OP 404

The UNITI Jr Study: Safety and Efficacy Results of Ustekinumab in Pediatric Patients With Crohn's Disease

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SPEAKER DISCLOSURE

Anne M. Griffiths

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Background and Objective

Before 2025, infliximab and adalimumab were the only approved compounds for the treatment of Crohn's disease (CD) in children and adolescents under 18 years of age

Ustekinumab, an interleukin-12/23p40 antagonist, has been approved in the European Union and the United States for the treatment of moderately to severely active CD in patients ≥2 years old[1-4]

In a Phase 1 study, mg/kg dosing did not consistently result in similar exposures in the lowest body weight subgroups, prompting the adoption of body surface area (BSA)-based dosing[1]

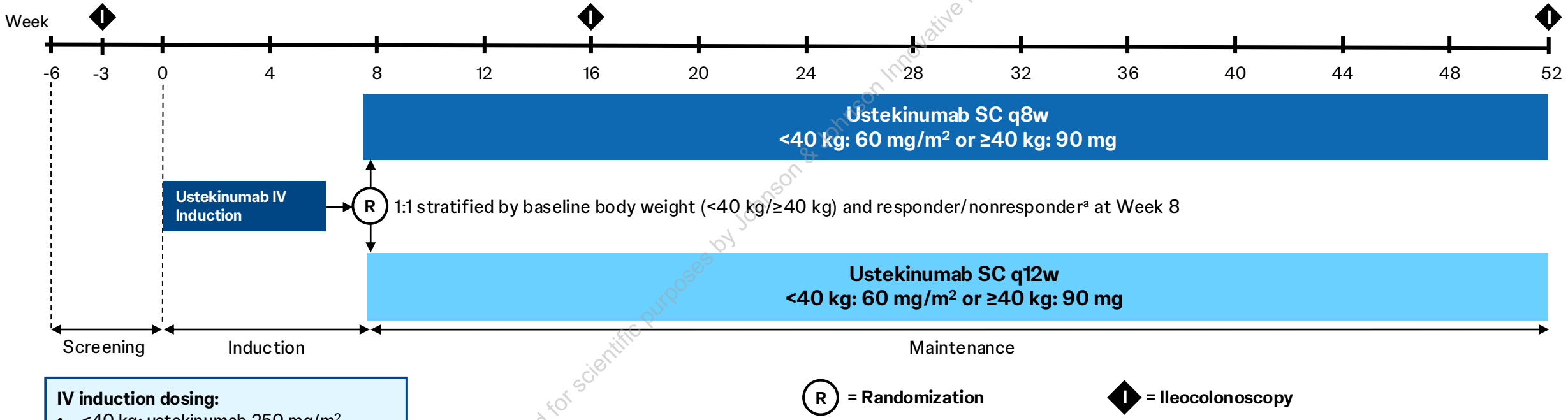
Study Objective: UNITI Jr is a Phase 3, randomized, controlled trial (NCT04673357) evaluating the efficacy and safety of ustekinumab in pediatric patients with moderately to severely active CD

1. Rosh JR, et al. *J Crohns Colitis*. 2021;15(11):1931–42; 2. Turner D, et al. *J Pediatr Gastroenterol Nutr*. 2024;79:315–24; 3. Stelara - opinion on variation to marketing authorisation. European Medicines Agency. URL: https://www.ema.europa.eu/en/medicines/human/variation/stelara; 4. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2026/761044Orig1s020,%20125261Orig1s172ltr.pdf.

