Bimekizumab Long-Term Efficacy and Safety Over 96 Weeks in Patients with Ankylosing Spondylitis (AS): Interim Results from a Phase 2b Open-Label Extension Study

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**Background:** We report 2-year interim efficacy and safety of bimekizumab (BKZ), an inhibitor of interleukin (IL)-17A and IL-17F, in patients with active AS from a phase 2b dose-ranging study (BE AGILE; NCT02963506) and ongoing open-label extension (OLE; NCT03355573).

**Methods:** BE AGILE consisted of a 12-week dose-ranging period followed by a 36-week randomized period (BKZ 160/320 mg).1 Patients who completed 48 weeks’ treatment in BE AGILE were eligible for entry into the OLE. All OLE patients received BKZ 160 mg every 4 weeks (Q4W). Efficacy and safety outcomes are presented from BE AGILE baseline to Week 96. Efficacy outcomes are reported for the OLE Full Analysis Set (FAS; patients who had ≥1 dose BKZ and ≥1 valid efficacy variable measurement since OLE entry). Missing data were imputed using non-responder imputation (binary variables) or multiple imputation (continuous variables). The exposure-adjusted incidence rates (EAIR) per 100 patient-years (PY) for treatment-emergent adverse events (TEAEs) are reported separately for the BE AGILE and OLE Safety Sets (patients who received ≥1 dose BKZ).

**Results:** 262/303 patients randomized at BE AGILE baseline completed to Week 48 of treatment, and 254/262 were included in the OLE FAS. 130/254 continued on BKZ 160 mg Q4W and 124/254 dose-reduced from BKZ 320 mg Q4W. 238/254 had an efficacy assessment at Week 96. In BE AGILE, rapid improvements in efficacy outcomes were observed in BKZ-treated patients at Week 12; these increased to Week 48 and were maintained during the OLE (**Table 1/2**). Responses were similar for patients on BKZ 160 mg and 320 mg at Week 48 and remained similar to Week 96 irrespective of prior dose regimen (**Table 1/2**). The EAIR of TEAEs was 186.2/100PY in BE AGILE and 111.7/100PY in the OLE, and 5.1 and 6.1/100PY for serious TEAEs, respectively.

**Conclusion:** BKZ provided sustained long-term improvements in key efficacy outcome measures over 96 weeks of treatment. Dose reduction to 160 mg Q4W was not followed by loss of response. There were no unexpected safety findings versus previous studies.

**Reference: 1.** van der Heijde D. Ann Rheum Dis 2020;79:595–604. **Funding:** UCB Pharma.

**Table 1**: Efficacy responses to Week 96 (OLE Week 48; non-responder imputation)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **BKZ 160 mg 🡪 160 mg (n=130)** | | **BKZ 320 mg 🡪 160 mg (n=124)** | |
| **Response (%)** | **Week 48** | **Week 96** | **Week 48** | **Week 96** |
| ASAS40 | 57.7 | 64.6 | 62.1 | 66.9 |
| ASAS20 | 76.9 | 76.9 | 75.0 | 79.8 |
| ASAS PR | 27.7 | 36.2 | 35.5 | 36.3 |
| ASDAS<2.1 | 56.2 | 61.5 | 58.9 | 58.9 |
| ASDAS-ID | 21.5 | 27.7 | 24.2 | 29.0 |

**Table 2**: Continuous efficacy outcomes to Week 96 (OLE Week 48; multiple imputation)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **BKZ 160 mg 🡪 160 mg (n=130)** | | | **BKZ 320 mg 🡪 160 mg (n=124)** | | | **All BKZ (N=254)** | | |
| **Mean (SD)** | **Baseline** | **Week 48** | **Week 96** | **Baseline** | **Week 48** | **Week 96** | **Baseline** | **Week 48** | **Week 96** |
| ASDAS-CRP | **3.9** (0.8) | **2.1** (0.9) | **1.9** (0.9) | **3.9** (0.8) | **2.0** (0.9) | **1.9** (0.9) | **3.9** (0.8) | **2.0** (0.9) | **1.9** (0.9) |
| BASDAI | **6.3** (1.3) | **2.8** (1.8) | **2.5** (1.8) | **6.5** (1.4) | **2.8** (2.1) | **2.7** (2.1) | **6.4** (1.4) | **2.8** (2.0) | **2.6** (2.0) |
| BASFI | **5.6** (1.9) | **3.0** (2.0) | **2.7** (2.1) | **5.8** (2.0) | **3.0** (2.4) | **2.8** (2.4) | **5.7** (1.9) | **3.0** (2.2) | **2.8** (2.2) |
| BASMI | **4.6** (1.7) | **4.0** (1.8) | **3.9** (1.7) | **4.8**a(1.7) | **3.9**a (1.8) | **3.9**a (1.9) | **4.7**b(1.7) | **4.0**b (1.8) | **3.9**b (1.8) |

an=123; bn=253. Full Analysis Set (N=254). BL corresponds to BE AGILE study BL. ASAS: Assessment of SpondyloArthritis international Society; ASAS20/40: ASAS 20%/40% response; ASAS PR: ASAS partial remission; ASDAS: Ankylosing Spondylitis Disease Activity Score; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; BKZ: bimekizumab; BL: baseline; CRP: C‑reactive protein; ID: inactive disease (ASDAS<1.3); OLE: open-label extension; SD: standard deviation.