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**Janssen Biotech, Inc.**
**Exhibit 2095**
**Accord v. Janssen**
**IPR2026-00259**
Ex. 2095-001

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## SUPPLEMENTAL APPENDIX

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## SUPPLEMENTAL APPENDIX

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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]



Ex. 2095-006

## 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

## 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) |



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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) |
| **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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## 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) |
| 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

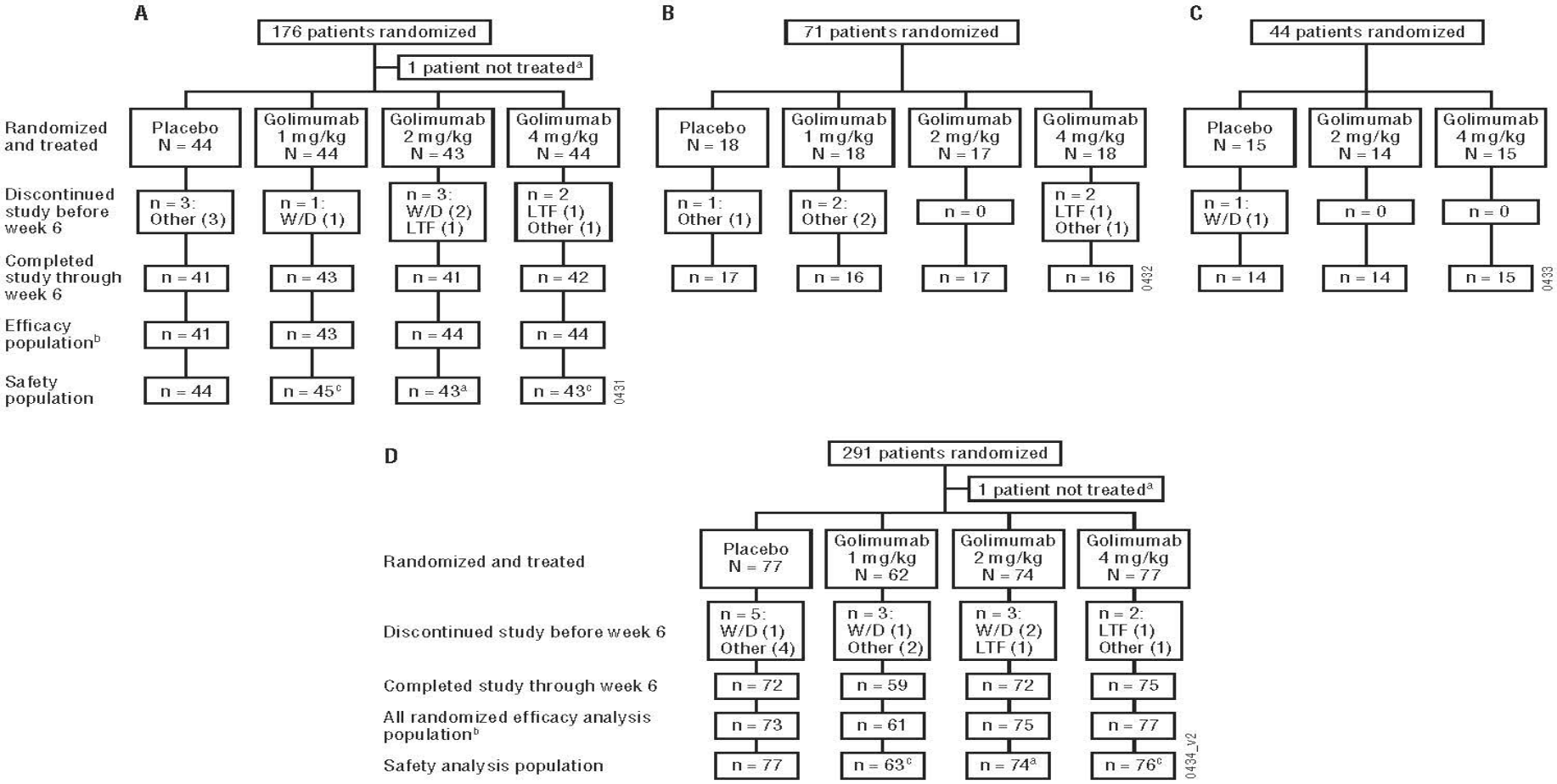
b Patients who had all 4 mayo subscores missing at the designated analysis timepoint were considered not tobe in clinical response or clinical remission and had their last available Mayo subscores carried forward to impute the Missing Mayo score or partial Mayo scores. Patients who had a missing endoscopy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

