Growth Analysis in Children Aged 6 to 11 Years With Severe Atopic Dermatitis and Impact of Dupilumab Treatment on Height

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AD

Conclusions

Prompt and effective management of AD with dupilumab in children may have a lifelong benefit in those who are below expected height by improving vertical growth

Objective

To report the proportion of children aged 6 to 11 years with severe AD and reduced stature who reach a ≥5-percentile improvement in height following 16 weeks' treatment with dupilumab compared with children in the placebo group

Background

- Children with AD and under the 25th height percentile are at higher risk of low bone mineral density[1,2]
- The mechanisms underlying this phenomenon are unclear and may relate to chronically poor sleep associated with AD, use of oral and topical corticosteroids, and the effects of a prolonged inflammatory state

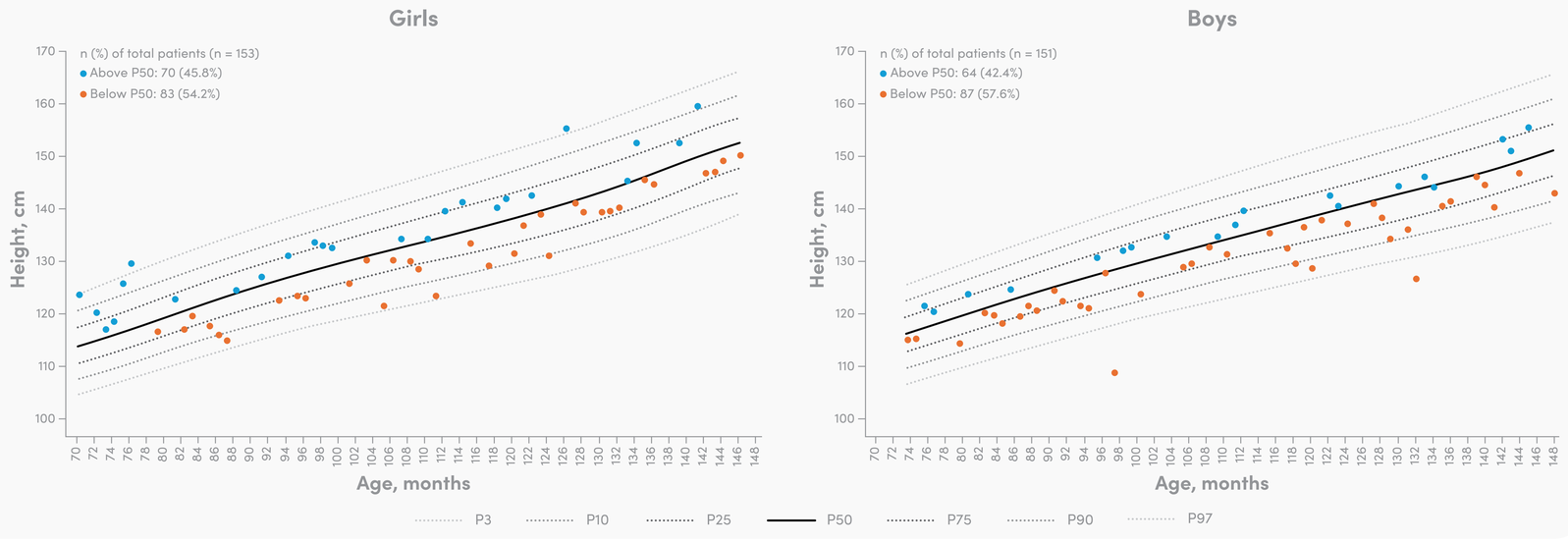
Methods

- Height and weight were recorded for children aged 6 to 11 years who participated in:
  - LIBERTY AD PEDS (PEDS; NCT03345914; severe AD), a phase 3, placebo-controlled 16-week trial
  - LIBERTY AD PED-OLE (PED-OLE; NCT02612454; moderate-to-severe AD), an open-label extension trial where all eligible patients received dupilumab

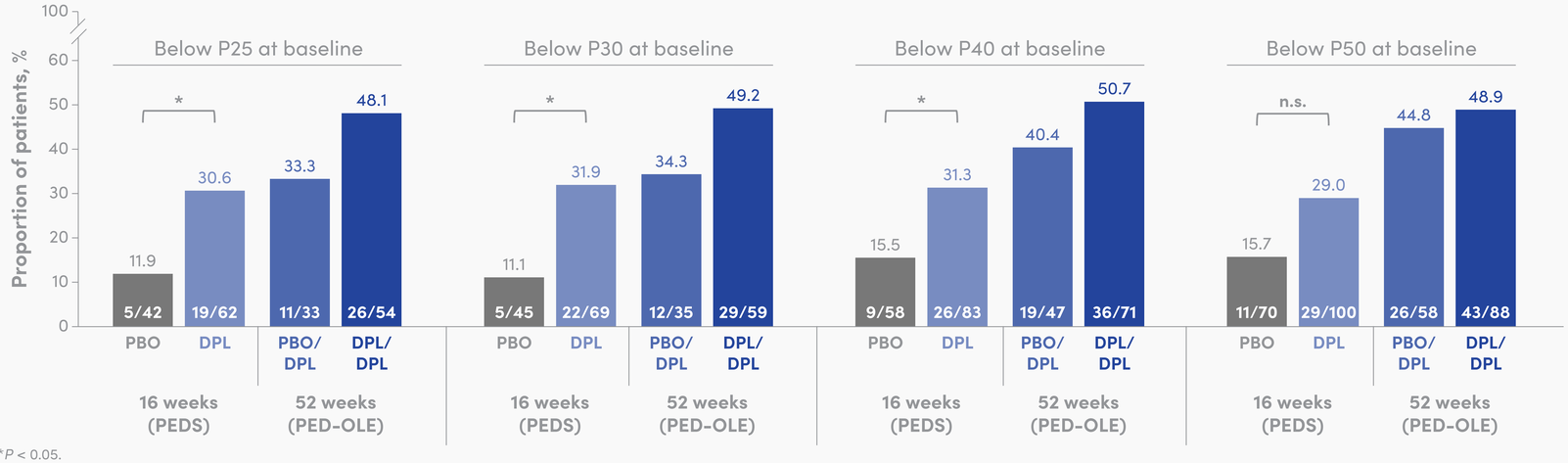
- Proportion of patients (below the 25th, 30th, 40th, and 50th height percentiles at parent study baseline) with change from baseline in height percentile ≥5 was reported at Week 16 and Week 52
- All height percentiles (baseline and post dupilumab treatment) are derived from the CDC growth charts

Results

Girls and boys aged 6 to 11 years with severe AD were overrepresented in the lower height percentiles at baseline.



