**Efficacy and Safety of 108 Weeks’ Bimekizumab Treatment in Patients with Psoriatic Arthritis: Interim Results from a Phase 2 Open-Label Extension Study**

Iain B McInnes,1 Joseph F Merola,2 Philip J Mease,3 Laura C Coates,4 Paulatsya Joshi,5 Jason Coarse,6 Barbara Ink,5 Christopher T Ritchlin7

*1University of Glasgow, Glasgow, UK; 2Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA; 3Swedish Medical Center and University of Washington, Seattle, WA, USA; 4University of Oxford, Oxford, UK; 5UCB Pharma, Slough, UK; 6UCB Pharma, Raleigh, NC, USA; 7University of Rochester Medical Center, Rochester, NY, USA*

**Background:** Bimekizumab, a monoclonal antibody that selectively neutralizes interleukin (IL)-17A and IL-17F, has shown clinical improvements in skin and joint outcomes over 48 weeks in patients (pts) with active psoriatic arthritis (PsA).1 We report 2-year interim results from a phase 2b dose-ranging study (NCT02969525) and open-label extension (OLE; NCT03347110) of bimekizumab in pts with PsA.

**Methods:** Design of the dose-ranging study is described elsewhere.1 Pts who completed 48 weeks’ bimekizumab treatment without meeting withdrawal criteria were eligible for OLE entry. All OLE pts received bimekizumab 160 mg Q4W, irrespective of prior dosing regimen. Data are presented from dose-ranging study baseline (BL) to OLE Week 60 (Week 108 total). Efficacy outcomes are reported for the Full Analysis Set (FAS): pts who received ≥1 dose bimekizumab (specifically those randomized to 160 mg, 160 mg with 320 mg loading dose [LD], or 320 mg at BL), with BL efficacy measurements to allow subsequent determination of ACR50. Outcomes include ACR20/50/70, body surface area (BSA) 0%, minimal disease activity (MDA), and enthesitis/dactylitis resolution. Rates of treatment-emergent adverse events (TEAEs) are reported for the safety set (SS; pts who received ≥1 dose bimekizumab in the dose-ranging study).

**Results:** BL mean (SD) tender/swollen joint counts were 21.7 (15.7)/11.2 (8.4). 80 (65.0%) pts had BSA ≥3% and dactylitis/enthesitis was present in 41 (33.3%)/68 (55.3%) pts. Over 108’ bimekizumab treatment, improvements were observed in skin/joint outcomes: ACR50 (66.7%), BSA 0% (75.4%), MDA (65.6% [data from Week 120]), and resolution of dactylitis (63.4%) and enthesitis (63.2% [data from Week 120]) **(Table)**. Serious TEAEs occurred in 9.3% of pts **(Table)**; no deaths or major adverse cardiac events were reported. Oral candidiasis occurred in 16 (7.8%) pts (no serious cases).

**Conclusion:** Bimekizumab leads to long-term efficacy for skin/joint manifestations of PsA, with >50% of pts achieving high thresholds of disease control (ACR50, BSA 0%, MDA) after 108 weeks’ treatment. The safety profile reflects previous observations.1

**References:** **1.** Ritchlin CT. Lancet 2020;395:427–440. **Funding:** UCB Pharma.

**Table.** Outcomes at OLE Week 60 (Week 108 total)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **BKZ 160 mga (n=82)** | | **BKZ 320 mga (n=41)** | | **BKZ total (N=123)** | |
| **OC** | **NRI** | **OC** | **NRI** | **OC** | **NRI** |
| ***Efficacy (FAS)* n (%)** | | | | | | |
| ACR20 | 53/62 (**85.5**) | 53 (**64.6**) | 29/37 (**78.4**) | 29 (**70.7**) | 82/99 (**82.8**) | 82 (**66.7**) |
| ACR50 | 41/62 (**66.1**) | 41 (**50.0**) | 25/37 (**67.6**) | 25 (**61.0**) | 66/99 (**66.7**) | 66 (**53.7**) |
| ACR70 | 34/62 (**54.8**) | 34 (**41.5**) | 19/37 (**51.4**) | 19 (**46.3**) | 53/99 (**53.5**) | 53 (**43.1**) |
| BSA 0%b | 35/42 (**83.3**) | – | 14/23 (**60.9**) | – | 49/65 (**75.4**) | – |
| MDAc | 43/61 (**70.5**) | 43 (**52.4**) | 20/35 (**57.1**) | 20 (**48.8**) | 63/96 (**65.6**) | 63 (**51.2**) |
| Dactylitis resolution | – | 14/27 (**51.9**) | – | 12/14 (**85.7**) | – | 26/41 (**63.4**) |
| Enthesitis resolutionc | – | 31/45 (**68.9**) | – | 12/23 (**52.2**) | – | 43/68 (**63.2**) |
| ***Safety (SS)* n (%) [EAER]** | **BKZ 160 mgd (n=198)** | | **BKZ 320 mgd (n=80)** | | **BKZ totald,e (N=204)** | |
| Any TEAE | 163 (82.3) [160.9] | | 57 (71.3) [299.8] | | 179 (87.7) [181.1] | |
| Study discontinuation due to TEAEs | 17 (8.6) | | 1 (1.3) | | 18 (8.8) | |
| Permanent withdrawal of study drug due to TEAEs | 16 (8.1) | | 2 (2.5) | | 18 (8.8) | |
| Drug-related TEAEs | 72 (36.4) | | 29 (36.3) | | 92 (45.1) | |
| Serious TEAEs | 19 (9.6) [4.8] | | 0 | | 19 (9.3) [4.1] | |

aBKZ 160 mg pts received this dose continuously to Week 108 (includes those originally assigned to 160 mg with LD); BKZ 320 mg pts were dose-reduced to 160 mg at OLE entry; bPts with BSA ≥3% at BL; cData from OLE Week 72 (Week 120 total); dDose received at TEAE onset (pts may be counted in multiple columns);eIncludes pt time on BKZ 16 mg. BKZ: bimekizumab; EAER: exposure-adjusted event rate; NRI: non-responder imputation; OC: observed case.