## SUPPLEMENTAL APPENDIX

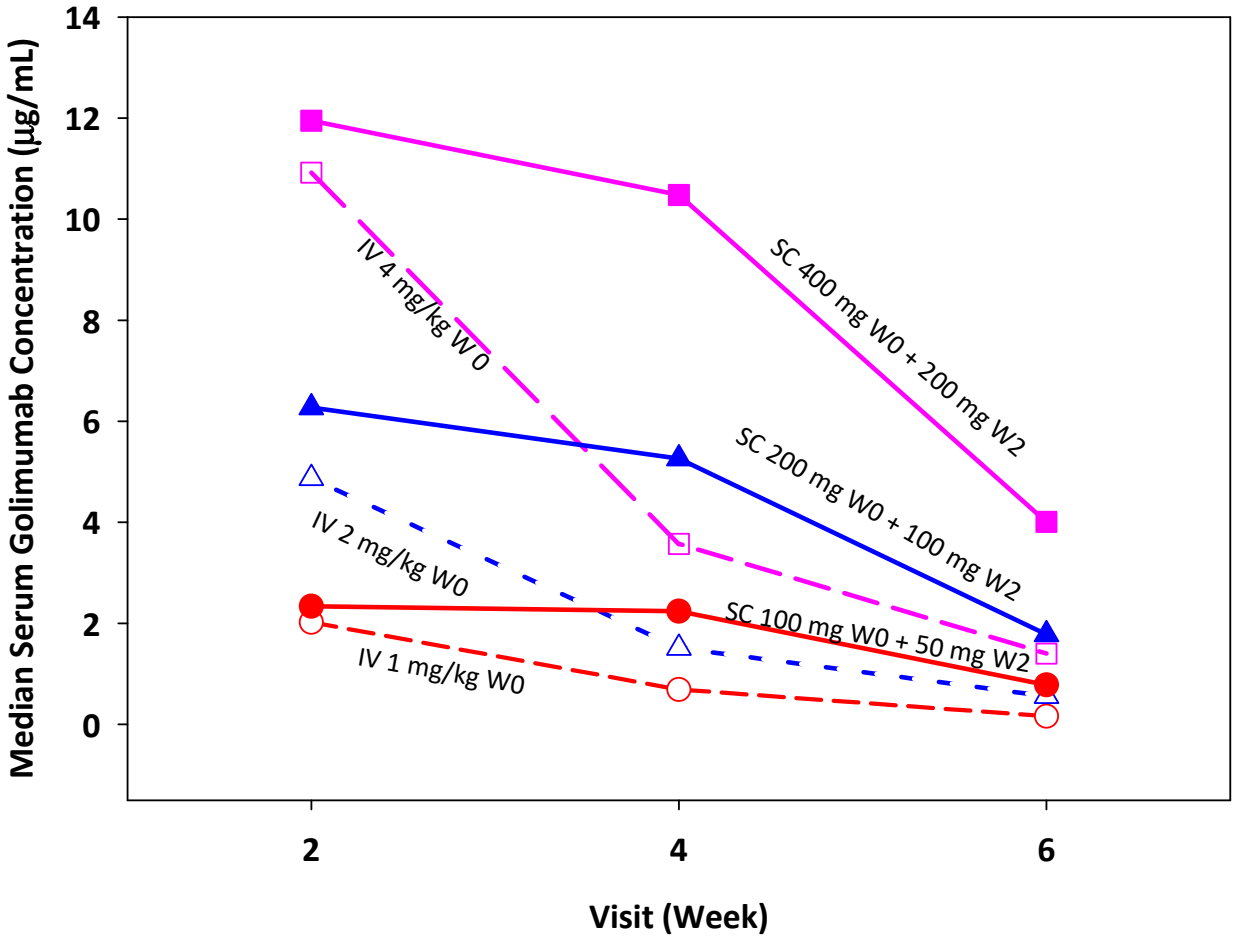
**Figure S1**. Patient disposition through Week 6 among patients randomized (A) in Phase 2, (B) while Phase 2 data were being analyzed, (C) in Phase 3, and (D) all randomized patients.

# SUPPLEMENTAL APPENDIX




[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)