

Improvements in clinical and patient-reported outcomes and durability of response with the targeted oral peptide icotrokinra in adolescents with moderate-to-severe plaque psoriasis: One-year results from the ICONIC-LEAD randomized controlled trial



Key Message: *Among adolescents with moderate-to-severe plaque psoriasis, icotrokinra demonstrated high and durable rates of skin clearance, symptom improvement/resolution, and health-related quality-of-life improvements through week 52, with a safety profile consistent with that established across all trial participants, highlighting its ability to address unmet needs.*

Psoriasis therapies approved for adolescents are limited.¹ Icotrokinra, a targeted oral peptide that precisely inhibits interleukin-23 pathway signaling,² is approved to treat moderate-to-severe plaque psoriasis in adults and pediatric patients (aged ≥ 12 years, ≥ 40 kg).³ Icotrokinra provided significant skin clearance in adults and adolescents with moderate-to-severe psoriasis through week (W) 16 of the phase 3 ICONIC-LEAD study.⁴ Clinical and patient-reported outcomes and icotrokinra safety were examined in adolescents through W52 in ICONIC-LEAD (Supplementary Methods, available via Mendeley at <https://data.mendeley.com/datasets/n3kcy792zy/1>). Maintenance of W24 icotrokinra response among adults entering randomized withdrawal and retreatment (W24-52) is detailed in a companion report.⁵

Of 66 randomized adolescents (icotrokinra: 44, placebo: 22), 95% completed treatment through W52 (Supplementary Fig 1, available via Mendeley at <https://data.mendeley.com/datasets/n3kcy792zy/1>). Baseline characteristics, well balanced across groups, indicated moderate-to-severe psoriasis and impacted health-related quality of life (HRQoL) (Supplementary Table I, available via Mendeley at <https://data.mendeley.com/datasets/n3kcy792zy/1>).

At W16, 84% and 41% of icotrokinra-randomized adolescents achieved Investigator's Global Assessment (IGA) 0/1 and IGA 0 versus 27% and 5% with placebo,

with a treatment differences of 56% (95% confidence interval [CI] [33%, 74%], nominal $P < .001$) and 36% (95% CI [15%, 52%], nominal $P = .002$), respectively (Fig 1). Response rates increased and were durable during W24-52 of icotrokinra (IGA 0/1 range: 82% to 91%; IGA 0: 61% to 75%). Among icotrokinra W24 IGA 0/1 ($N = 38$) responders, 89% maintained response at W52. Comparable W52 IGA 0/1 and IGA 0 response rates were achieved following W16 placebo-to-icotrokinra transition. Achievement and maintenance of Psoriasis Area and Severity Index 75/90/100 responses were consistent (Supplementary Fig 2, available via Mendeley at <https://data.mendeley.com/datasets/n3kcy792zy/1>).

At W16, 56% of 27 icotrokinra-randomized and 12% of 17 placebo-randomized adolescents with baseline Psoriasis Symptoms and Signs Diary (PSSD)-Itch ≥ 4 reported clinically meaningful improvements (treatment difference [95% CI]: 48% [20%, 68%], nominal $P = .002$), with increased icotrokinra response rates at W52 (81%; Supplementary Fig 3, available via Mendeley at <https://data.mendeley.com/datasets/n3kcy792zy/1>). Among 37 icotrokinra-randomized adolescents with baseline PSSD-Symptom > 0 , 35% reported symptom-free status at W16 versus 0% of 20 placebo-randomized adolescents (treatment difference [95% CI]: 34% [14%, 51%], nominal $P = .002$). Symptom-free rates increased with icotrokinra during W24-52 (Supplementary Fig 4, available via Mendeley at <https://data.mendeley.com/datasets/n3kcy792zy/1>). Achievement of PSSD-Sign = 0 (sign-free) status was consistent (Supplementary Fig 4, available via Mendeley at <https://data.mendeley.com/datasets/n3kcy792zy/1>). Among 59 adolescents (icotrokinra: 40; placebo: 19) reporting baseline Children's Dermatology Life Quality Index (CDLQI) > 1 , 68% of icotrokinra-randomized participants reported CDLQI 0/1 (no psoriasis impact on HRQoL) at W16 (treatment difference [95% CI] vs placebo: 54% [31%, 72%]; nominal $P < .001$), with increased icotrokinra response rates during W24-52 (CDLQI 0/1 range: 82% to 85%; Supplementary Fig 5, available via Mendeley at <https://data.mendeley.com/datasets/n3kcy792zy/1>). W52 itch resolution, symptom-free and sign-free rates, and HRQoL improvements reported by placebo-to-icotrokinra adolescents were comparable to those of icotrokinra-randomized participants. At W16, all adolescents rated overall icotrokinra acceptability/palatability as 'acceptable' (61%) or 'good' (39%).