UNITI Jr Study Design

Key Eligibility Criteria:

- Children ≥2 to <18 years old with a PCDAI score of >30
- Inadequate response/intolerance to biologic therapies, corticosteroids, or immunosuppressants (thiopurines/MTX)
- Ileocolonoscopic ulceration or increased CRP (>3.0 mg/L) or fecal calprotectin (≥250 µg/g)



IV induction dosing:

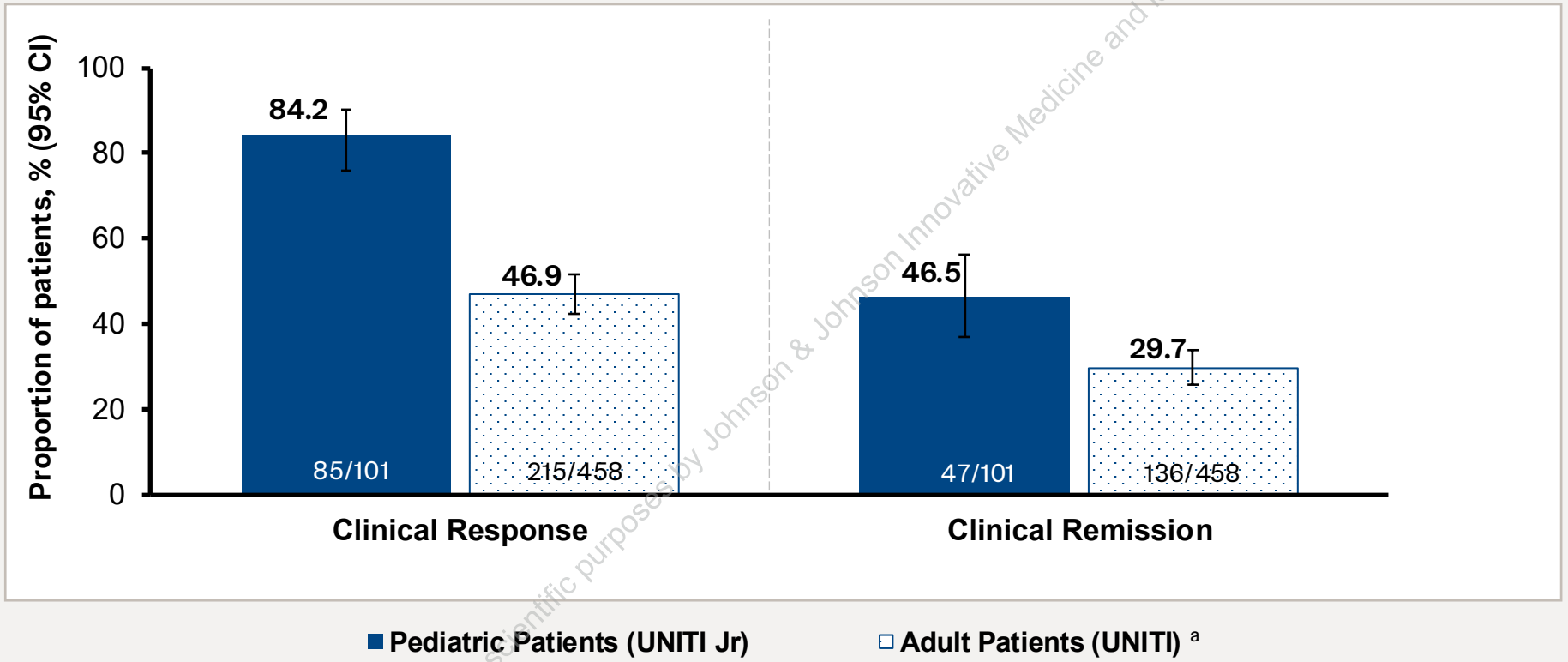
- <40 kg: ustekinumab 250 mg/m²
- ≥40 kg to ≤55 kg: ustekinumab 260 mg
- >55 kg to ≤85 kg: ustekinumab 390 mg
- >85 kg: ustekinumab 520 mg

[a]Response was defined as a PCDAI decline ≥12.5 points with a total PCDAI score ≤30 and nonresponse as a PCDAI decline <12.5 points. CRP, C-reactive protein; IV, intravenous; MTX, methotrexate; PCDAI, Pediatric Disease Activity Index; q8w, every 8 weeks; q12w, every 12 weeks; SC, subcutaneous.

Baseline Characteristics

	Ustekinumab		
	q8w (n=48)	q12w (n=49)	Total[a] (N=101)
Demographics			
Age, years, median (IQR)	14.0 (12.0; 15.0)	14.0 (12.0; 16.0)	14.0 (12.0; 15.0)
Female	37.5%	42.9%	40.6%
Race, Asian/Black/White	8.3/2.1/89.6%	20.1/4.1/85.7%	8.9/3.0/87.1%
BMI Z-score, median (IQR)	-0.37 (-0.87; 0.43)	-0.48 (-0.82; 0.35)	-0.46 (-0.84; 0.35)
Weight, <30 kg/≥30-<40 kg/≥40 kg	6.3/22.9/70.8%	16.3/10.2/73.5%	10.9/17.8/71.3%
Disease Characteristics			
CD disease duration, years	2.6 (2.0)	2.8 (2.5)	2.6 (2.2)
PCDAI score, median (IQR)	40.0 (35.0; 45.0)	40.0 (35.0; 47.5)	40.0 (35.0; 45.0)
CDAI score, mean (SD)	359.4 (135.9)	371.5 (105.7)	365.2 (120.6)
CRP, mg/L	18.2 (25.5)	20.5 (26.9)	19.2 (25.8)
Fecal calprotectin, mg/kg	2818.8 (3577.0)	2776.2 (2780.7)	2765.7 (3121.2)
Biologic naïve	37.5%	46.9%	42.6%
Biological failure	62.5%	49.0%	56.4%
Concomitant Medications			
Corticosteroids	27.1%	20.4%	24.8%
Immunomodulatory drugs	37.5%	46.9%	42.6%
5-Aminosalicylate	33.3%	32.7%	31.7%

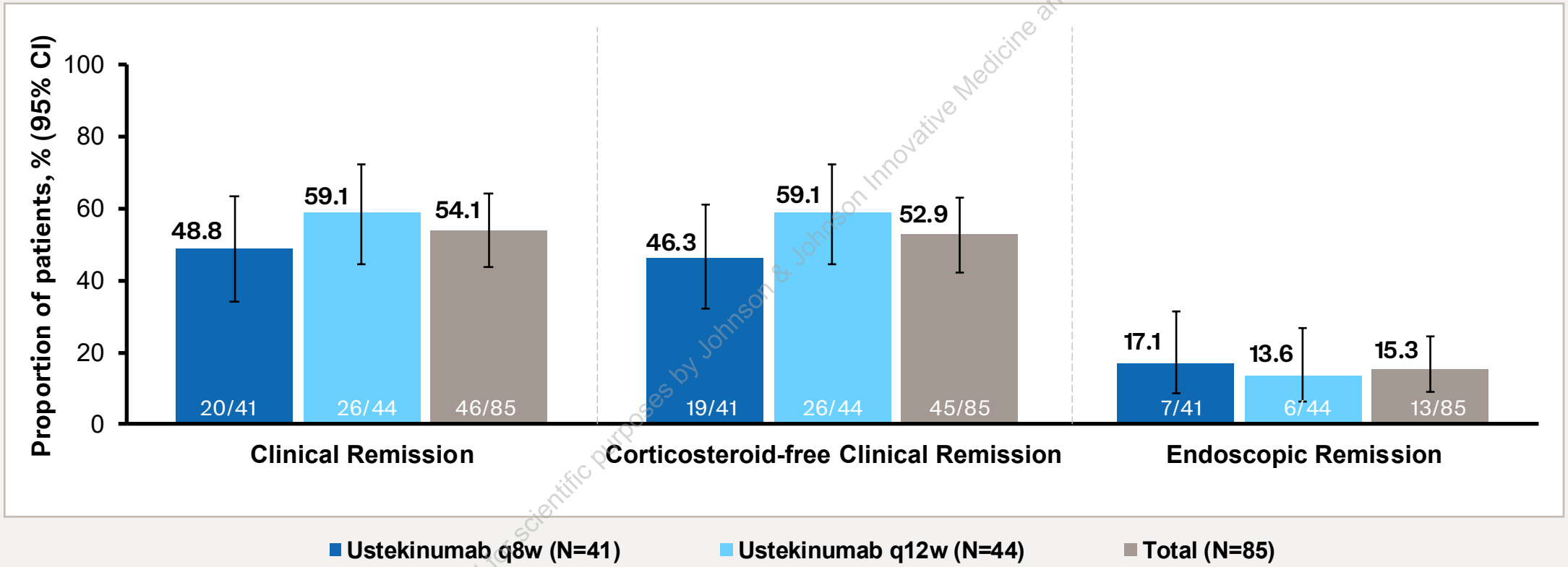
Week 8 Clinical Response and Clinical Remission Rates in Pediatric Patients vs Historical Rates in Adults



