FDA approves first topical treatment for vitiligo

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The U.S. Food and Drug Administration has approved Opzelura

(ruxolitinib) as the first topical treatment for vitiligo.

The 1.5 percent cream is approved for continuous topical use twice daily to affected areas of up to 10 percent of body surface area in patients aged 12 years and older. More than 24 weeks of treatment may be needed for satisfactory patient response.

The approval was based on results from the TRuE-V clinical trials, in which more than 600 patients were randomly assigned to Opzelura or placebo. At week 24, 30 percent of patients treated with Opzelura achieved ≥75 percent improvement from baseline in the facial Vitiligo Area Scoring Index (F-VASI75) versus 8 to 13 percent of patients treated with placebo. Approximately half of Opzelura-treated patients achieved F-VASI75 at week 52.

"There have been no FDA-approved therapies available to date and the approval of Opzelura therefore marks a significant milestone," David Rosmarin, M.D., from Tufts Medical Center in Boston, said in a company press release. "I welcome a medical treatment that helps my patients with nonsegmental vitiligo who are interested in potentially reversing the depigmentation caused by their disease."

Approval was granted to Incyte.

More information: FDA Approval