RXADVANCE
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Tremfya (guselkumab) Injection
Clinical Update

Clinical Update: New Indication- Tremfya (guselkumab) approved by U.S. Food and Drug Administration as the first selective Interleukin (IL)-23 Inhibitor for active psoriatic arthritis.
FDA approval date: July 13, 2020

Tremfya (guselkumab) is an interleukin-23 blocker indicated for the treatment of moderate-to-severe plaque psoriasis and psoriatic arthritis in adults. Developed by Janssen, Tremfya is the first approved fully human monoclonal antibody that selectively binds to the p19 subunitof interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor. It is approved:

1) In the U.S., Canada, European Union, Japan and a number of other countries worldwide for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light)
2) In the U.S., Japan and Brazil for the treatment of adult patients with active psoriatic arthritis. IL-23 is an important driver of the pathogenesis of inflammatory diseases such as psoriasis and psoriatic arthritis.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to Tremfya.

The approval of Tremfya was based on results from two pivotal Phase 3 clinical trials, DISCOVER-1 and DISCOVER-2, which evaluated the efficacy and safety of Tremfya administered by subcutaneous injection in adults with active PsA compared to placebo.

DISCOVER-1 and DISCOVER-2 were Phase 3 randomized, double-blind, placebo-controlled studies that evaluated the safety and efficacy of Tremfya in 1,120 adult patients with active PsA who had inadequate response to standard therapies. In DISCOVER-1, approximately 31 percent of patients had been previously treated with up to two anti-tumor necrosis factor alpha (anti-TNFα) agents whereas in DISCOVER-2 all patients were naïve to biologic therapy. Approximately 58 percent of patients from both studies had concomitant methotrexate (MTX) use. The DISCOVER-1 study showed that in patients who received Tremfya 100 mg every 8 weeks after two starter doses, 52 percent achieved an ACR20 response versus 22 percent treated with placebo ($p < 0.0001$), with a comparable response irrespective of prior TNF exposure. In DISCOVER-2, 64 percent of patients who received Tremfya every 8 weeks achieved an ACR20 response, versus 33 percent treated with placebo ($p < 0.0001$).

Tremfya was also shown to relieve patients' pain in their soft tissue and inflammation in their fingers and toes. In a pooled analysis of DISCOVER-1 and -2 at week 24, treatment with Tremfya every 8 weeks resolved enthesitis in 50 percent of patients, versus 29 percent in patients receiving placebo ($p=0.0301$). In another pooled analysis at week 24, treatment with Tremfya every 8 weeks also resolved dactylitis in 59 percent of patients, versus 42 percent receiving placebo ($p=0.0301$). Beyond its impact on improving symptoms of PsA in joints, among patients with psoriatic skin involvement, Tremfya also resulted in an improvement in the skin manifestations of psoriasis in patients with PsA.