Effect of high-dose subcutaneous spesolimab on skin manifestations: Results from the pivotal Effisayl 2 trial of flare prevention in generalized pustular psoriasis

Bruce Steober1, Matthias Augustin2, Yayo Tada1, Armi Garg1, Denis Julien1, Alice B. Gottlieb3, Johann E. Gudjonsson4, Na Hu5, Patrick Hofmann6, Christian Thoma7, Angelo V. Marzano8,9

Department of Dermatology, University Hospital of Bern, Switzerland; 1:1:1:1 randomization ratio of groups—placebo, medium-dose spesolimab, high-dose spesolimab, subcutaneous loading dose of 300 mg followed by 150 mg every 12 weeks

AIM

In this analysis of Effisayl 2, the effect of high-dose spesolimab on GPP flares was assessed using baseline and total scores on the GPPGA scale.

INTRODUCTION

GPP is a chronic, rare, and potentially life-threatening skin disease, characterized by the extensive development of sterile pustules, and has recently been recategorized to the group of superficial epidermal neutrophilic diseases. Current treatments are suboptimal in preventing flares, which are common and potentially life-threatening, but unpredictable. The GPPGA is an important tool to address chronic skin manifestations. In many patients, even in the absence of flares.

METHODS

Effisayl 2 trial design

The proportion of patients with a baseline score of 0 for each GPPGA subscore and total score were generally similar between treatment groups.

RESULTS

Greater proportions of patients with a GPPGA pushulation subscore of 0 were maintained with high-dose spesolimab vs placebo at Week 24 and Week 48. There were no new flares with high-dose spesolimab after Week 4.

GPPGA pushulation subscores over 48 weeks

The proportion of patients with a GPPGA score of 0 increased with high-dose spesolimab but decreased or remained similar with placebo at Week 4. The proportion of patients with GPP flares was lower with high-dose spesolimab than with placebo.

GPPGA erythema subscores over 48 weeks

The proportion of patients with high-dose spesolimab had a flare after Week 4.

CONCLUSION

Compared with placebo, high-dose spesolimab (300 mg SC loading dose, 300 mg SC q4w) resulted in a greater proportion of patients with GPP achieving and maintaining GPPGA scores of 0.

COMMENTS

The proportions of patients with a baseline score of 0 for each GPPGA subscore and total score were generally similar between treatment groups.

ACKNOWLEDGMENTS

The authors met criteria for authorship as recommended by the International Committee of Medical Journal Editors (ICMJE). Writing, editorial, and formatting support were provided by the Foundation for Informed Medical Decision Making’s Health Scientific Communications (London, UK), which was contracted by Amgen. All funds go to the Icahn School of Medicine at Mount Sinai.