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Sustainability of Response With Upadacitinib in Patients With Moderately to Severely Active Psoriatic Arthritis: Week 152 Data From the SELECT-PsA 1 and SELECT-PsA 2 Trials

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Background:

In the phase 3 SELECT-PsA 1 and SELECT-PsA 2 studies, upadacitinib (UPA), an oral Janus kinase inhibitor, met the primary endpoint (≥20% improvement in ACR score at week [wk] 12) and demonstrated efficacy through 24 wks.

Objectives:

In this post-hoc analysis, the maintenance of clinical response rates with UPA 15 mg (UPA15) were evaluated through nearly 3 years of treatment among patients (pts) who achieved response at wk 24.

Methods:

Enrolled pts were adults with moderately to severely active PsA with inadequate response to non-biologic DMARDs (non–bDMARD-IR; SELECT-PsA 1, NCT03104400) or biologic DMARDs (bDMARD-IR; SELECT-PsA 2, NCT03104374). Both trials included a 24 wk double-blind, placebo-controlled treatment period followed by 32 wks of blinded UPA. SELECTPsA 1 also included an active-comparator arm (adalimumab 40 mg [ADA]) in the 56wk blinded period. Afterwards, pts received open-label UPA (both trials) or ADA (SELECTPsA 1) through wk 152. This analysis included pts originally randomized to UPA15 or ADA. Assessments included improvement in ACR score by ≥50% (ACR50) or ≥70% (ACR70), reduction in Psoriasis Area and Severity Index score by ≥75% (PASI75) or ≥90% (PASI90), minimal disease activity (MDA), low disease activity (Disease Activity in Psoriatic Arthritis score ≤14 [DAPSA-LDA]), resolution of dactylitis/enthesitis (Leeds Dactylitis/Enthesitis Index=0), and clinically meaningful improvement in HAQDisability Index (HAQ-DI, ≥0.35 decrease) or pain (≥1 decrease [0–10 numerical rating scale]). Sustainability of wk 24 responses for each efficacy endpoint was evaluated through wk 152. No imputation on missing data was performed; 95% CIs were based on Wald limits without continuity correction. Only pts with data at both wk 24 and a later visit were included to calculate response sustainability at that visit.

Results:

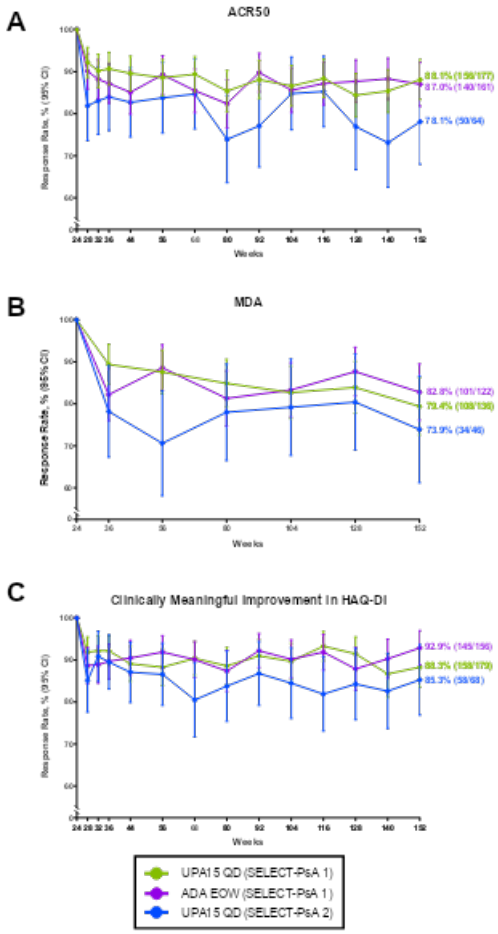
This analysis included 1069 pts originally randomized to UPA15 (SELECT-PsA 1, N=429; SELECT-PsA 2, N=211) or ADA (N=429). In UPA15-treated pts who achieved ACR50 at wk 24, most pts sustained the response at wk 152 (non–bDMARD-IR, 88.1% [156/177]; bDMARD-IR, 78.1% [50/64]; **Fig 1**). Similar results occurred for non–bDMARD-IR and bDMARD-IR, respectively, in ACR70 (77.7% [73/94] and 81.8% [27/33]), PASI75 (80.8% [84/104] and 82.5% [47/57]), and PASI90 (75.0% [48/64] and 66.7% [24/36]; **Fig 2**). At wk 152, sustained treatment effects were also observed on MDA (79.4% [108/136] and 73.9% [34/46]); DAPSA LDA (88.0% [139/158] and 76.8% [43/56]); resolution of dactylitis (97.7% [86/88] and 100% [28/28]) or enthesitis (87.6% [113/129] and 88.0% [44/50]); and clinically meaningful improvement in HAQ-DI (88.3% [158/179] and 85.3% [58/68]) or pain (94.0% [249/265] and 89.9% [98/109]; **Fig 1-2**). In SELECT-PsA 1, the maintenance of response for each assessment was similar between UPA15 and ADA (**Fig 1-2**).

