Efficacy and Safety of Subcutaneous Ustekinumab in Pediatric Participants With Active Juvenile Psoriatic Arthritis: Results of the Open-Label, Phase 3 PSUMMIT-Jr Study Through Week 52

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Key Takeaways

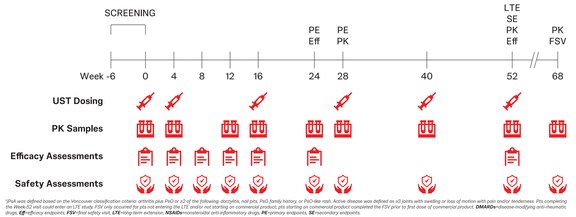
- Among pediatric pts with active jPsA, UST was associated with improvement in joint and skin symptoms
- UST PK in pts with jPsA was similar by age
- UST was well tolerated, with the majority of AEs being mild to moderate in severity and not related to treatment
- These results will be used to support an extrapolation approach to broaden the available treatment options for jPsA in Europe, addressing a significant unmet need

Background and Objective

- Ustekinumab (UST), a monoclonal antibody to the p40 subunit of interleukin (IL)-12/23, has demonstrated efficacy and safety in adults and children with moderate-to-severe plaque psoriasis (PsO), active psoriatic arthritis (PsA), active Crohn's disease, or active ulcerative colitis
- The open-label, phase 3, PSUMMIT-Jr study (NCT05083182) evaluated subcutaneous UST pharmacokinetics (PK), efficacy, immunogenicity, and safety in pediatric participants (pts) with active juvenile PsA (jPsA)

PSUMMIT-Jr Study Design

Target Population: Children aged ≥5 to <18 years diagnosed with active jPsA[a] for ≥3 months with inadequate response/intolerance to NSAIDs and/or nonbiologic DMARDs



[a]PsA was defined based on the Vancouver classification criteria: arthritis plus PsO or ≥2 of the following: dactylitis, nail pits, PsO family history, or PsO-like rash. Active disease was defined as ≥3 joints with swelling or loss of motion with pain and/or tenderness. Pts completing the Week-52 visit could enter an LTE study. FSV only occurred for pts not entering the LTE and/or not starting on commercial product; pts starting on commercial product completed the FSV prior to first dose of commercial product. **DMARDs**=disease-modifying anti-rheumatic drugs, **Eff**=efficacy endpoints, **FSV**=final safety visit, **LTE**=long-term extension, **NSAIDs**=nonsteroidal anti-inflammatory drugs, **PE**=primary endpoints, **SE**=secondary endpoints.

Methods

- Pts were assigned to receive subcutaneous UST administered by body weight (<60 kg, 0.75 mg/kg; ≥60 to ≤100 kg, 45 mg; >100 kg, 90 mg)

Endpoints

- The primary efficacy endpoint was Juvenile Idiopathic Arthritis American College of Rheumatology (JIA-ACR) 30 response at Week 24
- Secondary efficacy endpoints were
  - JIA-ACR 30/50/70 through Week 52
  - Median time to JIA-ACR 30 through Week 24
  - Mean change from baseline in clinical Juvenile Arthritis Disease Activity Score 10 (cJADAS-10), JADAS-10, JADAS-27, and JADAS-71 through Week 52
  - Mean change from baseline in Psoriasis Area and Severity Index (PASI) score at Weeks 24 and 52
- PK endpoints were steady-state serum trough concentrations ($C_{trough,ss}$) and model-predicted area under the serum concentration-time curve (AUC_{ss}) at Week 28 (primary) and Week 52 (secondary) by age group
- Antibodies to UST were assessed through Week 52
- Safety endpoints (frequency and types of adverse events (AEs), serious AEs, and reasonably related AEs) were assessed through study end

Statistical Considerations

- Pts were considered nonresponders or to have no change from baseline after the timepoint when any of the following occurred: discontinued study intervention for any reason, including COVID-19; terminated study participation for any reason; initiated or increased the dose of nonbiologic DMARDs or oral corticosteroids over baseline for jPsA; or initiated protocol-prohibited therapies for jPsA
- For JIA-ACR endpoints, after accounting for above rules, pts missing ≥3 components at a timepoint were considered nonresponders at that timepoint
- For JADAS and PASI endpoints, after accounting for above rules, missing data at a timepoint were excluded from analysis at that timepoint
- For pts who did not achieve response, time-to-response data were censored at occurrence of intercurrent event, Week 24, or time of study discontinuation, whichever occurred first

Results

- All 18 pts enrolled in PSUMMIT-Jr and treated with UST completed the Week-52 study visit

