14.7-27.3% of pts had initial PROMIS T-scores within 0.5SD of normal. There was a significant ($p<0.0001$) relationship between PI and F T-scores and the respective 4 questions on the P29v2.

Conclusion: Avoiding floor effects in pts who initiated TNFi therapy with near-normal PROMIS scores, PROMIS instruments demonstrated a robust T-score change in response to initiation of TNFi therapy.

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PROMIS Physical Function T-Score Change:

Effect of Baseline Assessment

PROMIS Pain Interference SF6b T-Score Change:

Effect of Baseline Assessment

PROMIS Fatigue SF7a T-Score Change:

Effect of Baseline Assessment

Figure 1

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AB0385

INTEGRATED SAFETY ANALYSIS ACROSS PHASE 3 CLINICAL STUDIES INCLUDING THE CONTROLLED AND UNCONTROLLED PERIODS FOR INTRAVENOUS GOLIMUMAB IN RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, AND ANKYLOSING SPONDYLITIS

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Background: The GO-FURTHER, GO-VIBRANT, and GO-ALIVE randomized controlled trials evaluated the efficacy and safety of intravenous

(IV) golimumab (GLM) in patients (pts) with active rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS), respectively.

Objectives: This integrated analysis assessed safety events across indications in pts who received IV GLM.

Methods: Integrated safety data from 3 Phase 3, double-blind, placebo (PBO)-controlled trials were analyzed up to week (WK) 112 in RA pts and up to WK 60 in PsA and AS pts. Pts received either IV PBO or IV GLM (2 mg/kg) at 0, 4, 12, and 20 WKS. PBO pts crossed over to IV GLM at WK 24, except RA pts randomized to PBO who met early escape criteria crossed over at WK 16 and AS pts randomized to PBO who crossed over at WK 16. Cumulative adverse events (AEs) were reported by indication and pooled by treatment. Anti-drug antibodies (ADAs) were evaluated.

Table 1.

Variables	RA ^a IV GLM	PsA ^b IV GLM	AS ^b IV GLM	All IV GLM
Treated patients, n	584	460	204	1248
Average duration of follow up, wks	95.9	47.2	51.8	70.7
Patients who discontinued due to an AE	41 (7.0)	17 (3.7)	4 (2.0)	62 (5.0)
Patients with ≥1 AE	462 (79.1)	234 (50.9)	113 (55.4)	809 (64.8)
Patients with ≥1 SAE	106 (18.2)	24 (5.2)	7 (3.4)	137 (11.0)
Patients with ≥1 infection	287 (49.1)	105 (22.8)	67 (32.8)	459 (36.8)
Patients with ≥1 serious infection	36 (6.2)	10 (2.2)	3 (1.5)	49 (3.9)
Patients with ≥1 infusion reaction	27 (4.6)	4 (0.9)	3 (1.5)	34 (2.7)
ADA-positive patients ^c , %	23.4	22.0	20.2	22.3

Patients n (%) reporting safety events during the placebo-controlled and uncontrolled study periods are reported, unless otherwise specified.
^aBased on safety events that occurred up to week 112; ^bBased on safety events that occurred up to week 60
^cAssessed using a drug-tolerant enzyme immunoassay based on IV GLM patients with appropriate samples through week 52 (RA, n=552; PsA, n=450; AS, n=203; and All, n=1205)
 ADA, anti-drug antibody; AE, adverse event; AS, ankylosing spondylitis; IV GLM, intravenous golimumab; PsA, psoriatic arthritis; RA, rheumatoid arthritis; SAE, serious adverse event

Table 2.

Variables	RA ^a		PsA ^b		AS ^b		All	
	IV GLM	Placebo	IV GLM	Placebo	IV GLM	Placebo	IV GLM	Placebo
Treated patients, n	584	197	460	239	204	103	1248	539
Average duration of follow up, wks	95.9	21.0	47.2	23.2	51.8	16.1	70.7	21.0
Opportunistic infections (95% confidence interval)	0.4 (0.1, 1.0)	0 (0, 3.8)	0 (0, 0.7)	0 (0, 2.8)	0 (0, 1.5)	0 (0, 9.4)	0.2 (0.1, 0.6)	0 (0, 1.4)
All malignancies (95% confidence interval)	0.5 (0.2, 1.1)	0 (0, 3.8)	0.5 (0.1, 1.7)	0.2 (0, 6.8)	0 (0, 1.5)	0 (0, 9.4)	0.2 (0, 0.9)	0 (0, 3.3)
Active TB (95% confidence interval)	0.2 (0, 0.7)	0 (0, 3.8)	0.5 (0.1, 1.7)	0 (0, 2.8)	0 (0, 2.7)	0 (0, 9.4)	0.3 (0, 1.4)	0 (0, 1.4)
Death (95% confidence interval)	0.5 (0.2, 1.1)	1.3 (0, 7.0)	0.2 (0, 1.3)	1.9 (0, 6.8)	0 (0, 1.5)	0 (0, 9.4)	0.4 (0.1, 0.8)	1.4 (0.3, 4.0)