Pediatric clinical response: reduction from baseline in the PCDAI of ≥12.5 points with total PCDAI ≤30
Adult clinical response: reduction from baseline in the CDAI of ≥100 points or total CDAI score ≤150
Pediatric clinical remission: PCDAI ≤10
Adult clinical remission: CDAI <150

[a]Adult patients received ustekinumab IV 6 mg/kg (Feagan BJ, et al. *N Engl J Med*. 2016;375(20):1946–60). CI, confidence interval.

Remission Rates in Pediatric Patients Were Maintained at Week 52[a]



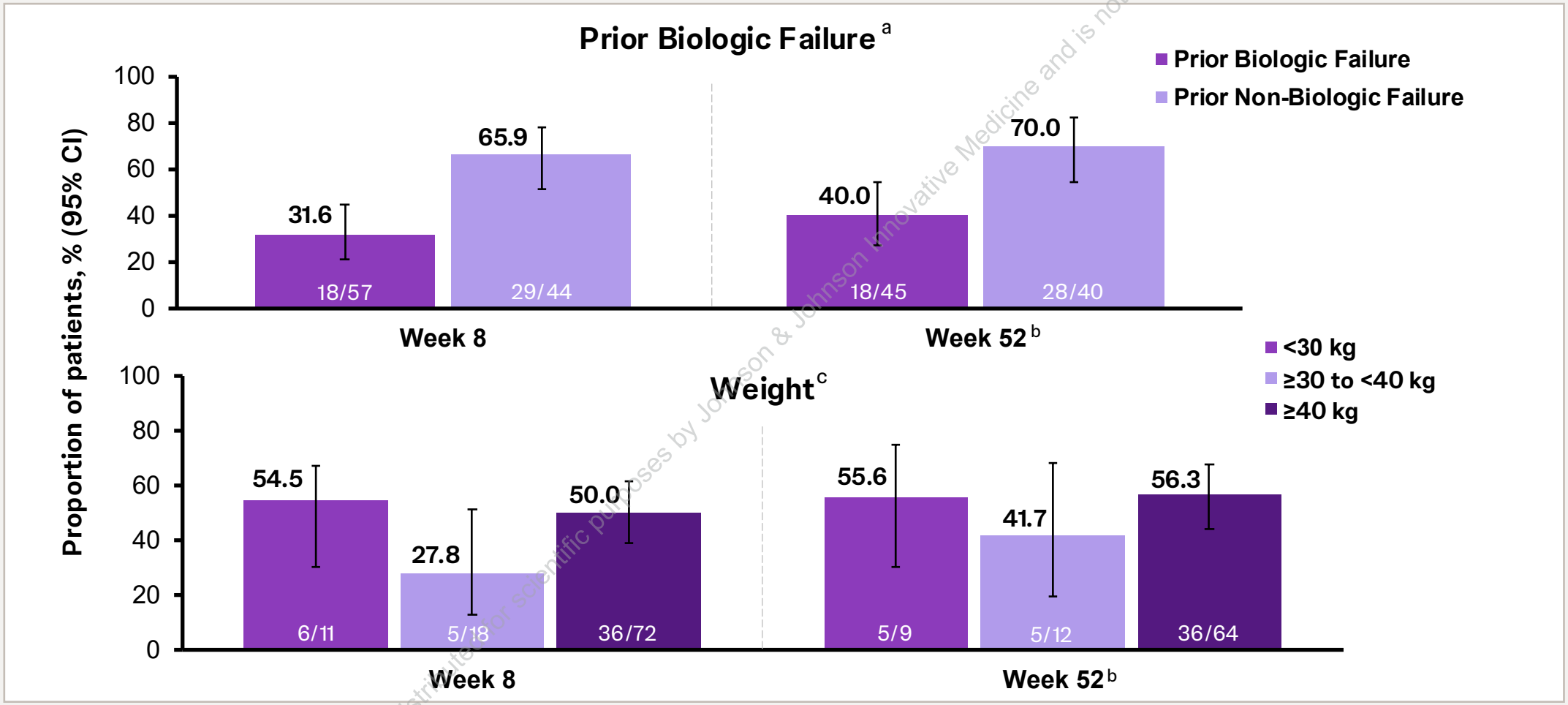
Clinical remission: PCDAI ≤10

Corticosteroid-free clinical remission: PCDAI ≤10 and not receiving corticosteroids for at least 90 days before Week 52

Endoscopic remission: SES-CD score of ≤2 in patients with a baseline SES-CD score of ≥3

[a]Among Week 8 clinical responders, defined as PCDAI reduction from baseline of ≥12.5 points with total PCDAI ≤30. SES-CD, Simple Endoscopic Score for Crohn's Disease.

Clinical Remission in Pediatric Patients by Prior Biologic Failure and Weight



Clinical remission: PCDAI ≤10

[a]At baseline, median CD duration was 2.7 years for the prior biologic failure group and 1.1 years for the prior non-biologic failure group; [b]Among Week 8 clinical responders, defined as PCDAI reduction from baseline of ≥12.5 points with total PCDAI ≤30; [c]**The proportion of patients with prior biologic failure at Week 8 was 64% for the <30 kg group, 72% for the ≥30-<40 kg group, and 51% for the ≥40 kg group, and at Week 52 was 56% for the <30 kg group, 67% for the ≥30-<40 kg group, and 50% for the ≥40 kg group.**

No New Safety Signals Were Observed Through Week 52

	Ustekinumab		