Conclusion:

Although this analysis only evaluated wk 24 treatment responders who did not discontinue the trials, pts with PsA who were non–bDMARD-IR or bDMARD-IR largely sustained wk 24 responses, achieving durable disease control with UPA15 through nearly 3 years of treatment. Future analyses can assess continuous endpoints rather than categorial response measures to confirm these results.

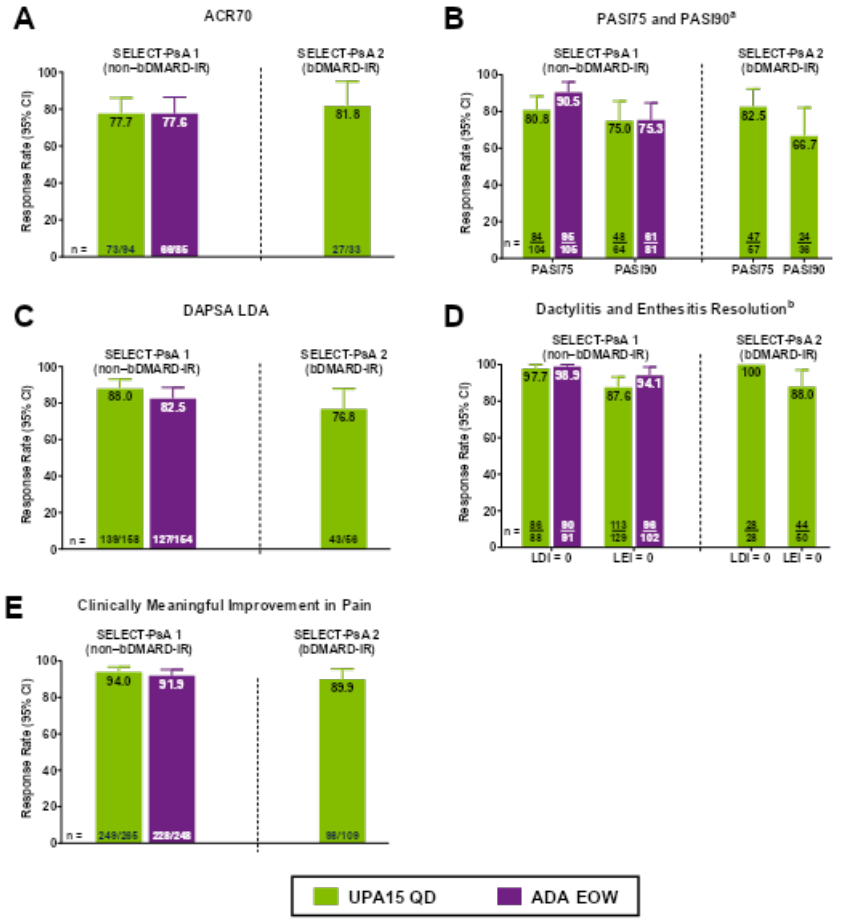
References:

Figure 1. Observed Response Rates at Week 24 Through Week 152 Among Patients Who Achieved ACR50 (**A**), MDA (**B**), or Clinically Meaningful Improvement in HAQ-DI (**C**) at Week 24



ACR50, ≥50% improvement in ACR score; ADA EOW, adalimumab 40 mg every other week; HAQ-DI, Health Assessment Questionnaire-Disability Index; MDA, minimal disease activity; UPA15 QD, upadacitinib 15 mg once daily.

Figure 2. Observed Response Rates at Week 152 Among Patients Who Demonstrated a Response in Each Efficacy Assessment at Week 24



ACR50/70, ≥50%/≥70% improvement in ACR score; ADA EOW, adalimumab 40 mg every other week; bDMARD-IR, inadequate response to at least 1 biologic DMARD; DAPSA LDA, low disease activity as defined by Disease Activity in Psoriatic Arthritis score; HAQ-DI, Health Assessment Questionnaire-Disability Index; LDI, Leeds Dactylitis Index; LEI, Leeds Enthesitis Index; non–bDMARD-IR, inadequate response to at least 1 non-biologic DMARD; NRS, numerical rating scale; PASI75/90, ≥75%/≥90% reduction in Psoriasis Area and Severity Index score; UPA15 QD, upadacitinib 15 mg once daily.
[a]Assessed in patients with ≥3% body surface area affected by psoriasis at baseline.
[b]Resolution of dactylitis assessed in patients with LDI >0 at baseline; resolution of enthesitis assessed in patients with LEI >0 at baseline.

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