Proportion of patients with reduced stature at baseline (below 25th, 30th, 40th, and 50th height percentiles), showing an improvement in growth chart trajectory by ≥5 percentile at Weeks 16 and 52.



*$P < 0.05$.

AD, atopic dermatitis; CDC, Centers for Disease Control and Prevention; DPL, dupilumab treated at Week 16; DPL/DPL, dupilumab treatment group in AD PEDS that remained on dupilumab treatment in PEDS OLE at Week 52; n.s., not significant; P, reference percentile; PBO, placebo at Week 16; PBO/DPL, placebo group in AD PEDS that transitioned to dupilumab treatment in PEDS OLE at Week 52.

References: 1. Silverberg JI, Paller AS. JAMA Dermatol. 2015;151:401-9. 2. Silverberg JI. Pediatr Allergy Immunol. 2015;26:54-61.
Acknowledgments and funding sources: Data first presented at the American Academy of Dermatology Annual Meeting; Orlando, Florida; March 7-11, 2025. Research sponsored by Sanofi and Regeneron Pharmaceuticals Inc. ClinicalTrials.gov Identifiers: NCT03345914 and NCT02612454. The authors thank Xiaojun You for his contributions to the statistical analysis. Medical writing/editorial assistance was provided by Mark C. Howell Jr, PhD, and Michael Röling, PhD, of Excerpta Medica, and was funded by Sanofi and Regeneron Pharmaceuticals Inc., according to the Good Publication Practice guidelines.
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Presented at the Relevant Advanced Practice Immuno-Dermatology Symposium (RAPIDS); Rio Grande, Puerto Rico; April 9 - 13, 2025.

Dupilumab Consistently **Reduces CCL-17 (TARC)** in Patients with **Atopic Dermatitis** Across All Age Groups

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AD

Conclusions

- **Across age groups, dupilumab treatment demonstrated rapid and sustained reduction of serum CCL17/TARC levels after the first dose**
- **This likely reflects a reduction in skin CCL17/TARC levels and could be considered a marker of improvement of sub-clinical inflammation in AD**

Objective

The objective of this analysis is to determine the effect of dupilumab treatment on serum CCL17/TARC levels across all age groups 6 months and older

Background

- CCL17 (also known as thymus- and activation-regulated chemokine [TARC]) is a key chemokine for attracting inflammatory leukocytes into the target tissue[1]
- In AD, CCL17/TARC is primarily secreted from keratinocytes and dendritic cells; serum CCL17/TARC levels are known to be correlated with severity of disease[1]
- Elevated levels of CCL17/TARC (collected by skin tape strips) have been shown to precede the development of childhood AD[2]
- Skin biopsies in AD patients treated with dupilumab have shown marked local reductions in expression of type 2 inflammatory pathway genes, including CCL17/TARC[3,4]

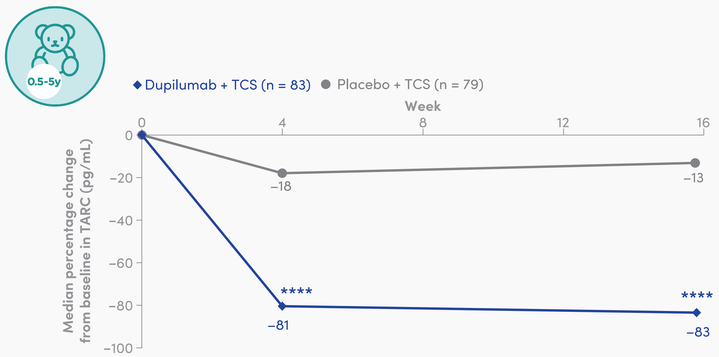
Methods

- We report serum CCL17/TARC (human TARC Quantikine ELISA kit; R&D Systems) levels from patients with moderate-to-severe or severe AD enrolled in the following randomized, double-blind, placebo-controlled phase 3 studies, receiving approved dupilumab dose regimens: LIBERTY AD PRESCHOOL (aged 6 months to 5 years; NCT03346434 part B); LIBERTY AD PEDS (aged 6 to 11 years; NCT03345914); LIBERTY AD ADOL (aged 12 to 17 years; NCT03054428); LIBERTY AD SOLO1 (aged 18 years or older; NCT02277743); LIBERTY AD SOLO2 (aged 18 years or older; NCT02277769)
- Both LIBERTY AD PRESCHOOL and LIBERTY AD PEDS studies allowed concomitant TCS use

Results

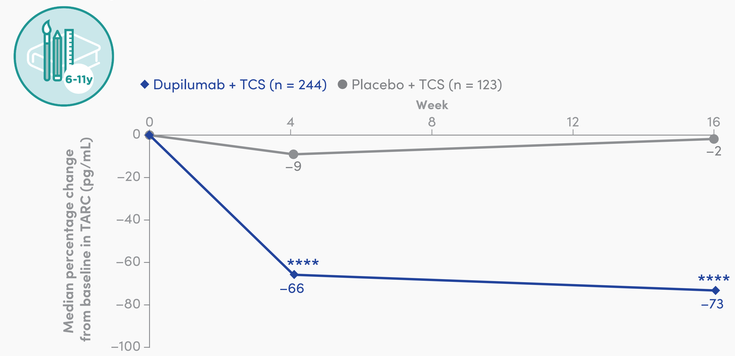
Percent changes in serum CCL17/TARC levels over time.

Infants and children aged 6 months to 5 years



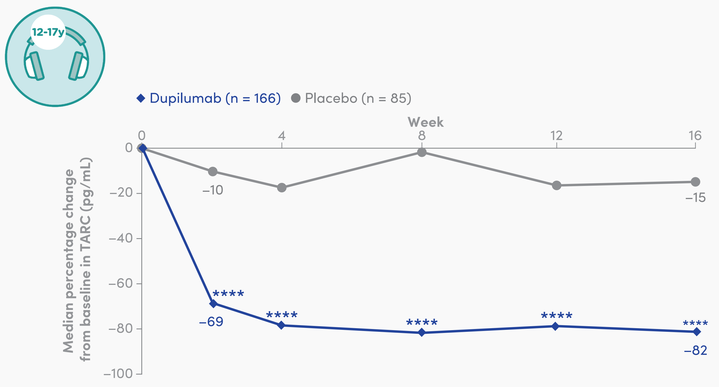
Treatment	Baseline			Week 16				
	Median (pg/mL)	Q1	Q3	Median (pg/mL)	Q1	Q3	Median (% change from baseline)	Q1	Q3
Dupilumab + TCS	3,295	1,430	11,100	522	315	967	−83	−92	−64
Placebo + TCS	3,190	1,625	10,300	1,845	951	5,625	−13	−52	28