Icotrokinra safety profile in adolescents was consistent with the overall ICONIC-LEAD population through W16⁴ and W52,⁵ with no increase in adverse

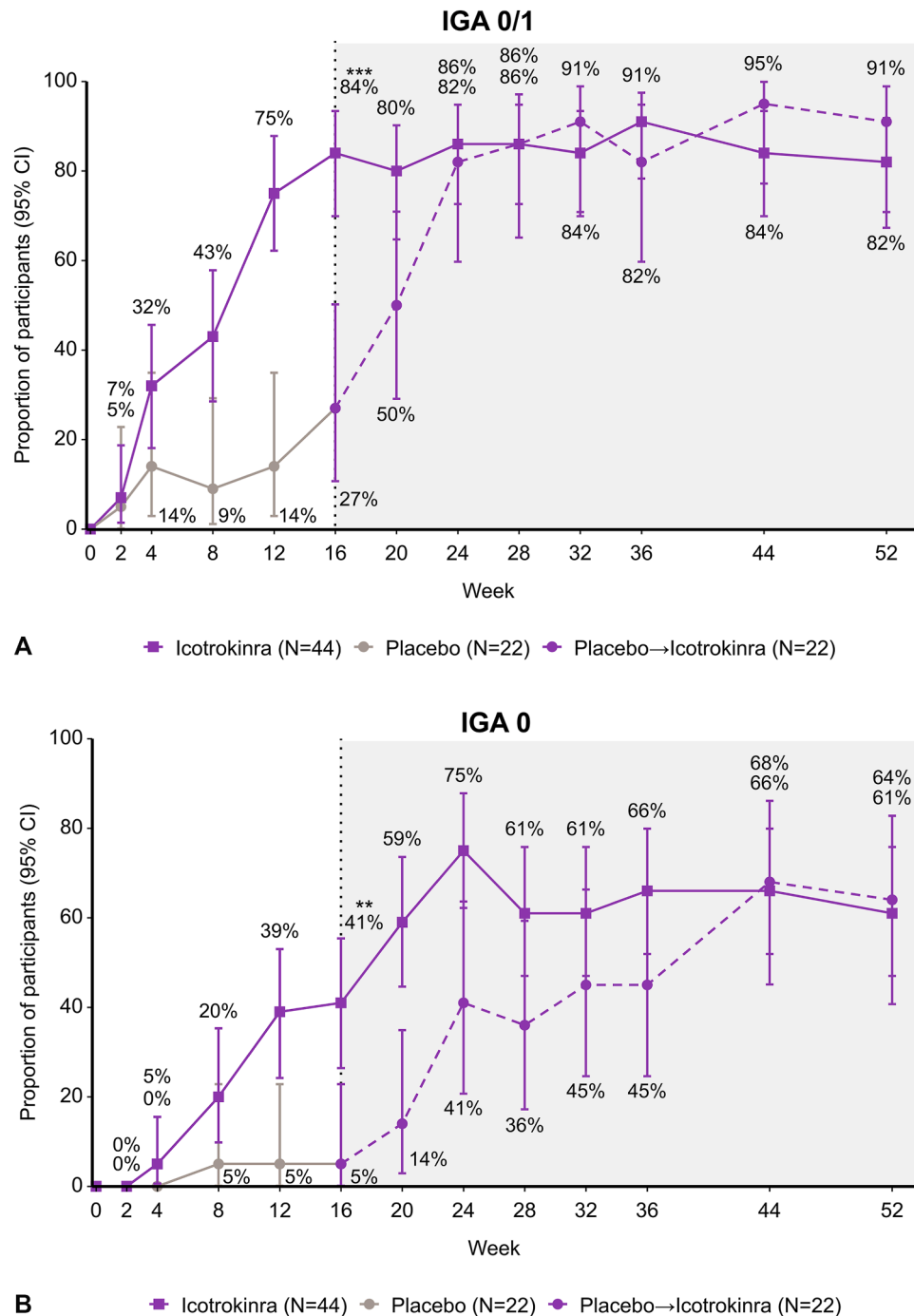


Fig 1. Proportions of adolescents achieving (A) IGA 0/1 and (B) IGA 0 responses through W52. Dotted line indicates placebo transition to icotrokinra (W16). Shaded area indicates postplacebo-controlled treatment period (W16-52). Nominal $**P < .01$, $***P < .001$ versus placebo. CI, Confidence interval; IGA, Investigator's Global Assessment; W, week.

events (AEs) or serious AEs with continuous icotrokinra or with placebo-to-icotrokinra transition. No AE leading to discontinuation, serious infection, malignancy, or active tuberculosis was reported through W52 (Supplementary Table II, available via Mendeley at <https://data.mendeley.com/datasets/n3kcy792zy/1>).

Among adolescents with moderate-to-severe plaque psoriasis, icotrokinra demonstrated high and durable rates of skin clearance, symptom improvement/resolution, and HRQoL improvements through W52, with a safety profile consistent with that established across all trial participants,³ highlighting its ability to address unmet needs.

Declaration of generative AI and AI-assisted technologies in the writing process

Not applicable.

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access to the study data can be submitted through the Yale Open Data Access (YODA) Project site at <http://yoda.yale.edu>.

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Conflicts of interest

Dr Soung is a speaker, consultant, advisory board member, and/or investigator for AbbVie, Amgen, Arcutis, Aslan, Bristol Myers Squibb, Coval Biopharma, Dermavant, Eli Lilly, Johnson & Johnson, KoBio Labs, National Psoriasis Foundation, Novartis, Ortho Dermatologic, Oruka, Pfizer, Regeneron/Sanofi, and UCB. Dr Lebwohl is an employee of Mount Sinai; received research funds from AbbVie, Arcutis, Avotres