Questions about the BE OPTIMAL trial – Authors' reply

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We thank Sogol Stephanie Javadi and colleagues for their interest in the phase 3 BE OPTIMAL study, which demonstrated the efficacy and tolerability of bimekizumab in biologic-naive patients with psoriatic arthritis.[1]

Concerning the efficacy results, Javadi and colleagues incorrectly state that this study showed superiority to adalimumab for 50% or greater improvement in the American College of Rheumatology response criteria (ACR50). Adalimumab was included as a reference group only and no statistical comparisons were made between adalimumab and bimekizumab. Moreover, the SPIRIT-H2H trial showed the superiority of ixekizumab over adalimumab only when considering a combined ACR50 and Psoriasis Area and Severity Index 100% improvement response. Ixekizumab was non-inferior to adalimumab for ACR50 responder rates (ixekizumab 50·5% *vs* adalimumab 46·6%; treatment difference 3·9%; p=0·338).[2] We respectfully disagree that the choice of adalimumab in our trial design will have produced a more favourable outcome for bimekizumab. Furthermore, tumour necrosis factor inhibitors such as adalimumab have been recommended as a first-line therapy option for patients with psoriatic arthritis, so this is a relevant choice of comparator for this biologic-naive patient population.[3] Additionally, in the era of adalimumab biosimilars, we feel this is a timely and key comparison for decision makers, including clinicians and payers.

Regarding the potential effects of oestrogen contraceptive use on efficacy, a formal analysis of this was not performed. We understand that sex distribution can affect outcomes in psoriatic arthritis trials;[4] however, sub-analyses of efficacy observed in different patient subgroups were beyond the scope of the study and are planned for future communications, for both BE OPTIMAL and its sister study, BE COMPLETE.[5]

We agree that increased diversity and representation in clinical trials in psoriatic disease is desirable. Indeed, underrepresentation of minoritised racial groups has been noted in trials of other inflammatory disease states.[6] In line with this, UCB Pharma has committed to increasing diversity in clinical trials, to advance health equity.

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