Incidence per 100 patient-years are reported, unless otherwise specified.
^aBased on safety events that occurred up to week 112
^bBased on safety events that occurred up to week 60
 AS, ankylosing spondylitis; IV GLM, intravenous golimumab; PsA, psoriatic arthritis; RA, rheumatoid arthritis; TB, tuberculosis

Results: Overall, 1248 pts were treated with IV GLM across indications. A numerically greater proportion (%) of IV GLM pts with RA reported safety events than pts with PsA or AS (Table 1): SAEs (18.2 vs 5.2 vs 3.4), infections (49.1 vs 22.8 vs 32.8), serious infections (6.2 vs 2.2 vs 1.5), and infusion reactions (4.6 vs 0.9 vs 1.5). Incidence (per 100 pt-years) of opportunistic infections, malignancy, active tuberculosis, and death with IV GLM was low (≤ 0.5) across indications (Table 2). Infections were the most commonly reported type of SAE among pooled IV GLM pts; the most frequent was pneumonia (10 [0.8%]). Incidence (per 100 pt-years) of serious infections was similar among IV GLM pts with and without corticosteroid use (3.35 vs 3.37, respectively). Overall, 1 IV GLM pt (PsA) experienced a demyelination event. A numerically greater proportion of IV GLM pts discontinued due to an AE than PBO pts (5.0% vs 0.9%, respectively). In IV GLM pts with baseline alanine aminotransferase (ALT) $\leq$ upper limit of normal (ULN), 1.2% had post-baseline ALT elevations $\geq 5\times$ ULN. The proportion of IV GLM and PBO pts with post-baseline ALT elevations $\geq 5\times$ ULN was 2.1% vs 0% with methotrexate and 0.7% vs 1.4% without methotrexate use at baseline, respectively. Using a drug-tolerant enzyme immunoassay, the incidence of ADAs was 22% through WK 52 across indications, which primarily consisted of low titer ADAs.

Conclusion: IV GLM demonstrated a consistent safety profile across indications in the PBO-controlled (up to WK 24) and uncontrolled study periods. Similar to WK 24 (1), more safety events occurred in RA pts, who represented the largest study population with older pts, longer disease duration, and more concomitant medication use.

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AB0386 RESPONSE TO BIOLOGIC THERAPY IS INFLUENCED BY THE BODY MASS INDEX IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Biologic therapies have been bringing huge advantage in the treatment of rheumatoid arthritis, but response to the therapy is heterogeneous. The influence of the body mass index to the treatment is still controversial.

Objectives: To identify the factors influencing in the response to biologic therapy (bio naïve).

Methods: The analysis of the patients with rheumatoid arthritis who were initiated biologics therapy (bio naïve) between January 2011 to December 2016 in the rheumatology department of a hospital in Japan, was conducted. The effects were evaluated by EULAR response criteria after 6 months of biologic therapy, and factors influencing the response were analyzed in terms of the baseline characteristics (sex, age, disease duration, body mass index, tender joint count, swollen joint count, Patient's visual analog scale, Doctor's visual analog scale, erythrocyte sedimentation rate, C-reactive protein, Disease Activity Score in 28 joints, Modified Health Assessment Questionnaire, Methotrexate use, Prednisolone use).

Table 1.

Table 1. Difference of the baseline characteristics of RA patients between "Good or Moderate response" and "No response" of EULAR response criteria after 6 months of biologic therapy.

