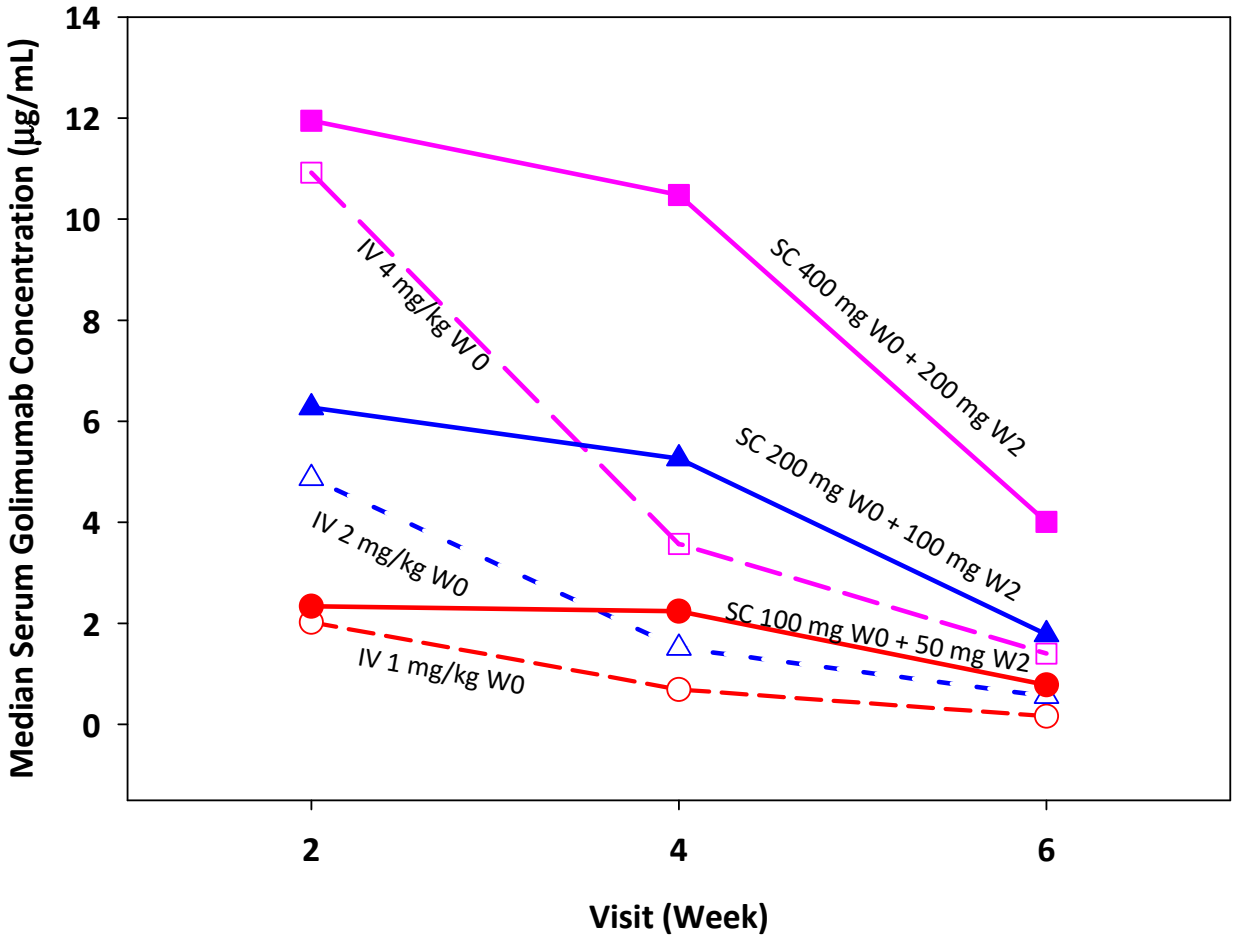


[a] The single patient randomized but never treated was assigned to the golimumab 2 mg/kg group.
[b] Excludes patients because of noncompliance at one study site.
[c] One patient randomized to golimumab 4 mg/kg only received 0.4 mg/kg and was analyzed for safety with the golimumab 1 mg/kg groups.
LTF = lost to follow-up; W/D = withdrew consent

Figure S2. Median Serum Golimumab Concentration by Study Visit (Week) and by Induction Dose and Regimen



PURSUIT-IV (dashed lines, open symbols); PURSUIT-SC (solid lines, solid symbols)