Efficacy and Safety of Subcutaneous Ustekinumab in Paediatric 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

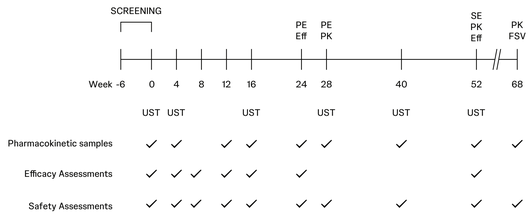
- **Among paediatric participants aged ≥5 to <18 years with active jPsA, UST was effective in improving joint and skin symptoms**
- **UST was well tolerated, with the majority of AEs being mild to moderate in severity and not related to treatment**
- **These results will be used to support an extrapolation approach to broaden the available treatment options for jPsA and address the 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 adult psoriatic arthritis (PsA)
- The phase 3, multicenter PSUMMIT-Jr study evaluated UST pharmacokinetics, efficacy, immunogenicity, and safety in paediatric participants (pts) with active juvenile PsA (jPsA)
- Here, we present open-label UST efficacy and safety data from PSUMMIT-Jr; pharmacokinetic and immunogenicity data will be presented separately

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]JIA 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. ***DMARDs****=disease-modifying anti-rheumatic drugs,* ***EFF****=efficacy endpoints,* ***FSV****=final safety visit,* ***NSAIDs****=nonsteroidal anti-inflammatory drugs,* ***PE****=primary endpoints,* ***PK****=pharmacokinetic endpoints,* ***SE****=secondary endpoints.*

Methods

- Pts were not randomized
- Ustekinumab was administered by body weight (<60 kg, 0.75 mg/kg; ≥60 to ≤100 kg, 45 mg; >100 kg, 90 mg) at Weeks 0, 4, and then every 12 weeks through Week 52

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
- Safety endpoints were frequency and types of adverse events (AEs), serious AEs, and reasonably related AEs

Statistical Considerations

- Pts who 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 were considered nonresponders at or after the timepoint where this occurred
- 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 participants 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

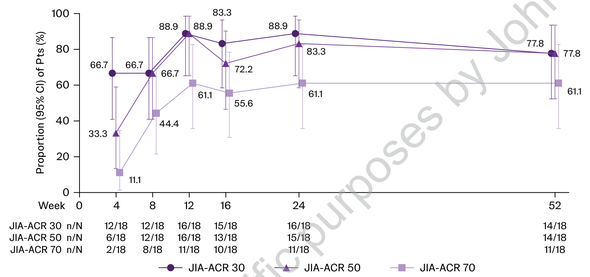
Baseline Demographics and Prior and Current jPsA and PsO Medication Exposure

	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)	2.7 (0.68)
% of BSA with PsO	13.2 (12.01)
PASI (0-72)[c]	4.3 (4.29)
jPsA/PsO Medication Use at Baseline	
Nonbiologic DMARDs (MTX, SSZ, LEF)	61%
Oral corticosteroids	17%
Prednisone or equivalent dose[d]	6.3 (3.2)
NSAIDs	50%
Prior jPsA/PsO Medication Use	
Nonbiologic DMARDs	89%
NSAIDs	78%
Anti-TNFα	56%
Biologics (excluding anti-TNFα)	6%
JAK 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 to severe) at baseline, N=10. [d]N=3. ***BSA****=body surface area,* ***IQR****=interquartile range,* ***JAK****=Janus kinase,* ***LEF****=leflunomide,* ***MTX****=methotrexate,* ***PGA****=Physician Global Assessment,* ***SSZ****=sulfasalazine,* ***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

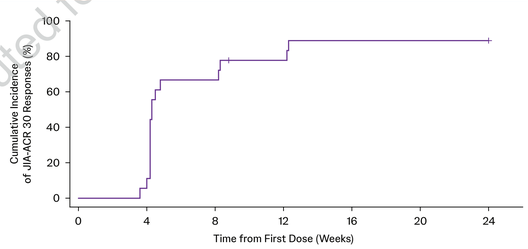
- Although JIA-ACR 30/50/70 response rates decreased slightly from Week 24 to Week 52, the overall trend shows maintenance of response over time



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.*

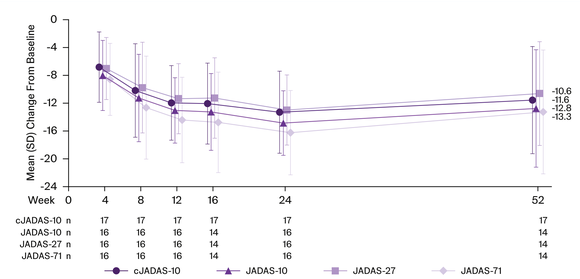
Rapid onset of JIA-ACR 30 response through Week 24 was observed (median time 4.3 [95% CI 4.1, 8.1] weeks)

- 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

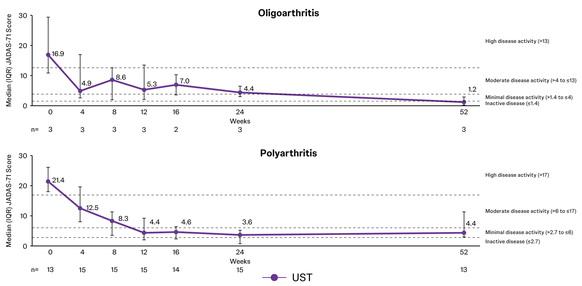
- Similar decreases (improvement) were observed at Week 52



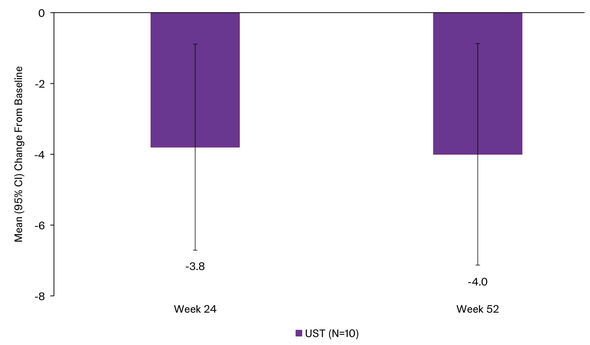
The cJADAS-10 is the sum of active joints (based on 10 joints) plus physician global rating (assessed on a 0-10 cm VAS) and parent/child assessment of well-being. JADAS is the sum of the following component: physician global rating, parent/child assessment of well-being, number of active joints (based 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-71 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



Mean PASI score consistently improved from baseline at Weeks 24 and 52



Mean change from baseline PASI score was evaluated among pts with ≥3% BSA involvement and PGA of PsO score ≥2 (mild to severe) at baseline. PASI is a composite of the state of erythema, induration, and scaling over the body along with the area of the involvement of PsO lesions. Higher scores indicate more severe disease. 95% CIs were calculated based on a 2-sided, 1-sample t distribution.

Summary of safety through end of study

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

- 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]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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