	Good or Moderate response (n=82)	No response (n=63)	p-value
Female sex, no. (%)	69 (84.1%)	53 (84.1%)	0.9975
Age, years	55.4 ± 15.6	59.2 ± 12.9	0.1115
Disease duration, years	6.6 ± 3.6	7.8 ± 3.9	0.0477
BMI, kg/m ²	22.0 ± 3.4	24.4 ± 5.2	0.0008
≥ 25, no. (%)	12 (14.6%)	22 (35%)	0.0043
TJC	5.6 ± 6.1	4.0 ± 5.4	0.0972
SJC	3.4 ± 4.8	1.5 ± 2.4	0.0018
Patient's VAS (range 0-100)	46.6 ± 24.6	34.4 ± 27.4	0.0052
Doctor's VAS (range 0-100)	44.6 ± 25.8	34.3 ± 28.0	0.0223
ESR mm/hour	62.8 ± 34.2	59.0 ± 31.8	0.5702
CRP mg/dL	1.7 ± 2.1	0.9 ± 1.7	0.0094
DAS28-ESR	4.9 ± 1.2	4.2 ± 1.3	0.0015
DAS28-CRP	3.9 ± 1.2	3.1 ± 1.3	<0.0001
mHAQ	0.5 ± 0.5	0.5 ± 0.6	0.3829
Concomitant therapy			
MTX, no. (%)	62 (75.6%)	47 (74.6%)	0.8894
MTX dose, mg/week	7.4 ± 4.6	7.8 ± 5.0	0.7134
Steroid, no. (%)	46 (56.1%)	48 (76.2%)	0.0120
Prednisolone dose, mg/day	1.6 ± 2.3	3.9 ± 8.8	0.5156

* Values are the mean ± SD unless otherwise indicated. RA = rheumatoid arthritis; BMI = body mass index; TJC = tender joint count; SJC = swollen joint count; VAS = visual analog scale; ESR = erythrocyte sedimentation rate; CRP = C-reactive protein; DAS28 = Disease Activity Score in 28 joints; mHAQ = Modified Health Assessment Questionnaire; MTX = Methotrexate; PSL = Prednisolone.

Table 2.

Table 2. Logistic regression analysis of "Good or Moderate response" of EULAR response criteria after 6 months of biologic therapy by baseline body mass index among Tumor Necrosis Factor users, IL-6 receptor inhibitor users and CTLA4-Ig users.

Biologics	Odds Ratio	95% confidence interval	p-value
TNF inhibitor	0.88	0.78-0.99	0.0428
IL-6 receptor inhibitor	0.75	0.61-0.93	0.0093
CTLA4-Ig	0.95	0.79-1.13	0.5757

Results: There were differences of baseline characteristics in disease duration and body mass index between the patients who achieved "Good or Moderate response" and "No response" of EULAR response criteria after 6 months of biologic therapy (table 1). The latter was more significant, and the difference was found among biologics (table 2).

Conclusion: Body mass index influence in the response to first biologic therapy in patients with rheumatoid arthritis.

Disclosure of Interests: None declared

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AB0387 SATISFACTION OF PATIENTS AND PHYSICIANS WITH TREATMENTS FOR RHEUMATOID ARTHRITIS: A NATIONWIDE SURVEY IN CHINA

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Background: Treatment satisfaction is important for adherence to therapy both for patients and physicians. There is no full understanding of the treatment satisfaction for rheumatoid arthritis (RA) in China.

Objectives: The aim is to explore the treatment satisfaction between rheumatologists and RA patients across China and the factors associated with patients' satisfaction.

Table 1.

Table 1. TSQM-II summary scores of patients' and physicians' satisfaction.

Treatment		Patients	Physicians	P
All medications for patients/ csDMARDs for physicians	N	1237	146	
Effectiveness	Median (range)	83.3 (0-100)	66.7 (33.3-100)	
Side effects	Median (range)	100 (16.7-100)	75 (16.7-100)	
Convenience	Median (range)	81.3 (18.6-100)	68.8 (31.3-100)	
Global satisfaction	Median (range)	83.3 (100)	66.7 (16.7-100)	
bDMARDs	N	335	146	
Effectiveness	Median (range)	83.3 (0-100)	75 (33.3-100)*	0.302
Side effects	Median (range)	100 (8.3-100)	87.5 (16.7-100)*	<0.001
Convenience	Median (range)	75 (0-100)	68.8 (12.5-100)	0.001
Global satisfaction	Median (range)	75 (0-100)	75 (16.7-100)*	0.889

*p < 0.05, bDMARDs vs. csDMARDs in physicians.