Children aged 6 to 11 years



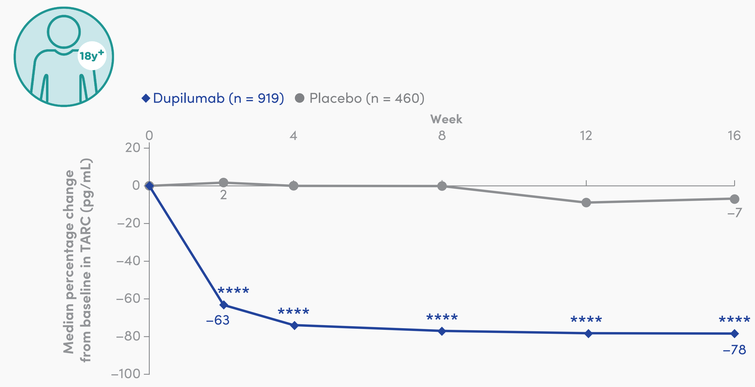
Treatment	Baseline			Week 16				
	Median (pg/mL)	Q1	Q3	Median (pg/mL)	Q1	Q3	Median (% change from baseline)	Q1	Q3
Dupilumab + TCS	1,620	738	4,000	355	234	639	−73	−86	−51
Placebo + TCS	1,655	743	4,000	1,450	973	2,810	−2	−48	51

Adolescents



Treatment	Baseline			Week 16				
	Median (pg/mL)	Q1	Q3	Median (pg/mL)	Q1	Q3	Median (% change from baseline)	Q1	Q3
Dupilumab	2,450	1,040	6,310	408	241	795	−82	−92	−61
Placebo	2,160	1,120	6,000	1,685	780	3,550	−15	−51	29

Adults



Treatment	Baseline			Week 16				
	Median (pg/mL)	Q1	Q3	Median (pg/mL)	Q1	Q3	Median (% change from baseline)	Q1	Q3
Dupilumab	1,938	813	6,698	407	253	703	−78	−90	−59
Placebo	2,195	891	6,419	1,677	667	5,098	−7	−43	43

****P-value (vs placebo) < 0.0001. The p-value was based on treatment difference (dupilumab or dupilumab groups vs placebo) of the median change using rank-based ANCOVA model with baseline measurement as covariate and the treatment, baseline IGA strata as fixed factors. LOCF method censoring after rescue treatment use.

AD, atopic dermatitis; ANCOVA, analysis of covariance; CCL17, C-C motif chemokine ligand 17; LOCF, last observation carried forward; Q1, first quartile; Q3, third quartile; TARC, thymus- and activation-regulated chemokine; TCS, topical corticosteroid(s).

References: 1. Renert-Yuval Y, et al. J Allergy Clin Immunol. 2021; 147:1174-1190. 2. Halling AS, et al. J Allergy Clin Immunol. 2023;151:1550-7. 3. Guttman- Yassky E, et al. J Allergy Clin Immunol. 2019;143:155-72. 4. Hamilton JD, et al. J Allergy Clin Immunol. 2014;134:1293-300.

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Dupilumab Treatment Significantly **Reduces Age-Dependent Total IgE Levels** in **Young Children** With **Atopic Dermatitis**

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AD

Conclusions

- **IgE levels increase with age in infants and young children with moderate-to-severe AD**
- **Dupilumab significantly reduced IgE levels in all age cohorts evaluated**
- **Early dupilumab treatment in infants and young children with AD reduces serum IgE, which may mark a decreased risk of developing atopic sensitization and associated atopic morbidities**

Objective

To evaluate impact of age and dupilumab treatment over time on IgE levels in infants and young children with moderate-to-severe AD aged 0.5 to <6 years

Background

- Elevated serum levels of allergen-specific IgE is often referred to as "IgE sensitization"
- IgE sensitization has been associated with AD disease severity and may serve as a biomarker for development of associated atopic morbidities, such as food allergies and asthma[1,2]
- Previous reports document a reduction in dupilumab-associated aeroallergen-specific IgE levels in AD patients with comorbid asthma or allergic rhinitis[3], as well as decreases in total[4] and food allergen-specific-IgE levels in patients with AD[5]
- IL-4Ra expressed on B cells plays a crucial role in inducing B cell proliferation and isotype switching, resulting in high levels of circulating IgE[6]
- Binding of dupilumab to IL-4Ra results in significant reductions in type 2 memory B cells, leading to reduced IgE levels[7,8]

Methods

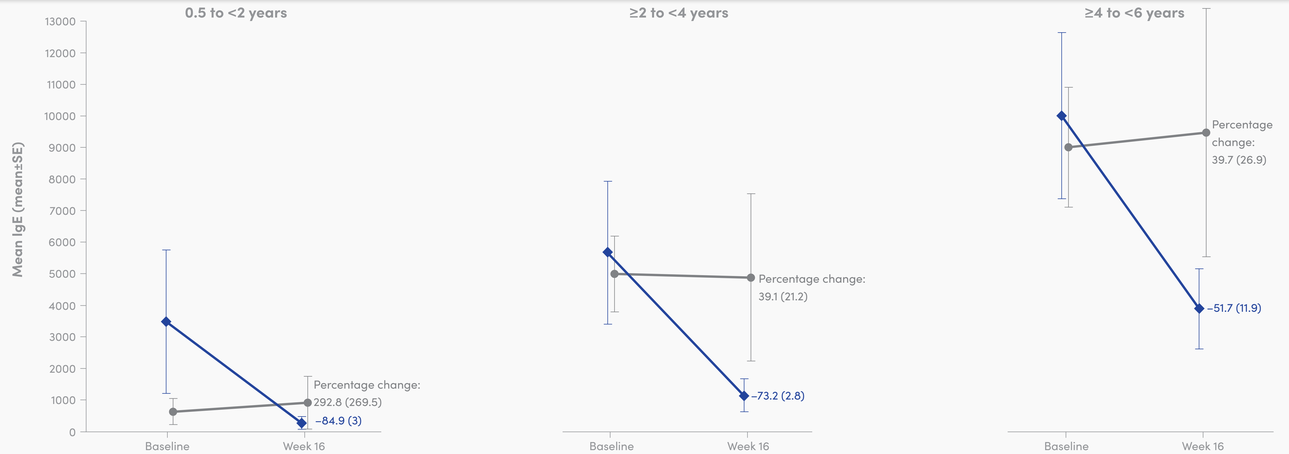
LIBERTY AD PRESCHOOL (NCT03346434)

- Infants and young children aged 0.5 to <6 years received dupilumab or placebo, with topical corticosteroids (TCS), for 16 weeks
- Infants and young children were stratified by age: 0.5 to <2 years, ≥2 to <4 years, and ≥4 to <6 years
- Baseline and Week 16 total serum IgE levels are reported as observed
- IgE ratios between Week 16 and baseline were assessed using a MMRM

Results

Total baseline IgE levels (IU/mL) increase with age in infants and young children; dupilumab treatment reduces IgE levels in all age cohorts evaluated.

