# Importance of Complete Skin Clearance on Quality of Life: Analysis of Three Phase 3 Studies of Brodalumab

April Armstrong, Andrew Blauvelt, Scott Drew, Roger Ho, Abby Jacobson

'University of Southern California, Los Angeles, CA; Oregon Medical Research Center, Portland, OR; OhioHealth, Marion, OH; The Ronald O. Perelman Department of Dermatology, New York, NY; Ortho Dermatologics (a division of Bausch Health US, LLC), Bridgewater, NI



## INTRODUCTION

- Complete skin clearance is an important treatment goal for patients with psoriasis'
- Evidence shows that complete skin clearance is associated with several benefits over almost-clear skin, including improved quality of life'
- Brodalumab is a human anti-interleukin-17 receptor A monoclonal antibody that is efficacious in treating moderate-to-severe psoriasis<sup>2-4</sup>
- In the phase 3 brodalumab trials AMAGINE-1, -2, and -3, 42%, 44%, and 37% of patients receiving brodalumab 210 mg every 2 weeks (Q2W), respectively, achieved a psoriasis area and severity index score of 100 (PASI 100) at week 12<sup>2,3</sup>



## **OBJECTIVE**

• To explore whether patients with psoriasis achieving complete skin clearance experienced greater improvements in quality of life than those achieving a good but less-than-complete response



### **METHODS**

- Data for this post hoc analysis were pooled from the nonplacebo groups of the 12-week induction phases of three phase 3 clinical trials (AMAGINE-I/-2/-3) of brodalumab in patients with moderate-to-severe plaque psoriasis
- Patients included in the analysis were treated with brodalumab (140 or 210 mg) or ustekinumab (45 or 90 mg) and had achieved complete skin clearance, defined as 100% improvement in PASI score (PASI 100), or good but incomplete skin clearance, defined as PASI 90 to <100</li>
- Patient-reported outcomes were used to evaluate quality of life (Figure I), stratified by complete or good but incomplete skin clearance

Figure I. Quality of life measures assessed in this post hoc analysis.

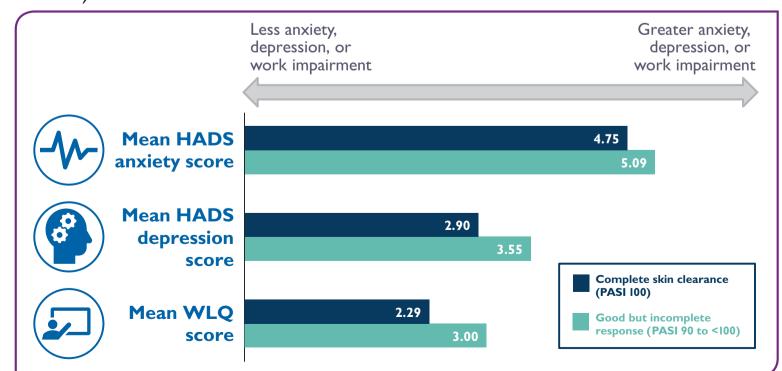


HADS, hospital anxiety and depression scale; MCS, mental component summary; PCS, physical component summary; SF-36, Short Form 36 health survey; WLQ, work limitations questionnaire.

#### **RESULTS**

- At week I2, mean (standard deviation [SD]) hospital anxiety and depression scale anxiety and depression scores were numerically lower for patients achieving PASI I00 (anxiety, 4.75 [3.30]; depression, 2.90 [3.00]) than for patients achieving PASI 90 to <100 (anxiety, 5.09 [4.16]; depression, 3.55 [3.18]; Figure 2)
- Numerically fewer work limitations, indicated by mean (SD) work limitations questionnaire scores, were reported by patients achieving PASI 100 (2.29 [3.11]) than by those achieving PASI 90 to <100 (3.00 [3.58]; Figure 2)

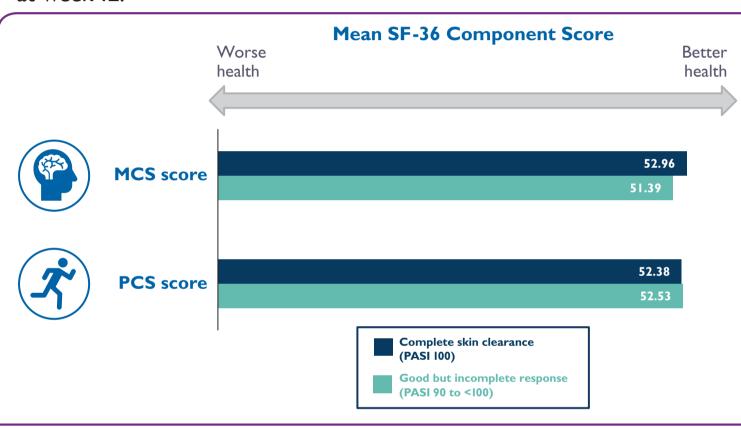
**Figure 2.** Mean quality of life measure scores by categories of complete skin clearance (PASI I00) or good but incomplete response (PASI 90 to <100) at week I2.



The HADS is a I4-item questionnaire, with higher scores indicating worse anxiety or depression. The WLQ measures on-the-job limitations due to health problems and health-related productivity loss, with higher scores indicating greater impairment. HADS, hospital anxiety and depression scale; PASI, psoriasis area and severity index; WLQ, work limitations questionnaire.

• At week I2, mean (SD) SF-36 mental component summary (MCS) and physical component summary (PCS) scores were similar among patients who achieved PASI 90 to <100 (MCS, 51.39 [7.68]; PCS, 52.53 [7.82]) and PASI I00 (MCS, 52.96 [7.99]; PCS, 52.38 [8.71]; Figure 3)

**Figure 3.** Mean MCS and PCS scores by categories of complete skin clearance (PASI I00) or good but incomplete response (PASI 90 to <100) at week I2.



SF-36 scores include 8 health domains yielding the MCS and PCS scores, with higher scores indicating better health. MCS, mental component summary; PASI, psoriasis area and severity index; PCS, physical component summary; SF-36, Short Form 36 health survey.

#### **CONCLUSIONS**

- Achievement of complete skin clearance (PASI 100) was associated with greater numeric improvements in quality-of-life measures than achievement of a good but less-than-complete response in patients with moderate-to-severe plaque psoriasis
- These results suggest that therapies likely to help patients achieve complete skin clearance, such as brodalumab, are important to consider when making treatment decisions

**Acknowledgments:** This study was sponsored by Ortho Dermatologics. Medical writing support was provided by MedThink SciCom and funded by Ortho Dermatologics. Ortho Dermatologics is a division of Bausch Health US, LLC.

**References: I.** Takeshita et al. *J Am Acad Dermatol.* 2014;71:633-641. **2.** Siliq [package insert]. Valeant Pharmaceuticals North America LLC; 2017. **3.** Lebwohl et al. *N Engl J Med.* 2015;373:1318-1328. **4.** Papp et al. *Br J Dermatol.* 2016;175:273-286. **5.** Allaire. *Arthritis Rheum.* 2003;49(suppl 5S): S85-S89. **6.** Grassi et al. *Value Health.* 2010;13:469-478.

© 2019. All Rights Reserved