



## Otezla<sup>®</sup> (apremilast) – New orphan indication

- On July 19, 2019, [Celgene announced](#) the FDA approval of [Otezla \(apremilast\)](#), for the treatment of adult patients with oral ulcers associated with Behçet's disease (BD).
- Otezla is also approved for the treatment of adult patients with active psoriatic arthritis and patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- BD is associated with abnormalities of the immune system and inflammation of the blood vessels.
  - BD affects approximately 5 in 100,000 people in the U.S.
  - Oral ulcers are present in more than 98% of BD patients.
- The approval of Otezla's new indication was based on a double-blind study in 207 adult patients with BD with active oral ulcers. Patients were randomized to receive either Otezla or placebo for 12 weeks. Efficacy was assessed based on the number and pain of oral ulcers.
  - Patients receiving Otezla had a 42.7 point reduction from baseline in the pain of oral ulcers as measured by the visual analog scale at week 12 vs. an 18.7 point reduction with placebo (treatment difference: -24.1; 95% CI: -32.4, -15.7).
  - The proportion of patients achieving oral ulcer complete response (oral ulcer-free) at week 12 was 52.9% and 22.3% for Otezla and placebo, respectively (treatment difference: 30.6; 95% CI: 18.1, 43.1).
  - The daily average number of oral ulcers was 1.5 and 2.6 for Otezla and placebo, respectively (treatment difference: -1.1; 95% CI: -1.6, -0.7).
- The most common adverse reactions ( $\geq 10\%$ ) with Otezla use for treatment of BD were diarrhea, nausea, headache, and upper respiratory tract infection.
- Following a 5-day dose titration, the recommended maintenance dosage of Otezla for all indications (including BD) is 30 mg twice daily taken orally starting on day 6. This titration is intended to reduce the gastrointestinal symptoms associated with initial therapy.
  - Refer to the Otezla drug label for additional details regarding the dose titration.



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