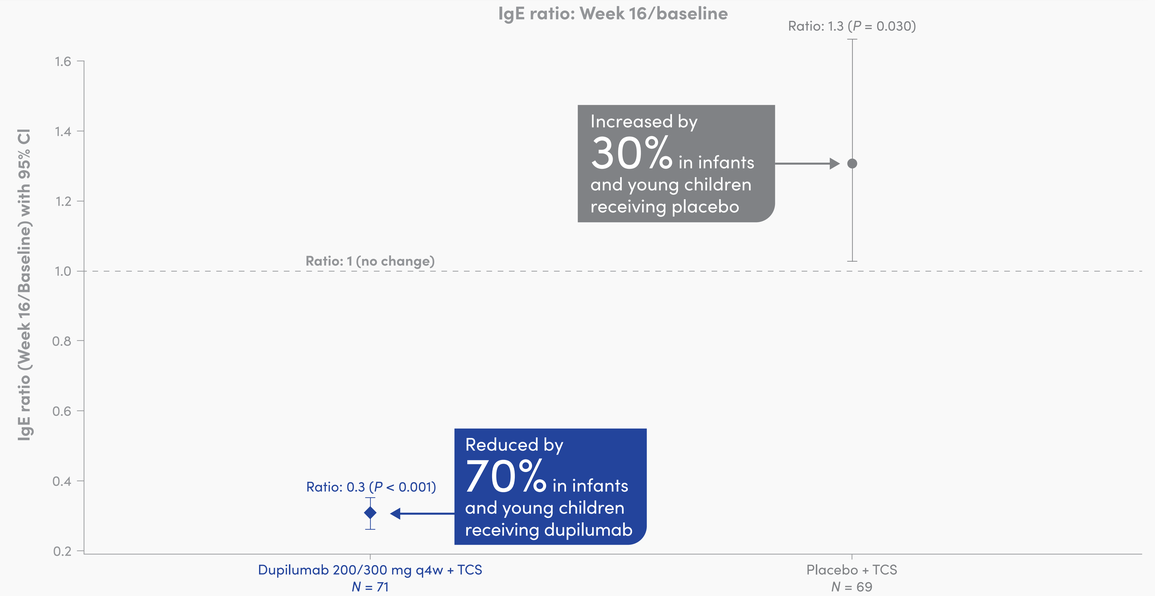
- Study limitation: Small sample size for infants and young children aged 0.5 to <2 years



		0.5 to <2 years		≥2 to <4 years		≥4 to <6 years	
		Baseline	Week 16	Baseline	Week 16	Baseline	Week 16
◆ Dupilumab 200/300 mg q4w + TCS	*N*	6	4	24	19	41	32
	Mean (SE)	3481.8 (2270.0)	275.9 (188.7)	5736.4 (2258.3)	1233.3 (522.9)	10046.0 (2628.1)	3932.8 (1266.7)
● Placebo + TCS	*N*	3	2	33	10	33	9
	Mean (SE)	636.3 (414.0)	918.0 (832.0)	5066.7 (1192.8)	4960.0 (2643.9)	9044.9 (1896.5)	9510.4 (3927.8)

In infants and young children (0.5 to <6 years), dupilumab + TCS significantly reduced IgE levels compared to placebo + TCS; total IgE significantly increased from baseline to Week 16 in infants and young children receiving placebo + TCS.

- Overall, mean IgE levels in infants and young children were:
  - Reduced by 70% in those receiving dupilumab + TCS ($P < 0.001$)
  - Increased by 30% in those receiving placebo + TCS ($P = 0.03$)
- Overall safety was consistent with the known dupilumab safety profile[9]



AD, atopic dermatitis; IL-4Ra, interleukin-4 receptor a; MMRM, mixed-effect model for repeated measures; N, number of infants and young children; q4w, every 4 weeks; SE, standard error; TCS, topical corticosteroid(s).

References: 1. Beck LA, et al. Am J Respir Crit Care Med. 2023;207:632–3. 2. Hill DA, Spergel JM. Ann Allergy Asthma Immunol. 2018;120:131–7. 3. van der Rijst LP, et al. Pediatr Allergy Immunol. 2024;35:e14178. 4. Dekkers C, et al. Clin Exp Allergy. 2023;53:1222–5. 5. Spekhorst LS, et al. Allergy. 2022;78:675–8. 6. Hadebe S, et al. J Allergy Clin Immunol. 2021;148:99–109.e5. 7. Gandhi NA, et al. Nat Rev Immunol. 2017;13:425–37. 8. Siegfried et al. JACI. 2023;151:AB149. 9. Paller et al. Lancet September 2022:17;400:908–19.

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FREQUENCY AND PATIENT-REPORTED IMPACT OF PSORIATIC ARTHRITIS AND OTHER COMORBIDITIES IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS FROM THE VISIBLE TRIAL

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BACKGROUND

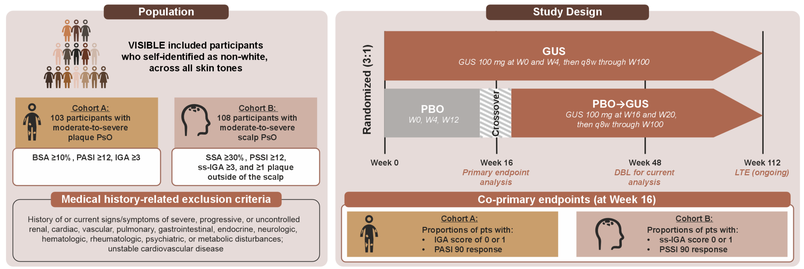
- Psoriasis frequently occurs with psoriatic arthritis (PsA) and/or cardiovascular and metabolic conditions
- VISIBLE (NCT05272150) evaluated the efficacy of guselkumab versus placebo in skin of color participants with moderate-to-severe body or scalp predominant plaque psoriasis
- As a first of its kind study 100% dedicated to people of color, VISIBLE provides insights into the frequency of psoriatic comorbidities in a diverse population

OBJECTIVES

- To examine the frequency of comorbid cardiometabolic conditions and PsA at baseline in VISIBLE clinical trial participants
- To evaluate treatment-related changes in patient-reported PsA impact in the subset of VISIBLE participants with PsA

METHODS

Figure 1. VISIBLE Population and Study Design



BSA=Body surface area; DBL=Database lock; GUS=Guselkumab; IGA=Investigator's Global Assessment; LTE=Long-term extension; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsO=Psoriasis; PSSI=Psoriasis Scalp Severity Index; pts=Participants; q8w=Every 8 weeks; SSA=Scalp surface area; ss-IGA=Scalp-specific IGA; W=Week.

