Invited Correspondence

Reply to Correspondence on 'Bimekizumab in patients with active psoriatic arthritis and previous inadequate response or intolerance to tumour necrosis factor-α inhibitors: a randomised, double-blind, placebo-controlled, phase 3 trial (BE COMPLETE)'

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We thank our colleagues for their interest in the phase 3 BE COMPLETE study which demonstrated the efficacy and tolerability of bimekizumab in people with psoriatic arthritis (PsA) with prior inadequate response or intolerance to tumour necrosis factor-α inhibitors.[1]

The correspondents raise the issue of adverse events. In both BE COMPLETE and its sister study BE OPTIMAL,[2] we describe increased rates of fungal infection compared with placebo, commensurate with previously reported rates in PsA trials of bimekizumab and indeed lower than those reported in psoriasis trials of bimekizumab.[3,4] We continue to monitor fungal infection rates and severity closely in ongoing extension studies. Whilst it will be important to assess the effect of comorbidities on fungal infections, we point out that neither well-controlled cardiometabolic syndrome nor diabetes were excluded from these trials.[1,2]

Regarding immunogenicity, assays for anti-drug antibodies (ADAb) and neutralising antibodies (NAb) were conducted in both studies to consider pharmacokinetics, safety, and efficacy by ADAb and NAb subgroups, as well as by methotrexate use.

We agree on the importance of increased diversity in clinical trials in psoriatic disease. Underrepresentation of minoritised racial groups has also been noted in trials of other inflammatory disease states and connective tissue diseases.[5] This is often due to the populations attending trial centres, which may not represent the diversity in the general population. Racial diversity may also vary in the populations of different countries recruiting to multi-centre trials. Going forward it will be important to confirm the efficacy and tolerability of bimekizumab across more diverse, representative patient populations, in clinical trials as well as in real-world studies. In line with this, UCB Pharma has committed to increasing community engagement and greater diversity in clinical trial recruitment, to advance health equity.[6]

References

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Author Disclosures

JFM is a consultant and/or investigator for AbbVie, Amgen, Biogen, BMS, Dermavant, Eli Lilly, Janssen, LEO Pharma, Pfizer, Novartis, Regeneron, Sanofi, Sun Pharma, and UCB Pharma.

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