FDA approves Skyrizi for moderately to severely active Crohn disease

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Skyrizi (risankizumab-rzaa), an interleukin-23 inhibitor, has received

U.S. Food and Drug Administration approval to treat moderately to severely active Crohn disease (CD) in adults, according to AbbVie.

Approved dosing for Skyrizi for the treatment of CD is 600 mg by intravenous infusion over at least one hour at week 0, week 4, and week 8, followed by 360 mg self-administered by subcutaneous injection with an on-body injector at week 12 and every eight weeks thereafter.

The company reported that in two induction trials and one maintenance clinical trial, Skyrizi demonstrated significant improvements in endoscopic response (defined as a decrease of >50 percent from the baseline Simple Endoscopic Score in Crohn disease [SES-CD] or for patients with isolated ileal disease and SES-CD of 4, at least a 2-point reduction from baseline) compared with placebo. Additionally, Skyrizi was associated with clinical remission (defined as a Crohn Disease Activity Index of less than 150) versus placebo, as both an induction and maintenance therapy. Clinical response and clinical remission were seen as early as week 4 in induction studies.

"In both the induction and maintenance clinical trials, a significantly greater number of adult patients saw few or no symptoms and a meaningful reduction of visible signs of intestinal inflammation, compared to placebo," Marla Dubinsky, M.D., a paid consultant and advisor for AbbVie, said in a statement. "This approval provides health care professionals with a greatly needed additional option for treating the disruptive symptoms of Crohn's disease."

More information: SKYRIZI Receives FDA Approval

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