FDA approves SPEVIGO for generalized pustular psoriasis flares

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

(spesolimab-sbzo) as the first treatment option for generalized pustular psoriasis (GPP) flares in adults.

SPEVIGO is a novel, selective antibody infusion that blocks the activation of the interleukin-36 receptor, which is part of an immune system signaling pathway thought to be involved in the cause of GPP. The approval was based on a 12-week trial in which 53 patients with a GPP flare were treated with SPEVIGO or placebo. After one week, more patients treated with SPEVIGO showed no visible pustules than those treated with placebo (54 versus 6 percent).

The most common adverse reactions (≥5 percent) reported in patients taking SPEVIGO were asthenia and fatigue, nausea and vomiting, headache, pruritus and prurigo, infusion site hematoma and bruising, and urinary tract infection.

"GPP flares can greatly impact a patient's life and lead to serious, life-threatening complications," Mark Lebwohl, M.D., lead investigator for the trial, said in a statement. "The approval of SPEVIGO is a turning point for dermatologists and clinicians."

Approval of SPEVIGO was granted to Boehringer Ingelheim.

More information: FDA Approval