Otezla® (apremilast) – Expanded indication

- On December 20, 2021, Amgen announced the FDA approval of Otezla (apremilast), for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy.
    - Otezla was previously approved in adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- Otezla is also approved for the treatment of adult patients with active psoriatic arthritis and for the treatment of adult patients with oral ulcers associated with Behçet's Disease.
- The approval of Otezla for the expanded indication was based on PSOR-4, a randomized, double-blind, placebo-controlled study in 595 adult patients with mild to moderate plaque psoriasis. Patients were randomized to receive either Otezla or placebo for 16 weeks. The primary endpoint was the proportion of patients who achieved a static Physician Global Assessment (sPGA) response (defined as an sPGA score of clear [0] or almost clear [1] with at least a 2-point reduction from baseline) at week 16.
    - sPGA response was achieved in 21.6% of patients treated with Otezla vs. 4.1% of patients treated with placebo (treatment difference 17.5, 95% CI: 12.2, 22.8).
- The recommended initial dosage titration of Otezla from day 1 to day 5 for all indications is shown in the table below. Following the 5-day titration, the recommended maintenance dosage is 30 mg twice daily taken orally starting on day 6. This titration is intended to reduce the gastrointestinal symptoms associated with initial therapy.

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & thereafter	
AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg