Skyrizi® (risankizumab-rzaa) – New indication

- On January 21, 2022, AbbVie announced the FDA approval of Skyrizi (risankizumab-rzaa), for the treatment of active psoriatic arthritis in adults.

- Skyrizi is also approved for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

- The approval of Skyrizi for the new indication was based on two randomized, double-blind, placebo-controlled studies in 1,407 patients 18 years and older with active psoriatic arthritis. In both studies, patients were randomized to receive Skyrizi 150 mg or placebo at weeks 0, 4, and 16. Starting from week 28, all patients received Skyrizi every 12 weeks. For both studies, the primary endpoint was the proportion of patients who achieved an American College of Rheumatology (ACR) 20 response at week 24.

    — In the first study, ACR20 response at week 24 was achieved in 33.5% and 57.3% of patients treated with placebo and Skyrizi, respectively (difference 24.0, 95% CI: 18.0, 30.0).
    — In the second study, ACR20 response at week 24 was achieved in 26.5% and 51.3% of patients treated with placebo and Skyrizi, respectively (difference 24.5, 95% CI: 15.9, 33.0).

- The recommended dosage of Skyrizi for both plaque psoriasis and plaque arthritis is 150 mg administered by subcutaneous (SC) injection at week 0, week 4, and every 12 weeks thereafter.

    — For plaque arthritis, Skyrizi may be administered alone or in combination with non-biologic disease-modifying antirheumatic drugs.
    — Skyrizi is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject Skyrizi after training in SC injection technique.