Therapeutics, Boehringer Ingelheim, Bristol Meyers Squibb, Cara Therapeutics, Clexio, Dermavant Sciences, Eli Lilly, Incyte, Inozyme, Johnson & Johnson, Oruka, Pfizer, Sanofi-Regeneron, and UCB; and is a consultant for AbbVie, Added Health, Aikium, Almirall, AltruBio Inc, Alumis, Amgen, Apogee, Arcutis, Inc, AstraZeneca, Atomwise, Avotres Therapeutics, Boehringer-Ingelheim, Bristol-Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant Sciences, Dermsquared, Edessa, Eli Lilly, Evomune, Inc, Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Johnson & Johnson, Incyte, LEO Pharma, Mayne Pharmaceuticals, Meiji Seika Pharma, Mindera, Mirium Pharmaceuticals, Moonlake, Oruka, Pfizer, Sanofi-Regeneron, Revolo, Seanergy, Strata, Sun Pharma, Takeda, Trevi, and Verrica. Dr Hebert is an employee of UTHealth McGovern Medical School-Houston; research grants were paid to medical school by AbbVie, Arcutis, Dermavant, Eli Lilly, Johnson & Johnson, Pfizer, and Takeda; has received honoraria from Almirall, Apogee, Arcutis, Castle Biosciences, Dermavant, Incyte, Johnson & Johnson, Pfizer, and Verrica; and has served on Data and Safety Monitoring Boards for GlaxoSmithKline, OrthoDermatologics, and Sanofi-Regeneron. Dr Pink is an investigator, advisor, and/or speaker and/or received educational support from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Galderma, Incyte, Johnson & Johnson, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB. Dr Hong is a consultant and/or investigator and/or speaker for AbbVie, Amgen, Arcutis, ASLAN, Bausch, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Cutanea, Dermavant, Dermira, DS Biopharma, Eli Lilly, Evelo Biosciences, Galderma, GlaxoSmithKline, Immagene, Incyte, Johnson & Johnson, LEO Pharma, Medimmune, Merck, Mirimar, Novartis, Organon, Oruka, Pfizer, Regeneron, Roche, Sanofi, Takeda, and UCB. Dr Iaconangelo, Megan Miller-Kassamali, Dr Cafone, Jingzhi Jiang, Dr DeKlotz, Dr Li, Dr

