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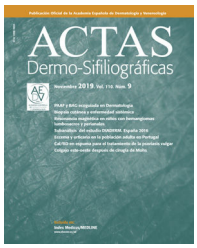

CASE AND RESEARCH LETTERS

[Translated article] Four-Year Maintenance of Complete Skin Clearance With Bimekizumab in 10 Spanish Patients from the Be Radiant Trial

Mantenimiento a 4 años del aclaramiento completo con bimekizumab en 10 pacientes en España procedentes del estudio BE RADIANT

To the Editor,

Bimekizumab is the first dual and selective inhibitor of the A and F isoforms of interleukin 17 (IL-17).[1] Bimekizumab has been approved for the indication of moderate-to-severe plaque psoriasis[1–3] and has completed phase 3 clinical development in psoriatic arthritis,[4,5] axial spondyloarthritis,[6] and hidradenitis suppurativa.[7] Its innovative mechanism of action has led to skin clearance rates in patients that have demonstrated superiority in head-to-head studies vs adalimumab,[3] ustekinumab,[2] and secukinumab.[8] Beyond the superiority in direct comparisons, in the network meta-analysis by Armstrong et al. (2022), bimekizumab ranks as the drug with the highest probability of achieving Psoriasis Area and Severity Index (PASI) 75, PASI 90, and PASI 100 responses across all approved treatments for psoriasis.[9] Skin clearance with bimekizumab is achieved quickly (PASI 90 at week 4: 45.3%)[1] and remains persistent over time (PASI 90 at week 104: 89.7% up to 96.9%).[10]

The BE RADIANT study is a phase 3b randomized clinical trial evaluating the safety and efficacy profile of bimekizumab up to week 48 vs secukinumab in patients with moderate-to-severe plaque psoriasis. The results of this clinical trial indicate that most patients on bimekizumab achieve complete skin clearance (100% reduction of baseline PASI: 100) from week 4 up to week 48, demonstrating statistically significant superiority ($p < 0.001$) vs secukinumab in all primary and secondary study endpoints.[8]

The completion of a clinical trial typically involves the suspension of the study drug. Continuation of post-trial treatment offers an advantage for patients with a good response and tolerability to the drug, thus avoiding the exhaustion of an effective therapeutic line. In Spain, a total of 10 patients were included in the BE RADIANT study. Once the open-label extension period concluded, patients were allowed to maintain treatment with bimekizumab thanks to a post-trial access program from the commercializing laboratory. Patients continued treatment with bimekizumab 320 mg/every 8 weeks, with a 1-year follow-up time after trial for a total 4 years into therapy. The objective of the present study is to evaluate the long-term therapeutic response and safety of these patients who completed the BE RADIANT study in Spain and continue treatment with bimekizumab after the trial was completed.

The demographic characteristics of the patients are shown in Table 1. A total of 7 men and 3 women were included, with a mean age of 46.3 years and a mean body mass index (BMI) of 26.1. Two of the patients had a past medical history of psoriatic arthritis that was not active when treatment with bimekizumab was started, and no disease flares were detected at their follow-up. Most patients had received conventional systemic treatment or phototherapy (8/10), with a mean of 1.5 previous treatments, being methotrexate the most widely used drug in 7/10 patients, followed by cyclosporine and phototherapy in 3/10, and acitretin in 2/10 patients. In 9/10 cases, patients were naïve to biological therapy, and 1 patient was on adalimumab prior to entering the trial.

All patients had a PASI = 0 at the end of the BE RADIANT study. During the post-trial follow-up, 100% of the patients maintained complete skin clearance (PASI = 0) at 6 and 12 months (after 3.5 and 4 years on bimekizumab, respectively). None of the patients showed nail, scalp, or palmoplantar involvement at the 6- and 12-month follow-up. None of the patients reported any impact of psoriasis on their quality of life at the 6- or 12-month follow-up after trial. All patients had a Dermatology Life Quality Index (DLQI) = 0. Although bimekizumab was well tolerated in all cases, no new safety alerts were detected at the post-trial follow-up. Two patients experienced mild oral candidiasis that did not lead to treatment discontinuation and was managed with standard antifungal therapy.

Given the recent approval of bimekizumab by regulatory agencies, real-world evidence of the drug in the routine

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Table 1 Characteristics of the patients.

Sex (male/female)	7 men / 3 women
Age (mean ± SD) years	46.3 ± 15.7 years
BMI (kg/m^2 ± SD)	26.1 ± 3.3
Psoriatic arthritis	2/10
Years with psoriasis (mean ± SD)	14.6 ± 6.2 years
Previous systemic treatment or phototherapy	8/10
No. of previous treatments (mean ± SD)	1.5 ± 1.2
Previous biological therapy	1 (adalimumab) / 10

SD: standard deviation; BMI: body mass index.

clinical practice is limited and based on case reports. With this post-trial follow-up work, we present the first series of patients on bimekizumab under real-world clinical practice conditions. The 10 Spanish patients included in the BE RADIANT study achieved early and sustained complete response with a favorable safety profile at 4 years, the longest follow-up published to date.

Authorship

ALF, IBR, RR, and PH collaborated in the study conception and design, or data acquisition, or data analysis and interpretation; article drafting or the critical review of its intellectual content. They all gave their final approval of the version presented.

Conflicts of interest

ALF has received fees as a speaker, consultant, and clinical trial investigator for UCB, AbbVie, Almirall, Janssen, Novartis, Lilly, and Leo Pharma.

IBR has received fees as a speaker, consultant, and clinical trial investigator for Pfizer-Wyeth; Janssen Pharmaceuticals Inc, MSD, Almirall SA, Lilly, Leo-Pharma, AbbVie, Novartis, and UCB.

RR has received fees as a speaker, consultant, and clinical trial investigator for UCB, AbbVie, Almirall, Boehringer, Janssen, Novartis, Lilly, and Leo Pharma.

PH has received fees as a speaker, consultant, and clinical trial investigator for AbbVie, Almirall, Janssen, Novartis, Lilly, Leo Pharma, Pfizer, Sanofi, and UCB.

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