Comorbid medical conditions were identified based on medical history and/or laboratory results and vital signs at screening/baseline of the VISIBLE study (Table 1)

Table 1. Criteria for Identification of Baseline Psoriatic Comorbidities in VISIBLE

Hypertension	• MedDRA preferred term of Hypertension OR • Systolic BP ≥130 mmHg or diastolic BP ≥80 mmHg at ≥2 assessments across screening, Week 0, and Week 4
Diabetes	• MedDRA preferred term of Diabetes mellitus or Type 2 diabetes mellitus OR • HbA1c ≥6.5% at Week 0
Dyslipidemia	• MedDRA preferred term of Blood cholesterol increased, Hypercholesterolemia, High-density lipoprotein decreased, Hyperlipidemia, or Hypertriglyceridemia OR • Total cholesterol ≥200 mg/dL, LDL ≥160 mg/dL, triglycerides ≥200 mg/dL, or HDL <40 (males) or <50 (females) mg/dL at Week 0
Metabolic syndrome	Any 3 of the following criteria at Week 0: • BMI >30 kg/m^2 • Triglycerides ≥150 mg/dL • HDL <40 (males) or <50 (females) mg/dL • BP ≥130/85 mmHg • Fasting glucose ≥110 mg/dL
PsA	• Rheumatologist-confirmed diagnosis of PsA OR • PEST score ≥3 at screening

BMI=Body mass index; BP=Blood pressure; HbA1c=Hemoglobin A1c; HDL=High-density lipoprotein; LDL=Low-density lipoprotein; MedDRA=Medical Dictionary for Regulatory Activities; PEST=Psoriasis Epidemiology Screening Tool; PsA=Psoriatic arthritis.

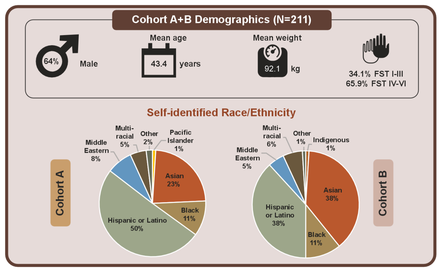
Patient-reported impact and symptoms of PsA by PsAID-12

In the efficacy analysis set of participants with PsA (either prior rheumatologist-confirmed diagnosis of PsA or Psoriasis Epidemiology Screening Tool [PEST] score ≥3 at the VISIBLE screening visit), PsA impact was measured using the Psoriatic Arthritis Impact of Disease 12 (PsAID-12) instrument:

- Numeric rating scale covering 12 physical and psychological domains considered important to patients with PsA[1]
- Final PsAID-12 scores range from 0 to 10 (higher results indicate worse status)

RESULTS

VISIBLE participant baseline characteristics are reflective of a diverse population with extensive skin/scalp psoriasis across all skin tones



Baseline Disease Characteristics	
Cohort A (N=103)	
PsO disease duration, y	14.9 (10.5)
PASI score (0–72)	20.8 (9.1)
BSA, %	26.8 (19.3)
IGA score, n (%)	
3	78 (75.7%)
4	25 (24.3%)
Cohort B (N=102)	
PsO disease duration, y	11.3 (10.6)
PSSI score (0–72)	34.3 (13.2)
SSA, %	59.8 (26.0)
ss-IGA score, n (%)	
3	84 (82.4%)
4	18 (17.6%)

Data are mean (standard deviation) unless otherwise specified. BSA=Body surface area; FST=Fitzpatrick skin type; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PsO=Psoriasis; PSSI=Psoriasis Scalp Severity Index; SSA=Scalp surface area; ss-IGA=Scalp-specific-Investigator's Global Assessment.

VISIBLE participants have a high burden of psoriasis comorbidities at baseline (Table 2)

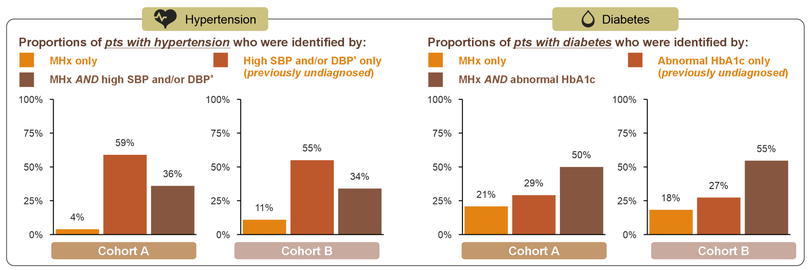
Table 2. Rates of Psoriasis Comorbidities in VISIBLE Participants

Comorbid condition	Cohort A PBO (N=26)	Cohort A GUS (N=77)	Cohort A Total (N=103)	Cohort B PBO (N=27)	Cohort B GUS (N=81)	Cohort B Total (N=108)
Hypertension	57.7% (n=15)	70.1% (n=54)	67.0% (n=69)	51.9% (n=14)	61.7% (n=50)	59.3% (n=64)
Diabetes	19.2% (n=5)	24.7% (n=19)	23.3% (n=24)	14.8% (n=4)	22.2% (n=18)	20.4% (n=22)
Dyslipidemia	92.3% (n=24)	71.4% (n=55)	76.7% (n=79)	63.0% (n=17)	67.9% (n=55)	66.7% (n=72)
Metabolic syndrome	42.3% (n=11)	37.7% (n=29)	38.8% (n=40)	14.8% (n=4)	29.6% (n=24)	25.9% (n=28)
PsA	30.1% (n=8)	32.5% (n=25)	32.0% (n=33)	23.1% (n=6)[a]	28.9% (n=22)[a]	27.5% (n=28)[a]

[a]*Efficacy analysis set, N=102 (PBO: N=26; GUS: N=76). GUS=Guselkumab; PBO=Placebo; PsA=Psoriatic arthritis.*

Mode of identification of comorbidities, whether by medical history and/or laboratory values/vital signs, provides information about whether a participant has a well-controlled comorbidity, undiagnosed comorbidity, or sub-optimally controlled comorbidity (Figure 2)

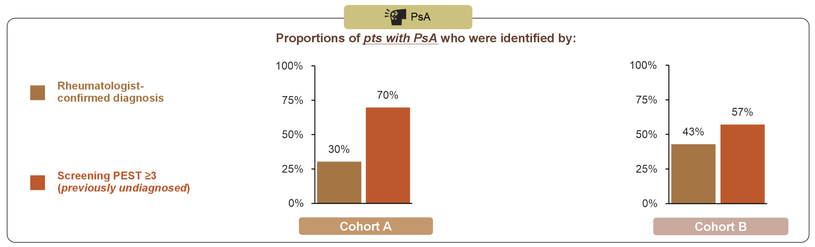
Figure 2. Identification of Hypertension and Diabetes by Medical History and/or Laboratory Values/Vital Signs



FAS participants, unless otherwise indicated. [a]Among Cohort A/B pts with hypertension, 58%/59% had high SBP and 80%/72% had high DBP (including 42%/44% with both high SBP and DBP). DBP=Diastolic blood pressure; FAS=Full analysis set; HbA1c=Hemoglobin A1c; MHx=Medical history; pts=Participants; SBP=Systolic blood pressure.