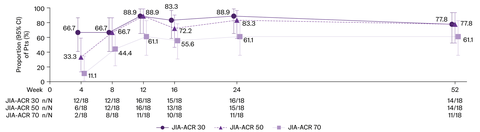
Baseline Demographics and Prior and Current jPsA and PsO Medication Exposure

	UST (N=18)
Demographics	
Age, yrs, median (IQR)	13.0 (11.0; 16.0)
Female	56%
Race	
White	94%
Asian	6%
Weight, kg, median (IQR)	52.1 (41.9; 63.3)
<60	72%
≥60 to 100	28%
Disease Activity	
cJADAS-10, median (IQR)[a]	18.7(16.4, 21.4)
JADAS-10, median (IQR)[b]	20.5 (13.9, 22.6)
JADAS-27, median (IQR)[b]	16.3 (11.8, 23.3)
JADAS-71, median (IQR)[b]	20.9 (13.9, 26.6)
PGA of PsO (0-4)[c]	2.7 (0.68)
% BSA with PsO[c]	13.2 (12.01)
PASI (0-72)[c]	4.3 (4.29)
jPsA/PsO Medication Use at Baseline	
Nonbiologic DMARDs[d]	61%
Oral corticosteroids	17%
Prednisone or equivalent dose[e]	6.3 (3.2)
NSAIDs	50%
Prior jPsA/PsO Medication Use	
Nonbiologic DMARDs	89%
NSAIDs	78%
Anti-TNFα	56%
Biologics (excluding anti-TNFα)	6%
Janus kinase inhibitors	6%

Data are mean (SD) unless otherwise noted. [a]N=17. [b]N=16. [c]Evaluated among pts with ≥3% BSA involvement and PGA of PsO score ≥2 (mild) at baseline, N=10. [d]Methotrexate. [e]N=3. ***BSA****=body surface area,* ***IQR****=interquartile range,* ***PGA****=Physician Global Assessment,* ***SD****=standard deviation,* ***TNF****=tumor necrosis factor.*

At Week 24, 88.9% of pts achieved JIA-ACR 30 response (primary endpoint) and 83.3% and 61.1% achieved JIA-ACR 50 and 70, respectively

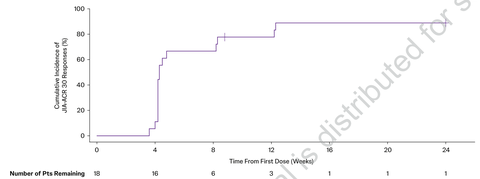
- Although JIA-ACR 30/50/70 response rates decreased slightly from Week 24 to Week 52, the overall trend shows maintenance of response over time



JIA-ACR 30/50/70 were defined as 30%/50%/70% improvement from baseline in ≥3 of the following components with worsening of ≥30% in no more than 1 component (PGA of jPsA disease activity, parent/pt assessment of overall well-being, number of active joints, number of joints with limited range of motion, physical function by Childhood Health Assessment Questionnaire, CRP). 95% CIs were calculated based on the Clopper-Pearson method. ***CI****=confidence intervals,* ***CRP****=C-reactive protein.*

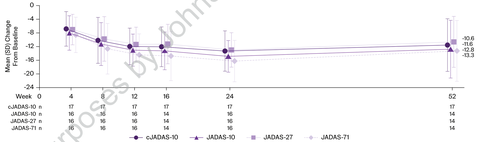
Rapid onset of JIA-ACR 30 response through Week 24 was observed (median time 4.3 [95% CI 4.1, 8.1] weeks)

- 67% of pts achieved JIA-ACR 30 response at the nominal Week 4 visit



At Week 24, mean decreases (improvement) from baseline in cJADAS-10, JADAS-10, JADAS-27, and JADAS-71 were 13.3, 14.9, 13.0, and 16.2, respectively

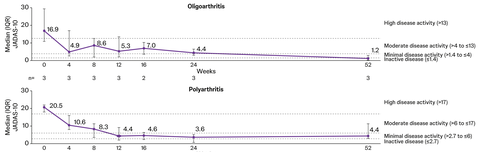
- Similar decreases (improvement) were observed at Week 52



The cJADAS-10 is the sum of active joints (based on 10 joints) plus physician global rating (assessed on a 0-10 cm VAS) and parent/child assessment of well-being. JADAS is the sum of the following components: physician global rating, parent/child assessment of well-being, number of active joints (based on 10, 27, or 71 joints for JADAS-10, -27 and -71, respectively), and CRP. Higher scores indicate greater disease activity. ***VAS****=visual analogue scale.*

