

FDA approves Bristol Myers Squibb's Sotyktu for psoriatic arthritis

Market Event Summary

FDA approval of Sotyktu introduces TYK2 inhibition as a new oral option for psoriatic arthritis

Subject

- Bristol Myers Squibb's Sotyktu (deucravacitinib) is a first-in-class, oral, selective TYK2 inhibitor previously approved for adults with moderate to severe plaque psoriasis.
- The psoriatic arthritis treatment landscape is dominated by biologics targeting TNF- α , IL-17, and IL-23, alongside oral therapies such as JAK inhibitors and PDE4 inhibitors. Despite multiple available therapies, physicians continue to value oral options that can offer biologic-like efficacy without the safety concerns associated with JAK inhibitors.

Event

- The FDA, on March 6, 2026, approved Sotyktu for the treatment of adults with active psoriatic arthritis, expanding its label beyond plaque psoriasis. The approval is based on the Phase 3 POETYK PsA-1 and POETYK PsA-2 trials, in which deucravacitinib achieved significantly higher ACR20 response rates at week 16 compared with placebo; the trials included both bDMARD-naive patients and those previously treated with TNF- α inhibitors.
- The trials also demonstrated improvements in skin symptoms, joint disease activity, and patient-reported outcomes, with responses maintained through 52 weeks; serious adverse events and infection rates were low and broadly comparable to placebo, consistent with the safety profile observed in psoriasis studies.

Clarivate's takeaways



Positioning within the treatment landscape

- With this approval, Sotyktu becomes the first TYK2 inhibitor approved for psoriatic arthritis, introducing a novel oral mechanism distinct from biologics and JAK inhibitors. The drug's once-daily oral dosing and differentiated mechanism will support its use in patients who prefer oral therapies or are reluctant to initiate injectable biologics.
- However, given the highly competitive market, uptake will initially be limited, as physicians typically favor biologics with established long-term efficacy and extensive real-world experience.
- Sotyktu will be positioned as an oral alternative to biologics. Its use will primarily occur in later lines of therapy among patients with inadequate response or intolerance to other targeted treatments.



Market implications

- This approval expands Sotyktu's addressable patient population beyond psoriasis, strengthening Bristol Myers Squibb's immunology portfolio, and reinforcing the broader potential of TYK2 inhibition across autoimmune diseases.
- Physician adoption will depend on familiarity with TYK2 inhibition and comparative performance against established oral therapies, particularly JAK inhibitors and apremilast. Pricing and reimbursement considerations will also influence uptake, given the strong payer coverage and clinical experience associated with existing biologics.

About the authors



Vaishnavi Dhiman

Associate Healthcare Research & Data Analyst

DRG Commercial Solutions

Before joining Clarivate, Ms. Dhiman was a research analyst at Prescient Healthcare Group and a drug safety associate (Regulatory) at Parexel International. She has substantial experience in secondary research, clinical trials and regulatory analysis of drug products, and competitive intelligence. She holds an M.Sc. and a B.Sc. (Honors) in microbiology from Panjab University in Chandigarh, India.



Mohit Nasa, M.B.A.

Senior Manager, Healthcare Research & Data Analytics, Immune & Inflammation

DRG Commercial Solutions

Mr. Nasa has authored content on such indications as systemic lupus erythematosus, psoriasis, asthma, COPD, and rheumatoid arthritis. Prior to joining Clarivate, he worked as a senior business analyst at Novartis, where he was responsible for end-to-end market assessment and related projects for the company's asthma brand, Xolair. Mr. Nasa holds a bachelor's degree in pharmacy and an M.B.A. in marketing and CRM from Amity Business School in India.

Clarivate coverage of psoriatic arthritis

- Disease Landscape & Forecast: Psoriatic Arthritis (G7), providing comprehensive market insights
- Epidemiology: Total and diagnosed prevalence data for various population segments of psoriatic arthritis across the mature markets
- Access & Reimbursement (US): Evaluates payer coverage, restriction policies, and reimbursement dynamics shaping market access for psoriatic arthritis therapies
- Treatment Algorithms: Claims Data Analysis (US): Explores the current treatment journey of psoriatic arthritis through longitudinal patient claims data
- Unmet Need: Psoriatic Arthritis (US / EU), including an Excel-based target product profile simulator



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lsh.support@clarivate.com
clarivate.com

+1 215 386 0100 (U.S.)

+44 (0) 20 7433 4000 (Europe)

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