Comorbid PsA at baseline was identified based on history of rheumatologist-confirmed PsA or PEST score ≥3 at the VISIBLE screening visit (Figure 3)

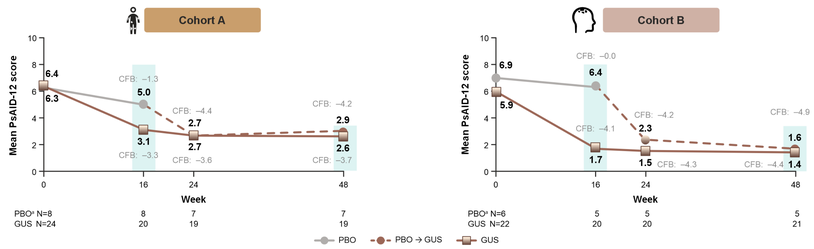
Figure 3. Identification of Comorbid PsA by Rheumatologist-Confirmed Diagnosis vs Screening PEST



FAS participants, unless otherwise indicated. FAS=Full analysis set; PEST=Psoriasis Epidemiology Screening Tool; PsA=Psoriatic arthritis; pts=Participants.

Mean baseline PsAID-12 scores for participants with PsA in both cohorts indicate substantial PsA burden at enrollment

Figure 4. Mean PsAID-12 Scores Over Time Among VISIBLE Participants With PsA



[a]*For participants who were randomized to PBO at Week 0, only those participants who crossed over to GUS at or after Week 16 were included in Weeks 24 and 48. When participants discontinued study agent due to lack of efficacy, worsening of psoriasis, or use of a prohibited psoriasis treatment, baseline values (at Week 0) were assigned from that point onward. CFB=Mean change from baseline; GUS=Guselkumab; PBO=Placebo; PsA=Psoriatic arthritis; PsAID-12=Psoriatic Arthritis Impact of Disease 12.*

Overall, Cohort A and B participants randomized to guselkumab achieved clinically meaningful improvements (mean decrease from baseline of ≥3 points) and mean PsAID-12 scores indicative of patient-acceptable scores (≤3.95) at Week 16 that were sustained at Week 48 (Figure 4)

CONCLUSIONS

- VISIBLE participants have a high burden of psoriasis-associated comorbidities, including pre-existing hypertension, diabetes, dyslipidemia, metabolic syndrome, and PsA
- Substantial proportions of VISIBLE participants had pre-existing PsA and cardiometabolic disease that was either undiagnosed or diagnosed but sub-optimally controlled at enrollment
- Participants with PsA reported high impact at baseline but achieved rapid and clinically meaningful improvements with guselkumab treatment at Week 16 that were sustained through Week 48
- Moderate-to-severe plaque psoriasis often comes with multiple comorbidities that could be managed in collaboration with other medical specialties

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Icotrokinra, a Targeted Oral Peptide That Selectively Blocks the Interleukin-23 Receptor, for the Treatment of Moderate-to-Severe Plaque Psoriasis: Results Through Week 24 of the Phase 3, Randomized, Double-Blind, Placebo-Controlled ICONIC-LEAD Trial

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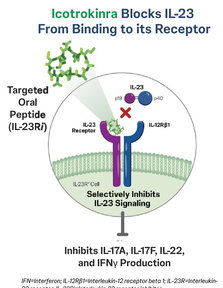
Background

Patients with moderate-to-severe plaque psoriasis (PsO) are generally limited to injectable therapies to achieve high-level efficacy with a favorable safety profile

Icotrokinra (ICO) is a first-in-class, targeted oral peptide that:

- Selectively binds the interleukin (IL)-23 receptor and inhibits IL-23 pathway signaling[1]
- Demonstrated significant skin clearance and no safety signals through 1 year in Phase 2 PsO studies[2,3]
- Is being evaluated in Phase 3 studies in adults and adolescents with moderate-to-severe plaque PsO (ICONIC-LEAD)



IFN=interferon; IL-12Rβ1=interleukin-12 receptor beta 1; IL-23R=interleukin-23 receptor; IL-23R=interleukin-23 receptor inhibitor.

Objectives

Here we report key clinical and patient-reported outcomes (PROs) and safety-related findings from the pivotal ICONIC-LEAD study through Week (W) 24

ICONIC-LEAD study design

Moderate-to-severe plaque PsO (N=684)

Key inclusion criteria

- ≥12 years
- Plaque PsO for ≥26 weeks
- Body surface area (BSA) ≥10%, Psoriasis Area and Severity Index (PASI) score ≥12, and Investigator's Global Assessment (IGA) score ≥3
- Candidate for phototherapy or systemic treatment for plaque PsO

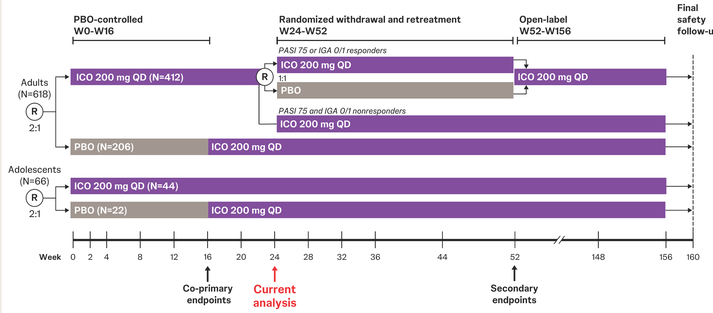
Endpoints

Co-primary endpoints:

- IGA 0/1 at W16
- PASI 90 at W16

Key secondary endpoints:

- **Clinical outcomes** (PASI 75/90/100, IGA 0) at W4, W8, and/or W16
- **PROs** (≥4-point improvement from baseline in PSSD Itch, PSSD Symptom 0) at W4, W8, and/or W16
- **Scalp PsO** (ss-IGA 0/1) at W16



Participants with the following intercurrent events were considered as nonresponders: discontinued study drug due to a lack of efficacy or AE of worsening PsO or initiated prohibited medication that could impact PsO. After accounting for these intercurrent events, nonresponder imputation was applied to participants with missing data. AE=Adverse event, ICO=Icotrokinra; IGA 0/1=IGA score of 0 (clear)/1 (almost-clear) and a ≥2-grade improvement; PASI=Psoriasis Area and Severity Index; PASI 75/90/100=Reduction from baseline of 75%/90%/100% in the PASI score; PBO=Placebo; PsO=Plaque psoriasis; PSSD=Psoriasis Symptom and Sign Diary; QD=Once daily; R=Randomization; ss-IGA =Scalp-specific Investigator's Global Assessment; ss-IGA 0/1=ss-IGA score of 0 (clear)/1 (almost clear) and a ≥2-grade improvement from baseline.

Key Takeaways

In ICONIC-LEAD, among the first pivotal trials evaluating the novel targeted oral peptide ICO in adults and adolescents with moderate-to-severe plaque PsO:

- **ICO demonstrated *significantly higher rates of clear/almost clear skin and scalp* disease and *PsO symptom relief* than PBO at W16**
- **ICO demonstrated *separation from PBO as early as W4*, with *increasing response rates through W24***
- ***Rates of AEs were similar* between the ICO and PBO groups**
- ***No safety signal* was identified through W24**

Results

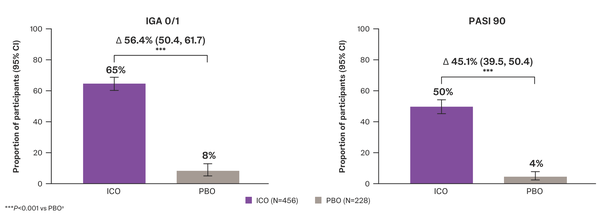
Baseline characteristics were similar between groups

- Overall, 5% of participants (ICO: 4%; PBO: 6%) discontinued prior to W16[a]

Baseline characteristics	ICO 200 mg QD (N=456)	PBO (N=228)
Demographic characteristics		
Age, year, mean (SD)	42.4 (16.3)	43.2 (16.6)
Adolescent cohort, year	15.0 (1.8)	15.0 (1.5)
Male	64%	68%
White	72%	72%
BMI, kg/m^2, mean (SD)[b]	29.2 (6.9)	29.3 (7.0)
Disease characteristics		
Psoriasis disease duration, year, mean (SD)	17.3 (13.9)	16.6 (12.7)
% BSA with psoriasis, mean (SD)	24.6 (14.3)	27.1 (16.2)
IGA score		
Moderate (3)	75%	76%
Severe (4)	25%	24%
PASI (0-72), mean (SD)	19.4 (7.1)	20.8 (8.1)
PsO involving the scalp area		
ss-IGA score[c]		
Moderate (3)	59%	51%
Severe (4)	17%	22%
Prior treatment for PsO		
Phototherapy (PUVA and UVB)	30%	29%
Systemic therapy[d]	72%	71%
Biologic therapy[e]	32%	37%

[a]Among the participants who discontinued prior to W16 (ICO: n=19 [4%]; PBO: n=14 [6%]), the most common reasons for discontinuation were withdrawal by participant in the ICO group (n=8 [2%]) and lack of efficacy in the PBO group (n=8 [4%]). [b]ICO: N=455; PBO: N=227. [c]ICO: N=457; PBO: N=227. [d]Conventional nonbiologic systemics, novel nonbiologic systemics, 1,25-vitamin D3 and analogues, phototherapy, and biologics. [e]Adalimumab, abtacept, briakinumab, brodalumab, certolizumab pegol, efalizumab, etanercept, guselkumab, ixifolimab, ixekizumab, natalizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab. BMI=Body mass index; BSA=Body surface area; ICO=Icotrokinra; IGA = Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo; PsO=Plaque psoriasis; PUVA=Psoralen plus ultraviolet A, QD=Once daily; SD=Standard deviation, UVB=Ultraviolet B; W=Week.

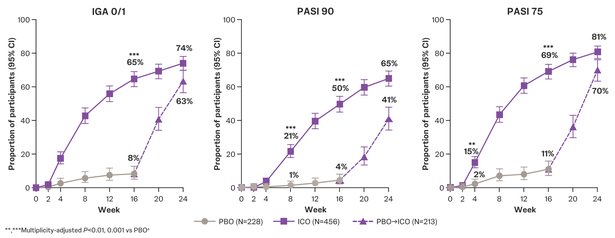
ICO demonstrated significantly higher rates of IGA 0/1 and PASI 90 vs PBO at W16 (co-primary endpoints)



***P<0.001 vs PBO[a]

[a]P values were calculated based on Cochran-Mantel-Haenszel chi-square test stratified by age group, baseline weight category (adults only), and geographic region. CI=Confidence interval; ICO=Icotrokinra; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo.

ICO demonstrated early separation from PBO; rates of clear/almost clear skin increased through W24

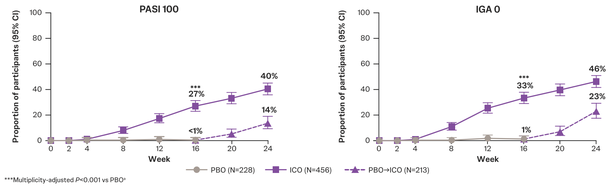


,*Multiplicity-adjusted P<0.01, 0.001 vs PBO[a]

[a]P values were calculated based on Cochran-Mantel-Haenszel chi-square test stratified by age group, baseline weight category (adults only), and geographic region, if applicable. CI=Confidence interval; ICO=Icotrokinra; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo.

ICO demonstrated significantly higher rates of complete skin clearance vs PBO

- ICO showed separation from PBO as early as W8; rates of complete skin clearance increased through W24

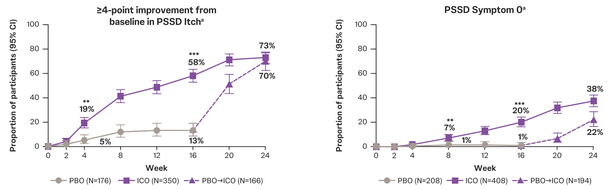


***Multiplicity-adjusted P<0.001 vs PBO[a]

[a]P values were calculated based on Cochran-Mantel-Haenszel chi-square test stratified by age group, baseline weight category (adults only), and geographic region. CI=Confidence interval; ICO=Icotrokinra; IGA=Investigator's Global Assessment; PASI=Psoriasis Area and Severity Index; PBO=Placebo.

Significantly higher proportions of ICO- vs PBO-treated participants reported meaningful improvements in PsO itch

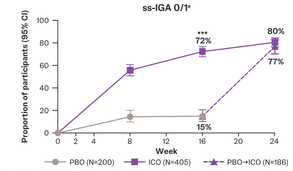
- ICO demonstrated early separation from PBO on improving itch and resolving symptoms; response rates increased through W24



**, ***Multiplicity-adjusted P<0.01 , P<0.001 vs PBO[a]

[a]Among participants with a baseline PSSD Itch score ≥4 or PSSD Symptom score >0, [b]P values were calculated based on Cochran-Mantel-Haenszel chi-square test stratified by age group, baseline weight category (adults only), and geographic region, if applicable. Fisher's exact test was used for PSSD Symptom 0 at W8. CI=Confidence interval; ICO=Icotrokinra; PBO=Placebo; PSSD=Psoriasis Symptom and Sign Diary.

