Skyrizi approved for psoriatic arthritis

January 26 2022

(HealthDay)—The U.S. Food and Drug Administration has expanded the approval of Skyrizi (risankizumab-rzaa) to treatment of adults with active psoriatic arthritis, the manufacturer announced Friday.

The dosing regimen of Skyrizi for psoriatic arthritis is consistent with the regimen for moderate-to-severe plaque psoriasis, which is a single 150-mg subcutaneous injection four times a year following two starter doses at weeks 0 and 4. Skyrizi can be administered alone or in combination with disease-modifying antirheumatic drugs (DMARDs).

The approval was based on data from the KEEPsAKE-1 and KEEPsAKE-2 phase 3 studies, which enrolled patients with active psoriatic arthritis, some of whom had responded inadequately or were intolerant to biologic therapy or nonbiologic DMARDs. In a press release announcing the approval, the manufacturer said 57.3 and 51.3 percent of patients receiving Skyrizi in the KEEPsAKE-1 and KEEPsAKE-2 trials, respectively, achieved the primary end point of ACR20 response at week 24 compared with 33.5 and 26.5 percent of patients receiving placebo. Skyrizi also showed improvement compared with placebo in dactylitis and enthesitis as well as improvements in skin lesions of psoriasis as measured by the Psoriasis Area Severity Index 90 at week 24 in patients with coexistent plaque psoriasis.

The most common side effects of Skyrizi include upper respiratory infections, fatigue, fungal skin infections, headache, and injection site reactions. Skyrizi may also increase the risk for infections. Health care providers should check patients for infections and tuberculosis before initiating treatment.

Approval was granted to AbbVie.

More information: More Information