	q8w (n=48)	q12w (n=49)	Total[a] (N=97)
Weeks of follow-up, mean	36.5	36.2	36.4
Patients with ≥1			
AE	40 (83.3%)	44 (89.8%)	84 (86.6%)
SAE	7 (14.6%)	6 (12.2%)	13 (13.4%)
Serious infection	2 (4.2%)	2 (4.1%)	4 (4.1%)
AE leading to discontinuation	2 (4.2%)	3 (6.1%)	5 (5.2%)[b]
Most common AEs (≥10%)[c]			
CD exacerbation	19 (39.6%)	17 (34.7%)	36 (37.1%)
Upper respiratory tract infection	7 (14.6%)	16 (32.7%)	23 (23.7%)
COVID-19	8 (16.7%)	7 (14.3%)	15 (15.5%)[d]
Nasopharyngitis	5 (10.4%)	7 (14.3%)	12 (12.4%)[d]
Anemia	5 (10.4%)	7 (14.3%)	12 (12.4%)

[a]Four patients who were not randomized were excluded; [b]All were exacerbated CD; [c]AEs that were considered to be reasonably related to the study drug included nasopharyngitis, upper respiratory tract infection, and rash in the q12w group (n=2) and headache in the q8w group (n=1); [d]One patient who underwent dose adjustment was included. AE, adverse event; SAE, serious adverse event.

Key Takeaways

- Overall, ustekinumab was effective in inducing and maintaining remission in children with moderately to severely active CD
- Clinical response and remission rates trended higher in children with CD compared to adults
- Among patients with clinical response at induction Week 8, similar proportions of patients in the q8w and q12w groups achieved remission at Week 52
- Clinical remission rates were lower among patients with prior biologic failure
- Ustekinumab was well-tolerated with no new safety signals. No deaths, malignancy, active tuberculosis, opportunistic infections, or injection-site reactions were reported.

Acknowledgements

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