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Sex-based disparities in Mohs micrographic surgery utilization and margin outcomes in dermatofibrosarcoma protuberans: A National Cancer Database analysis



Key Message: Male patients with dermatofibrosarcoma protuberans had lower utilization of Mohs micrographic surgery, higher rates of positive surgical margins, and worse overall survival, highlighting potential disparities in access to specialized surgical care.

Dermatofibrosarcoma protuberans (DFSP) is a rare, locally aggressive tumor with a high risk of local recurrence, for which complete surgical excision is the cornerstone of management.^{1,2} Achieving negative margins is critical, as margin status is closely associated with recurrence and long-term outcomes.³ Despite the central role of surgery in DFSP, sex-based differences in surgical management and outcomes remain poorly characterized.

We conducted a retrospective cohort study using the National Cancer Database, including adult patients (≥ 18 years) diagnosed with DFSP between 2004 and 2023, identified using ICD-O-3 histology codes (8832/3, 8833/3) and cutaneous primary site codes (C44.x). The primary outcomes were utilization of Mohs micrographic surgery (MMS), positive surgical margins, and overall survival (OS). Factors associated with MMS utilization and positive surgical margins were evaluated using multivariable logistic regression. OS was estimated using the Kaplan-Meier method and compared with the log-rank test, and multivariable Cox proportional hazards regression was used to assess the association between sex and OS after adjustment for demographic, clinical, and treatment-related factors (see Supplementary Methods, available via Mendeley at <https://data.mendeley.com/datasets/pnvhd6j9nn/1>).

A total of 8911 patients with DFSP were included, of whom 4159 (46.7%) were male and 4752 (53.3%) were female (Supplementary Table I, available via Mendeley at <https://data.mendeley.com/datasets/pnvhd6j9nn/1>). Male patients were slightly older at diagnosis (median age 44 vs 43 years, $P = .006$) and were more likely to be uninsured (10.0% vs 7.5%) ($P < .001$). Tumors in male patients were more frequently located on the head and neck (16.5% vs 11.0%) and were larger in size (median 35 vs 29 mm; $P < .001$). In terms of treatment, male patients were less likely to undergo MMS (11.4% vs 13.9%, $P = .003$), more likely to receive radiotherapy (8.6% vs 6.0%, $P < .001$). In multivariable analyses, male sex was independently associated with lower odds of undergoing MMS (adjusted odds ratio 0.82, 95% CI 0.72-0.93, $P = .003$, Table I). Male patients also had higher odds of positive surgical margins compared with female patients (adjusted odds ratio 1.27, 95% CI 1.11-1.45, $P = .001$). In stratified analyses by facility type, the associations between male sex and MMS utilization as well as positive surgical margins were not statistically significant in academic centers but remained significant in nonacademic settings (Supplementary Tables II and III, available via Mendeley at <https://data.mendeley.com/datasets/pnvhd6j9nn/1>). OS was significantly lower in male patients compared with female patients (Fig 1). In multivariable Cox regression analysis, male sex was independently associated with worse OS (adjusted hazard ratio 1.27, 95% CI 1.09-1.47, $P = .002$, Supplementary Table IV, available via Mendeley at <https://data.mendeley.com/datasets/pnvhd6j9nn/1>).

In this population-based analysis, male patients presented with larger tumors, which may suggest