Real-world effectiveness of deucravacitinib in patients with plaque psoriasis: a 6-month analysis of skin clearance from the RePhlect Registry

Mark Lebwohl, MD,[1] April W. Armstrong, MD, MPH,[2] Stefan Varga, PharmD, MS,[3] Yichen Zhong, PhD,[3] Joseph F. Merola, MD, MMSc,[4] Adam Sima, PhD,[5] Melinda Gooderham, MD,[6-8] Kim A. Papp, MD, PhD,[9,10] Alice B. Gottlieb, MD, PhD,[11] Andrew Napoli, PhD,[3] Bruce Strober, MD, MMSc[12]

[1]Icahn School of Medicine at Mount Sinai, New York, NY, USA; [2]University of California Los Angeles, Los Angeles, CA, USA; [3]Bristol Myers Squibb, Princeton, NJ, USA; [4]University of Texas Southwestern Medical Center, Dallas, TX, USA; [5]CorEvitas, LLC, Waltham, MA, USA; [6]SKiN Centre for Dermatology, Peterborough, ON, Canada; [7]Queen's University, Kingston, ON, Canada; [8]Probity Medical Research, Waterloo, ON, Canada; [9]Alliance Clinical Trials and Probity Medical Research, Waterloo, ON, Canada; [10]Division of Dermatology, Temerty School of Medicine, University of Toronto School of Medicine, Toronto, ON, Canada; [11]Yale University School of Medicine, New Haven, CT, USA; [12]Central Connecticut Dermatology Research, Cornwell, CT, USA

Introduction

- Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor is approved in the US, EU, and other countries for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy[1-4]
- While the efficacy of deucravacitinib has been demonstrated in phase 3 trials[5-6], the long-term, real-world effectiveness in a real-world population has not been established
- The Registry of Psoriasis Health Outcomes: A Longitudinal Real-World Collaboration Study (RePhlect) assesses deucravacitinib usage in a real-world, global population of patients with psoriasis
  - This study focuses on patients within the North American (US and Canada) region only

Objective

- To assess effectiveness of deucravacitinib as measured by skin clearance after 6 months of persistent treatment in patients treated in the US and Canada

Methods

- Demographics and clinical characteristics data were collected at baseline
- Skin clearance was measured at the 6-month visit (5-9 months window) using:
  - Percentage of affected body surface area (BSA)
  - Investigator's Global Assessment (IGA)
  - Psoriasis Area and Severity Index (PASI)

Inclusion criteria

- Physician-reported (dermatologist) diagnosis of plaque psoriasis
- Patient ≥18 years of age who provided written informed consent for registry participation
- Oral initiation of deucravacitinib for the treatment of plaque psoriasis on or after September 2022
- Persisted with deucravacitinib until their 6-month follow-up visit (data cut-off: December 2024)

Exclusion criteria

- Participation in an interventional clinical trial with a nonmarketed or marketed investigational drug
- Restart of treatment with study-eligible therapies previously received at any time during patient's treatment history

Statistical analysis

- Baseline demographic and clinical characteristics were analyzed descriptively
- Outcomes at the 6-month follow-up visit were summarized descriptively
- *P* values for mean changes from baseline to 6-month follow-up were calculated from paired t-tests

Results

- This interim analysis included 144 patients (**Table**)
  - At baseline, 55.2%, 64.3%, and 30.6% of patients had moderate PsO based on BSA, IGA, and PASI, respectively
  - 76.2% had BSA <10, 24.5% had IGA ≤3, and 77.1% had PASI <10 at baseline

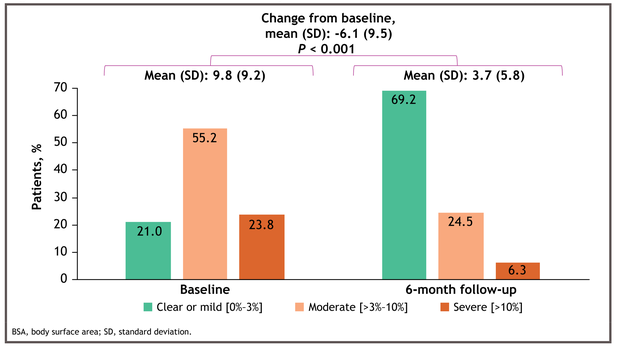
Table. Baseline demographic and clinical characteristics

