A New Drug for Psoriatic Arthritis Shows Promise

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Brodalumab, a new drug being developed by Amgen and AstraZeneca, for psoriatic arthritis, was shown to be effective following a year of treatment, with no new safety concerns.

Results of Amgen and AstraZeneca’s Phase 2 study evaluating brodalumab in 168 patients with psoriatic arthritis were published in The New England Journal of Medicine (NEJM).
Brodalumab is a human monoclonal antibody that binds to the interleukin-17 (IL-17) receptor and inhibits inflammatory signaling by blocking the binding of several IL-17 ligands to the receptor. The IL-17 pathway plays a central role in inducing and promoting inflammatory disease processes.

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Psoriatic Arthritis Can Affect Daily Activities
Psoriatic arthritis is a chronic disease of the immune system that causes joint pain, stiffness, and swelling and can become progressively worse over time. It may also include red patches of skin topped with silvery scales.

The progressive, irreversible joint damage, pain, and swelling, coupled with painful, scaly, red skin patches, can disrupt a person’s ability to perform daily activities, such as using their hands and standing for long periods or walking.

Psoriatic arthritis affects 30 to 50 percent of approximately 125 million people worldwide who have psoriasis.

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Drug Improved Tender and Swollen Joints
The Phase 2 study was a randomized, double-blind, placebo-controlled trial designed to assess the efficacy and safety of brodalumab in psoriatic arthritis. Patients with active psoriatic arthritis were randomized to receive brodalumab (140 or 280 mg subcutaneously) or placebo at day 1 and weeks 1, 2, 4, 6, 8, and 10. At week 12, patients were offered open-label brodalumab 280 mg every two weeks.

Treatment with brodalumab significantly improved signs and clinical symptoms associated with the disease, including tender and swollen joints, at 12 weeks, as measured by a 20 percent improvement in the American College of Rheumatology response criteria (ACR20). In addition, many patients continued to improve, and the improvements were sustained through the first 52 weeks of the study.

Commenting on the new drug, Gary Goldenberg, M.D., assistant professor, Dermatology and Pathology, at the Icahn School of Medicine at Mount Sinai in New York, told Healthline, "Psoriasis is a chronic disease for which there is no cure. Approximately 30 percent of patients also suffer from psoriatic arthritis, and that number is even higher in those with moderate to severe disease. Although good therapies are currently available, including biologics, not all patients respond and some lose the response over time. Brodalumab and other IL-17 antagonists target a different molecule in the immune system responsible for psoriasis and psoriatic arthritis, making this new class of medication a good option for patients with moderate to severe disease."

Sean E. Harper, M.D., executive vice president of Research and Development at Amgen, said in a press statement, "Given our understanding of the role of the IL-17 receptor, we have developed a robust clinical program for brodalumab across the spectrum of inflammatory disease, including psoriasis, psoriatic arthritis, and asthma."

Harper continued, "These encouraging psoriatic arthritis data showing that patients not only experienced improvements in clinical symptoms at week 12, but that those improvements continued over time and were sustained, were the basis for our decision to continue development of this molecule as a potential treatment for the many people who are looking to better control their disease."

Philip Mease, M.D., lead investigator and study author, at the Swedish Medical Center and University of Washington, said in the press statement, "We're encouraged that treatment with brodalumab significantly reduced clinical signs and joint symptoms, compared to
placebo, and that similar degrees of disease improvement were seen in biologic-treated and biologic-naive patients with psoriatic arthritis.

**IL-17 Receptor Shows Promise**

Mease added, "These results add to the growing body of evidence indicating the IL-17 receptor is a promising target for the treatment of inflammatory diseases, including psoriatic arthritis."

Overall, adverse events were similar across groups, with three percent of brodalumab-treated patients experiencing serious adverse events versus two percent of placebo recipients (four patients in total). Serious adverse events included skin infection (cellulitis, two cases), abdominal pain, and inflammation of the gallbladder (cholecystitis).

Briggs W. Morrison, M.D., executive vice president of Global Medicines Development at AstraZeneca, said in the press statement that a significant need for new treatment options exists for people living with psoriatic arthritis, and for whom currently available treatments do not work. "As an antibody targeting the IL-17 receptor, brodalumab is designed to work differently from existing treatment options," he said.

Morrison added, "We are encouraged by the efficacy and safety profile demonstrated in this study and are investigating the potential of brodalumab in Phase 3 trials for psoriatic arthritis."

Andrew F. Alexis, M.D., M.P.H., director of the Skin of Color Center at St. Luke's-Roosevelt Hospital Mount Sinai Health System in New York, told Healthline, "The results of this study are very encouraging. Brodalumab promises to be an advantageous new therapy for patients with psoriatic arthritis, particularly those who have failed other biologic therapies. Targeting the IL-17 receptor promises to be an effective strategy in the management of psoriatic arthritis, so the dermatologic and rheumatologic community will be following the results of future Phase 3 studies closely."

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**Otezla, a New Pill for Psoriatic Arthritis**

In March, Healthline reported that the Food and Drug Administration approved Celgene's Otezla, a new pill for psoriatic arthritis. The company recently announced that long-term (52-week) results from three studies demonstrated that treatment with the drug improved
measures of psoriatic arthritis disease activity, including tender and swollen joints, compared with placebo at 16 weeks.

Commenting on the Otezla study results, Georg Schett, M.D., Ph.D., director of the Department of Internal Medicine III - Rheumatology and Immunology, University Hospital Erlangen, Germany, said, “People with psoriatic arthritis live with persistent symptoms of this painful disease. These analyses of one-year data from the PALACE trials suggest that, based on the efficacy and safety data we’ve seen to date, Otezla has the potential to help patients for the long-term management of manifestations of their psoriatic arthritis.”