Electronic Supplementary Material

Improvement in patient-reported outcomes in patients with psoriatic arthritis treated with upadacitinib versus placebo or adalimumab: results from SELECT-PsA 1

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|          | Comissão Nacional de Ética em Pesquisa (CONEP)            |
|          | Seres Humanos da Irmandade da Santa Casa de Misericórdia de São Paulo |
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|          | Local Ethics Committee at Medical Center Excelsior OOD    |
|          | Local Ethics Committee at MHAT                            |
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| New Territories West Cluster Clinical & Research Ethics Committee (NTWC CREC) |
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Ethics Council at the Ministry of Health of the Russian Federation  
Local EC: Saint Petersburg  
Medical Center Healthy Family, LLC  
Moscow City Ethics Committee |
| Romania     | Comisia Nationala de Bioetica a Medicamentului si a Dispozitivelor Medicale  
National Agency for Medicines and Medical Devices |
| Country         | Independent ethics committee or institutional review board                                                                 |
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| Singapore      | Centralised Institutional Review Board (CIRB)                                                                             |
| Slovakia       | Eticka komisia Trencianskeho Samospravneho kraja                                                                          |
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| South Africa   | Pharma Ethics Independent Research Committee (Pty) Ltd                                                                        |
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|                | CCER                                                                                                                      |
|                | CER-VD                                                                                                                     |
|                | EK Nordwest und Zentralschweiz (EKNZ)                                                                                       |
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|                | The Institutional Review Board Chung Shan Medical University Hospital                                                     |
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| Ukraine        | Ethics and Deontology Commission of GI L.T. Malaya Therapy                                                                 |
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|                              | Ethics Commission at Medical Center of Private Higher Educational Institute, Institute of General Practice Family Medicine |
|                              | Ethics Commission at Municipal Institution of Kyiv Regional Council Kyiv Regional Clinical Hospital |
|                              | Ethics Commission of LLC Revmocentr |
|                              | Local Ethic Commission at Lviv, Regional Clinical Hospital |
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|                              | MetroHealth Medical Center Institutional Review Board |
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|                              | Shulman IRB |
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|                                        | The Partners Human Research Committee (PHRC)                                                                             |
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|                                        | UCLA Office of Human Research Protection Program                                                                          |
|                                        | Western Institutional Review Board                                                                                     |
Fig. S1 SF-36 domain scores at Week 24 relative to age- and gender-adjusted normative values (MMRM)

ADA, adalimumab; A/G Norms, age- and gender-matched normative values; BL, baseline; BP, bodily pain; GH, general health; MH, mental health; PBO, placebo; PF, physical functioning; RE, role emotional; RP, role physical; SF, social functioning; SF-36, 36-Item Short Form Health Survey; UPA, upadacitinib; US, United States; VT, vitality.
Fig. S2. Proportion of patients with resolution of itch (as observed)

*p < 0.001 for UPA versus ADA. Itch response (SAPS question 2) was assessed starting at Week 16. Data are reported for patients who had a baseline score >0.

ADA, adalimumab; CI, confidence interval; PBO, placebo; UPA, upadacitinib.
Fig. S3 Proportion of patients reporting improvements ≥ MCID and NNTs in PROs at Week 24 (NRI)
a. PROs, b. SF-36 domains.

*p < 0.05, †p ≤ 0.01, and ‡p ≤ 0.001 for UPA versus PBO and §p < 0.05 and ¶p ≤ 0.01 for UPA versus ADA. aReported only for patients with investigator-determined psoriatic spondylitis at baseline. bMean of BASDAI questions 5 and 6. NNTs were calculated for UPA versus PBO and for ADA versus PBO. NNT for UPA 30 mg was not calculated for MCS and RE because the proportion of patients reporting improvement was not significantly different for UPA 30 mg versus PBO. MCID definitions: ≥1-point decrease (PtGA, pain, and morning stiffness), ≥0.35-unit decrease (HAQ-DI), ≥4-point increase (FACIT-F), ≥0.05-unit increase (EQ-5D-5L), ≥1.1-point decrease (BASDAI), ≥2.5-point increase (SF-36 PCS and MCS), and ≥5-point increase (SF-36 domains).

ADA, adalimumab; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BP, bodily pain; EQ-5D-5L, EuroQoL 5-Dimension 5-Level index score; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; GH, general health; HAQ-DI, Health Assessment Questionnaire Disability Index; MCID, minimal clinically important difference; MCS, Mental Component Summary; MH, mental health; NNT, number needed to treat; NRI, non-responder imputation; PBO, placebo; PCS, Physical Component Summary; PF, physical functioning; PRO, patient-reported outcome; PtGA, Patient Global Assessment of Disease Activity; RE, role emotional; RP, role physical; SF, social functioning; SF-36, 36-Item Short Form Health Survey; UPA, upadacitinib; VT, vitality.
Fig. S4. Proportion of patients maintaining Week 12 reported improvements ≥ MCID in PROs at Week 56 (as observed)

a. PROs, b. SF-36 domains.

* $p < 0.05$ and $\dagger p \leq 0.01$ UPA versus ADA 40 mg. aReported only for patients with investigator-determined psoriatic spondylitis at baseline. bMean of BASDAI questions 5 and 6.

ADA, adalimumab; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BP, bodily pain; EQ-5D-5L, EuroQoL 5-Dimension 5-Level index score; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; GH, general health; HAQ-DI, Health Assessment Questionnaire Disability Index; MCID, minimal clinically important difference; MCS, Mental Component Summary; MH, mental health; PBO, placebo; PCS, Physical Component Summary;
PF, physical functioning; PRO, patient-reported outcome; PtGA, Patient Global Assessment of Disease Activity; RE, role emotional; RP, role physical; SF, social functioning; SF-36, 36-Item Short Form Health Survey; UPA, upadacitinib; VT, vitality.
Fig. S5 Patients reporting PRO scores ≥ normative values at baseline and Week 24 (NRI) and age- and gender-matched normative values in SF-36 domains

a. PROs, b. SF-36 domains.

* \( p < 0.05 \), † \( p \leq 0.01 \), and ‡ \( p \leq 0.001 \) for UPA versus PBO and § \( p < 0.05 \) and ¶ \( p \leq 0.01 \) for UPA versus ADA. The percentages at 24 weeks may or may not include the same patients that achieved that outcome at baseline.

ADA, adalimumab; BL, baseline; BP, bodily pain; EQ-5D-5L, EuroQoL 5-Dimension 5-Level index score; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; GH, general health; HAQ-DI, Health Assessment Questionnaire Disability Index; MCS, Mental Component Summary; MH, mental health; NRI, non-responder imputation; PBO, placebo; PCS, Physical Component Summary; PF, physical functioning; PRO, patient-reported outcome; PtGA, Patient...
Global Assessment of Disease Activity; RE, role emotional; RP, role physical; SF, social functioning; SF-36, 36-Item Short Form Health Survey; UPA, upadacitinib; VT, vitality.