Skyrizi™ (risankizumab-rzaa) – New drug approval

- On April 23, 2019, AbbVie announced the FDA approval of Skyrizi (risankizumab-rzaa), for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

- Affecting 7.5 million Americans, psoriasis is the most prevalent autoimmune disease in the U.S. It is characterized by over activation of the immune system and widespread inflammation that causes painful, itchy plaques anywhere on the skin.

- Skyrizi is an interleukin-23 (IL-23) inhibitor that selectively blocks IL-23 by binding to its p19 subunit. IL-23, a cytokine involved in inflammatory processes, is thought to be linked to a number of chronic immune-mediated diseases, including psoriasis.

- The efficacy of Skyrizi was primarily established in two double-blind studies (ULTIMMA-1 and ULTIMMA-2) in 997 patients with moderate-to-severe plaque psoriasis. Patients were randomized to receive Skyrizi, placebo, or an active control. The co-primary endpoints in the studies were the proportion of patients who achieved a static Physician's Global Assessment (sPGA) score of 0 ("clear") or 1 ("almost clear") and the proportion of patients who achieved at least a 90% reduction from baseline Psoriasis Area and Severity Index (PASI) (PASI 90).

    — In ULTIMMA-1 and ULTIMMA-2 at 16 weeks, a sPGA score of 0 or 1 was achieved in 88% and 84% of patients treated with Skyrizi vs. 8% and 5% with placebo, respectively. PASI 90 was achieved in 75% of patients treated with Skyrizi in each trial vs. 5% and 2% with placebo, respectively.

- The efficacy of Skyrizi was also demonstrated in the similarly designed IMMHANCE study. In this trial, 507 patients were randomized to either Skyrizi or placebo.

    — At week 16, Skyrizi was superior to placebo on the co-primary endpoints of sPGA 0 or 1 (84% Skyrizi vs. 7% placebo) and PASI 90 (73% Skyrizi vs. 2% placebo).

- Warnings and precautions of Skyrizi include infections, pre-treatment evaluation for tuberculosis, and immunizations.

- The most common adverse reactions (≥ 1%) with Skyrizi use were upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

- The recommended dose of Skyrizi is 150 mg (two 75 mg injections) administered by subcutaneous (SC) injection at week 0, week 4, and every 12 weeks thereafter.

    — 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.
    — For each dose, injections should be administered at different anatomic locations (such as thighs or abdomen), and not into areas where the skin is tender, bruised, erythematous, indurated or affected by psoriasis. Administration of Skyrizi in the upper, outer arm may only be performed by a healthcare professional or caregiver.

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- AbbVie plans to launch Skyrizi in early May. Skyrizi will be available as a 75 mg/0.83 mL solution in single-dose prefilled syringes