Maintenance of Response to Bimekizumab Over 3 Years of Treatment in Patients with Active Ankylosing Spondylitis: Post Hoc Analyses from the BE AGILE Study and its Open-Label Extension

CONTENT PROVIDED FOR SHAREHOLDERS, INVESTORS AND OTHER CAPITAL MARKET PARTICIPANTS ONLY

Presented at EULAR 2022 | 1–4 June

**Objective**

To report on the maintenance of clinical response, including achievement of sustained inactive disease or low disease activity, for supported and external previous findings on the long-term efficacy of bimekizumab (BKZ) in patients with active ankylosing spondylitis (AS) maintained up to 3 years in the phase 2b BE AGILE study and its open-label extension (OLE).

**Background**

- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, has demonstrated clinical efficacy and was well tolerated in patients with active AS who received action-directed therapy for up to 156 weeks in the phase 2b AGILE study.

- Maintaining stringent disease control—such as sustained inactive disease or low disease activity—improves clinical outcomes and quality of life in patients with active AS.

**Methods**

- Study design: 156-week AGILE study (NCT02967891) and 144-week OLE (NCT03355573)

- Patients: 121/303 patients were randomised to BKZ 160 mg (n=60) or 320 mg (n=61).

- Outcomes: Maintenance of response at Wk 156, with Bimekizumab (BKZ) Q4W.

**Results**

- **ASDAS states across Weeks 0–156 for patients randomised to BKZ 160 mg and 320 mg Q4W at baseline**

  - **Summary**
    - In Week 12 responders, maintenance of efficacy outcomes
    - **ASDAS <2.1**
    - **ASDAS <1.3–<2.1**

- **Week 12**
  - **Patients (%)**
    - BKZ 160 mg Q4W: 100, 80, 60, 40, 20, 10, 0
    - BKZ 320 mg Q4W: 100, 80, 60, 40, 20, 10, 0

- **Week 48**
  - **Patients (%)**
    - BKZ 160 mg Q4W: 100, 80, 60, 40, 20, 10, 0
    - BKZ 320 mg Q4W: 100, 80, 60, 40, 20, 10, 0

- **Week 156**
  - **Patients (%)**
    - BKZ 160 mg Q4W: 100, 80, 60, 40, 20, 10, 0
    - BKZ 320 mg Q4W: 100, 80, 60, 40, 20, 10, 0

**Conclusion**

- BKZ 160 mg and 320 mg Q4W maintained long-term improvements in disease activity as early as 3 years in patients with active AS, irrespective of the initial dose regimen (280 mg or 320 mg Q4W). Disease activity over time was sustained in patients who had initially responded at Week 12.

**Disclosure**

V. Navarro-Compán,1 M. Rudwaleit,2 N. de Peyrecave,3 C. Fleurinck,4 M. Oortgiesen,5 V. Taieb,6 X. Baraliakos6

References