Characteristics	Overall cohort (n = 144)
Demographic characteristics	
Age (years)	
Mean (SD)	53.6 (14.5)
Sex, n (%)	
Female	78 (54.2)
Race, n (%)	
White	122 (85.3)
BMI category, n (%)	
Underweight/normal	24 (17.9)
Overweight	56 (41.8)
Obesity	54 (40.3)
Clinical characteristics	
Psoriasis duration, years, mean (SD)	15.3 (12.9)
BSA, mean (SD)	9.8 (9.2)
BSA category, n (%)	
Clear or mild [0-3]	30 (21.0)
Moderate [>3-10]	79 (55.2)
Severe [>10]	34 (23.8)
IGA, mean (SD)	2.8 (0.8)
IGA, n (%)	
Clear/almost clear [0-1]	9 (6.3)
Mild [2]	26 (18.2)
Moderate [3]	92 (64.3)
Severe [4]	16 (11.2)
PASI, mean (SD)	6.5 (5.3)
PASI, n (%)	
Clear/nearly clear [0-1]	19 (13.2)
Mild [>1-5]	48 (33.3)
Moderate [>5-10]	44 (30.6)
Severe [>10]	33 (22.9)
DLQI, mean (SD)	7.1 (5.5)
VAS-Itch, mean (SD)	56.1 (30.1)
VAS-Skin pain, mean (SD)	33.3 (29.2)
VAS-Fatigue, mean (SD)	39.1 (30.3)
VAS-Joint pain, mean (SD)	48.1 (29.3)

BMI, body mass index; BSA, body surface area; DLQI, Dermatology Life Quality Index; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; SD, standard deviation; VAS, visual analog scale.

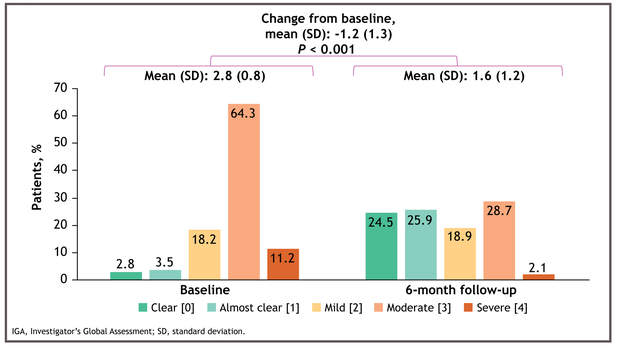
- Significant improvements in BSA-defined disease severity were observed after 6 months of continuous deucravacitinib treatment (*P* < 0.001; **Figure 1**)
  - Mean (SD) BSA decreased from 9.8 (9.2) at baseline to 3.7 (5.8) at the 6-month follow-up visit
  - Of the 30 patients with BSA 0%-3% at baseline, 90.0% (n = 27) maintained the response at the 6-month follow-up visit
  - Among patients with BSA >3% at baseline, 63.7% achieved BSA ≤3% at the 6-month follow-up visit
- Significant improvements in IGA-defined disease severity were observed after 6 months of continuous deucravacitinib treatment (*P* < 0.001; **Figure 2**)
  - Of the 9 patients with IGA 0/1 at baseline, 88.9% (n = 8) maintained the response at the 6-month follow-up visit
  - Among patients with IGA >1 at baseline, 47.8% achieved IGA 0/1 at the 6-month follow-up visit
- Significant improvements in PASI-defined disease severity were observed after 6 months of continuous deucravacitinib treatment (*P* < 0.001; **Figure 3**)
  - Mean (SD) PASI decreased from 6.5 (5.3) at baseline to 2.3 (3.0) at the 6-month follow-up visit
  - Of the 44 patients with PASI 0-3 at baseline, 93.2% (n = 41) maintained the response at the 6-month follow-up visit
  - Among patients with PASI >3 at baseline, 65.0% achieved PASI ≤3 at the 6-month follow-up visit

Figure 1. BSA-defined disease severity at baseline and 6-month follow-up



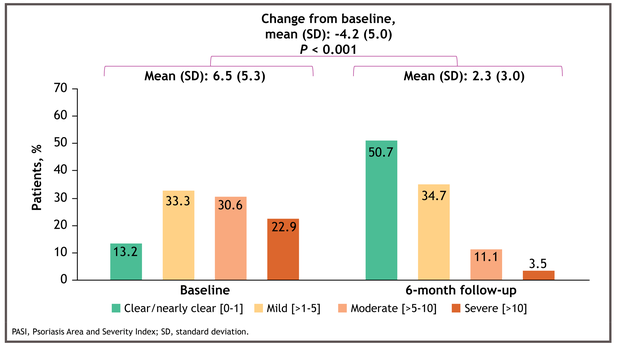
BSA, body surface area; SD, standard deviation.

Figure 2. IGA-defined disease severity at baseline and 6-month follow-up



IGA, Investigator's Global Assessment; SD, standard deviation.

Figure 3. PASI-defined disease severity at baseline and 6-month follow-up



PASI, Psoriasis Area and Severity Index; SD, standard deviation.

Conclusions

- Most of the real-world patients initiating deucravacitinib in this study had moderate or lower disease severity (BSA ≤10, IGA ≤3, or PASI ≤10)
- This real-world study demonstrated the effectiveness of 6 months of continuous deucravacitinib treatment in improving skin clearance in patients with psoriasis, as assessed by multiple clinician-reported measures (BSA, IGA, PASI)
- These findings support the use of deucravacitinib as an effective oral therapy for psoriasis in real-world clinical practice in the US and Canada

References

1. Sotyktu [package insert]. Princeton, NJ: Bristol Myers Squibb; September 2022.
2. Sotyktu [European summary of product characteristics]. Dublin, Ireland: Bristol Myers Squibb EEIG; December 2023.
3. Sotyktu [package insert]. Tokyo, Japan: Bristol Myers Squibb K.K.; September 2022.
4. Sotyktu [European summary of product characteristics]. Munich, Germany: Bristol Myers Squibb GmbH & Co; March 2023.
5. Armstrong AW, et al. *J Am Acad Dermatol*. 2023;88:29-39.
6. Strober B, et al. *J Am Acad Dermatol*. 2023;88:40-51.

Acknowledgments

- The design and conduct of this research study was a collaborative effort between CorEvitas and Bristol Myers Squibb, and financial support for the research study was provided by Bristol Myers Squibb
  - The CorEvitas Psoriasis Registry was developed in collaboration with the National Psoriasis Foundation (NPF)
- The registry study is sponsored by CorEvitas, LLC. CorEvitas has been supported through contracted subscriptions in the last two years by AbbVie, Amgen, Inc., Arena, Boehringer Ingelheim, Bristol Myers Squibb, Chugai, Eli Lilly and Company, Genentech, GSK, Janssen Pharmaceuticals, Inc., LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Inc., Sun Pharmaceutical Industries Ltd., and UCB S.A.
- The authors would like to thank all of the investigators, their clinical staff, and patients who participate in the CorEvitas Psoriasis Registry
- Medical writing and editorial assistance was provided by Michon Jackson, PhD, of Peloton Advantage, LLC, an OPEN Health company, and funded by Bristol Myers Squibb