Median JADAS-10 values decreased (improved) through Week 52

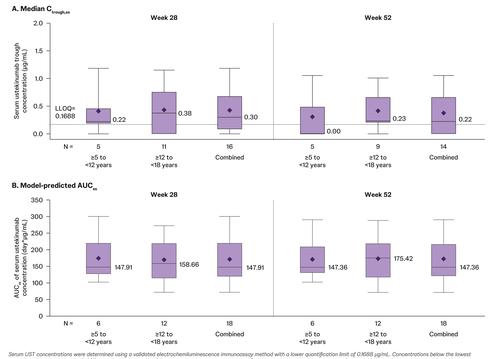
- Among pts with oligoarthritis, median values decreased (improved) from high disease activity at Week 0 to minimal disease activity/inactive at Week 52; interpretation is limited by small sample size
- Among pts with polyarthritis, median values decreased (improved) from high disease activity at Week 0 to minimal disease activity at Week 52



Among the 10 pts with ≥3% BSA involvement and PGA of PsO score ≥2 (mild) at baseline, mean PASI score consistently improved (decreased) from baseline by

- -3.8 (95% CI -6.8, -0.9) at Week 24
- -4.0 (95% CI -7.2, -0.9) at Week 52

Median $C_{trough,ss}$ and model-predicted AUC_{ss} were similar between age groups (≥5 to <12 yrs and ≥12 to <18 yrs) at Weeks 28 and 52



Serum UST concentrations were determined using a validated electrochemiluminescence immunoassay method with a lower quantification limit of 0.1688 µg/mL. Concentrations below the lowest quantifiable concentration (ie, 0.1688 µg/mL) were treated as 0 in calculating the summary statistics. For both panels, the box represents the first and third quartiles, the horizontal line indicates the median, the upper and lower whiskers represent the location of the maximum and minimum with the first and third quartiles +/-1.5 times the interquartile range, and the diamond represents the mean. ***LLOQ****=lower limit of quantification (µg/mL).*

There was no apparent relationship between PK and JIA-ACR 30, JIA-ACR 50, or JIA-ACR 70 responses at Week 24 or 52

	Ustekinumab Concentration Quartiles, µg/mL			
	0.224 to <0.538	0.538 to <1.057	1.057 to <1.850	1.850 to 2.479
Week 24, N	2	3	3	3
JIA-ACR 30, n (%)	2 (100%)	3 (100%)	3 (100%)	3 (100%)
JIA-ACR 50, n (%)	2 (100%)	3 (100%)	3 (100%)	3 (100%)
JIA-ACR 70, n (%)	2 (100%)	3 (100%)	2 (67%)	2 (67%)

	Ustekinumab Concentration Quartiles, µg/mL[a]		
	0 to <0.225	0.225 to <0.661	0.661 to 1.054
Week 52, N	7	3	4
JIA-ACR 30, n (%)	4 (57%)	3 (100%)	4 (100%)
JIA-ACR 50, n (%)	4 (57%)	3 (100%)	4 (100%)
JIA-ACR 70, n (%)	4 (57%)	3 (100%)	2 (50%)

Data are based on nonresponder imputation analysis. Concentrations below the lowest quantifiable concentration (ie, 0.1688 µg/mL) were treated as zero in calculating the quartiles. [a]At Week 52, the lowest 2 quartiles were combined into one quartile. Both the minimum and first quartile of concentrations are 0.

Summary of immunogenicity and safety through end of study

	UST (N=18)
Mean weeks of follow-up	55.6
Treatment-emergent antibodies to UST, n (%)	1 (6%)
Pts with ≥1, n (%)	
AE	18 (100%)
Serious AE[a]	1 (6%)
AE leading to discontinuation of study intervention	0
Severe AE[a,b]	1 (6%)
AE reasonably related to study intervention[c]	4 (22%)
Infection	16 (89%)
Serious infection[a]	1 (6%)

- One pt with JIA-ACR 30 response had neutralizing antibodies to UST without impact on efficacy or safety
- The most common AEs were upper respiratory tract infection (28%), jPsA (22%), nausea (17%), and vomiting (17%)
- No deaths were reported
- No pts had a malignancy, active tuberculosis, opportunistic infection, or injection-site reaction
- No new safety signals were identified

[a]Tooth abscess (n=1; not related to study intervention); [b]2 severe AEs (worsening of jPsA and tooth abscess) occurred in the same pt. [c]Upper respiratory tract infection (n=2); urinary tract infection, diarrhea, nausea, asthenia, pyrexia, oropharyngeal pain (all n=1) (some pts had >1 event).

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