ICO demonstrated significantly higher rates of clear/almost clear scalp PsO vs PBO



***Multiplicity-adjusted P<0.001 vs PBO[a]

[a]Among participants with a baseline ss-IGA score ≥2. [b]P values were calculated based on Cochran-Mantel-Haenszel chi-square test stratified by age group, baseline weight category (adults only), and geographic region. CI=Confidence interval; ICO=Icotrokinra; IGA=Investigator's Global Assessment; PBO=Placebo.

Adverse event rates were generally similar between groups through W16

- Through W24 of ICO treatment, the most commonly reported AEs were similar to those observed through W16 and no safety signal emerged

	ICO 200 mg QD (N=456)	PBO (N=228)
Safety through W16		
Mean weeks of follow-up	15.9	15.8
Any AE	225 (49%)	112 (49%)
Most common AEs (≥5%)		
Nasopharyngitis	31 (7%)	15 (7%)
Upper respiratory tract infection	30 (7%)	16 (7%)
SAE[a]	6 (1%)	6 (3%)
Infection	107 (23%)	51 (22%)
Serious infection	1 (<1%)	0
AE leading to discontinuation[b]	6 (1%)	1 (<1%)
Gastrointestinal AE	26 (6%)	13 (6%)
Active TB	0	0
Malignancy[c]	2 (<1%)	0

[a]SAEs through W16 included acute cholecystitis, concussion, craniofacial fracture, pelvic fracture, psoriasis, and hypertensive urgency in the PBO group; and adenocarcinoma of the colon, prostate cancer, pancreatitis, bacterial gastroenteritis (serious infection), arthralgia, and subarachnoid hemorrhage in the ICO group. [b]AEs leading to discontinuation through W16 included blood glucose increased in the PBO group; and adenocarcinoma of the colon, prostate cancer, hypertriglyceridemia, subarachnoid hemorrhage, erectile dysfunction, and psoriasis in the ICO group. [c]Malignancies reported were adenocarcinoma of the colon (n=1 in a participant who had a history of smoking; the participant reported mild gastroenteritis during screening, and severe colitis starting on study day 7, and severe ileus on day 14 leading up to the diagnosis of grade 3 adenocarcinoma of the colon on day 19) and prostate cancer (n=1, 62-year-old male, former smoker [30 pack years], with a family history [brother] of prostate cancer, and an elevated prostate-specific antigen level prior to baseline was diagnosed with grade 1 prostate cancer on study day 48 following a positive biopsy). AE=Adverse events; ICO=Icotrokinra; PBO=Placebo; QD=Once daily; SAE=Serious adverse event, TB=Tuberculosis, W=Week.

PRESENTED AT: Relevant Advanced Practice Immuno-Dermatology Symposium (RAPIDS); Rio Grand, Puerto Rico; April 9–13, 2025. **REFERENCES: 1.** Fourie AM, et al. *Sci Rep.* 2024;14:17515. **2.** Bissonnette R, et al. *N Engl J Med.* 2024;390:510-21. **3.** Ferris LK, et al. *J Am Acad Dermatol.* Published online November 14, 2024. doi: 10.1016/j.jaad.2024.10.076. **ACKNOWLEDGMENTS: Layout design and reformatting for this encore presentation was provided by Sandeep Chavan of SIRO Medical Writing Pvt Ltd, Thane, India.** Medical writing support was provided by Lumanity Communications, Inc. under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med.* 2022;175:1298-1304). This study was sponsored by Johnson & Johnson. **DISCLOSURES: RB:** served as an advisory board member, consultant, speaker, and/or investigator for and received honoraria and/or grants from AbbVie, Akamis, Amgen, Arcutis, Bausch Health, Bostpo Pharma, BMS/Celgene, Dermavant, Eli Lilly, Johnson & Johnson, LEO Pharma, Nimbus, Novartis, Pfizer, Regeneron, UCB, Vertyx Biosciences, Vyne, Xencor, and Zai Lab; and is an employee and shareholder of Innovaderm Research. **JS:** served as a speaker, consultant, and/or investigator for AbbVie, Amgen, Arcutis, Bristol Myers Squibb, Coval Biopharma, Dermavant, Eli Lilly, Johnson & Johnson, KoBioLabs, LEO Pharma, National Psoriasis Foundation, Novartis, Pfizer, Regeneron, Sanofi, and UCB. **AH:** had research grants paid to the medical school from Amgen, Arcutis, Dermavant, Johnson & Johnson, LEO Pharma, Eli Lilly, Pfizer, and Takeda; received honoraria from Arcutis, Dermavant, Galderma, Incyte, Johnson & Johnson, Ortho Dermatologics, Pfizer, Sun Pharma, and Verrica; and served on a data safety monitoring board for Ortho Dermatologics and Sanofi-Regeneron. **AEP:** served as an investigator, advisor, and/or speaker for and/or received educational support from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Galderma, Johnson & Johnson, LEO Pharma, Eli Lilly, Novartis, Pfizer, Sanofi, and UCB. **AP:** served as an advisor for, and/or received speaker's honoraria and/or grants from, and/or participated in clinical trials for AbbVie, Almirall Hermal, Amgen, Biogen Idec, BioNTech, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly, Galderma, GSK, Hexal, Johnson & Johnson, Klinge Pharma, LEO Pharma, MC2, Medac, Merck Serono, Mitsubishi, MSD, Novartis, Pascoe, Pfizer, Regeneron, Roche, Sandoz Biopharmaceuticals, Sanofi Genzyme, Schering-Plough, Tigercat Pharma, UCB Pharma, and Zuellig Pharma. **YS:** has no conflicts of interest. **MM, JC, JZJ,** and **CD:** are employees of Johnson & Johnson and may own stock/stock options in Johnson & Johnson. **MGL:** is an employee of Mount Sinai and receives research funds from AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Clexio, Dermavant, Eli Lilly, Incyte, Inozyme, Johnson & Johnson, Pfizer, Sanofi-Regeneron, and UCB; and is a consultant for Almirall, AltruBio Inc., Apogee, Arcutis, AstraZeneca, Atomwise, Avotres, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant, Dermsquared, Evommune, Inc., Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Sanofi-Regeneron, Seanergy, Strata, Takeda, Trevi, and Verrica. **PREVIOUSLY PRESENTED AT:** American Academy of Dermatology (AAD) Annual Meeting; March 7-11, 2025; Orlando, FL, USA.