Disclosures

- **ML:** Research funding on behalf of Mount Sinai: AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Clexio, Dermavant, Incyte, Inozyme, Janssen, Lilly, Pfizer, Sanofi-Regeneron, and UCB; Consulting fees: Almirall, AltruBio, Apogee, Arcutis, AstraZeneca, Atomwise, Avotres, Boehringer Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant, Dermsquared, Evommune, Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Incyte, Leo Pharma, Meiji Seika Pharma, Mindera Health, Pfizer, Sanofi-Regeneron, Seanergy, Strata Skin Sciences, Takeda Pharmaceuticals, Trevi Therapeutics, and Verrica
- **AWA:** Research investigator, scientific advisor, and/or speaker: AbbVie, Almirall, Arcutis, Aslan Pharmaceuticals, Beiersdorf, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, EPI Health, Incyte, Janssen, Leo Pharma, Lilly, Mindera Health, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB
- **SV, YZ,** and **AN:** Employees and shareholders: Bristol Myers Squibb
- **JFM:** Consultant and/or investigator: AbbVie, Amgen, Biogen, Bristol Myers Squibb, Dermavant, Janssen, Leo Pharma, Lilly, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, and UCB
- **AS:** Employee: CorEvitas, LLC
- **MG:** Advisory board, principal investigator, consulting and lecture fees: AbbVie, Amgen, Arcutis, Bausch Health, Boehringer Ingelheim International GmbH, Lilly, Janssen, Novartis, Sanofi Genzyme, Sun Pharma, and UCB; Advisory board, primary investigator, and lecture fees: Galderma SA, Leo Pharma, Pfizer, and Regeneron; Advisory board, primary investigator, and consultant fees: Aslan Pharmaceuticals; Primary investigator and consultant fees: Akros Pharma and Kyowa Kirin; Primary investigator: Aristea Therapeutics, AnaptysBio, Bristol Myers Squibb, Coherus Biosciences, Dermira, GSK, Incyte, MedImmune, Meiji Seika, Merck, MoonLake Immunotherapeutics, and Nimbus Therapeutics; Advisory board: Asana Biosciences
- **KAP:** Consultant: AbbVie, Acelyrin, Akros, Amgen, Aralez Pharmaceuticals, Arcutis, Avillion, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite BioPharma, Celltrion, Coherus, Dermavant, Dermira, Dice Therapeutics, Dow Pharma, Evelo Biosciences, Forbion, Galderma, Incyte, Janssen, Kyowa Hakko Kirin, Leo Pharma, Lilly, Meiji Seika Pharma, Merck, Mitsubishi Pharma, Novartis, Pfizer, Regeneron, Reistone Biopharma, Roche, Sanofi Genzyme, Sandoz, Sun Pharma, Takeda Pharmaceuticals, UCB, vTv Therapeutics, and Xencor; Speakers bureau: AbbVie, Amgen, Bausch Health/Valeant, Galderma, Incyte, Janssen, Kyowa Hakko Kirin, Leo Pharma, Lilly, Merck, Novartis, Pfizer, and Sanofi Genzyme; Clinical research grants: AbbVie, Akros, Amgen, Anacor, Arcutis, Avillion, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Can-Fite BioPharma, Coherus, Dermavant, Dermira, Dice Therapeutics, Dow Pharma, Evelo Biosciences, Galderma, Gilead, GSK, Incyte, Janssen, Kyowa Hakko Kirin, Leo Pharma, Lilly, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sun Pharma, Takeda Pharmaceuticals, and UCB; Honoraria: AbbVie, Acelyrin, Akros, Amgen, Aralez Pharmaceuticals, Bausch Health/Valeant, Boehringer Ingelheim, Celltrion, Coherus, Dermavant, Dice Therapeutics, Forbion, Galderma, Janssen, Kyowa Hakko Kirin, Leo Pharma, Lilly, Meiji Seika Pharma, Merck, Mitsubishi Pharma, Novartis, Pfizer, Reistone Biopharma, Sanofi Genzyme, Sandoz, Sun Pharma, Takeda Pharmaceuticals, UCB, vTv Therapeutics, and Xencor; Scientific officer: Akros, Anacor, Arcutis, Dice Therapeutics, and Kyowa Hakko Kirin; Steering committees: AbbVie, Amgen, Bausch Health/Valeant, Boehringer Ingelheim, Janssen, Kyowa Hakko Kirin, Lilly, Merck, Novartis, Pfizer, Regeneron, Reistone Biopharma, and Sanofi Genzyme; Advisory boards: AbbVie, Amgen, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Dice Therapeutics, Dow Pharma, Galderma, Janssen, Lilly, Merck, Novartis, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB
- **ABG:** Research/educational grants: Bristol Myers Squibb, Janssen, Moonlake, and UCB Pharma (all paid to Mount Sinai School of Medicine); Honoraria/speaker fees: Amgen, Eli Lilly, Highlight Therapeutics, Janssen, Novartis, Sanofi, SunPharma, Takeda, Teva, UCB, and Xbiotech (stock options for RA)
- **BS:** Consultant with honoraria: AbbVie, Acelyrin, Alamar, Almirall, Alumis, Amgen, Arcutis, Arena Pharmaceuticals, Aristea Therapeutics, Asana, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, Celltrion, CorEvitas, Dermavant, Inmagene, Janssen/J&J Innovative Medicine, Kangpu Biopharmaceuticals, Leo Pharma, Lilly, Maruho, Meiji Seika Pharma, Monte Rosa Therapeutics, Novartis, Pfizer, Protagonist, Rapt Therapeutics, Regeneron, Sanofi, Sun Pharma, Takeda Pharmaceuticals, TD Cowen, UCB, Union Therapeutics, Ventyx Biosciences, and vTv Therapeutics; Speaker: AbbVie, Arcutis, Dermavant, Incyte, Janssen/J&J Innovative Medicine, Lilly, Regeneron, and Sanofi; Co-scientific director (consulting fee) and investigator: CorEvitas Psoriasis Registry; Editor-in-chief with honorarium: *Journal of Psoriasis and Psoriatic Arthritis*; Stock options: Connect Biopharma, Mindera Health

Scientific Content on Demand

To view a copy of this poster:

Scan the QR code via a barcode reader application

QR codes are valid for 1 year after the congress presentation date.

Presented at the American Academy of Dermatology Annual Meeting; March 7-11, 2025; Orlando, Florida

Email: lebwohl@aol.com