Bimekizumab-Treated Patients with Axial Spondyloarthritis Maintained Stringent Clinical Responses Over 3 Years: Results from Two Phase 3 Studies and Their Open-Label Extension

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Fabian Proft,[1] Sergio Schwartzman,[2,3,4] Alexander Marten,[5] Vanessa Taieb,[6] Sarah Kavanagh,[7] Gaëlle Varkas,[8,9] Victoria Navarro-Compán,[10] Xenofon Baraliakos[11]

[1]Department of Gastroenterology, Infectiology and Rheumatology (including Nutrition Medicine), Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Berlin, Germany; [2]Weill Cornell Medical Center, New York, USA; [3]New York Presbyterian Hospital, New York, USA; [4]Hospital for Special Surgery, New York, USA; [5]UCB, Monheim am Rhein, Germany; [6]UCB, Colombes, France; [7]UCB, Morrisville, USA; [8]Department of Rheumatology, Ghent University Hospital, Ghent, Belgium; [9]Molecular Immunology and Inflammation Unit, VIB-UGent Center for Inflammation Research, Zwijnaarde, Belgium; [10]Department of Rheumatology, La Paz University Hospital, IdiPaz, Madrid, Spain; [11]Rheumazentrum Ruhrgebiet Herne, Ruhr-University Bochum, Germany.

Objective

To assess the maintenance of response to bimekizumab (BKZ) over 3 years in two phase 3 studies and their open-label extension (OLE), in patients across the full disease spectrum of axial spondyloarthritis (axSpA) who achieved stringent clinical outcomes at Week 16.

Background

- AxSpA is a chronic inflammatory disease requiring life-long management.[1]
- Maintenance of response, an internationally recommended treatment goal in axSpA, can be assessed by measuring whether the outcomes below are consistently met during long-term follow up:[1]
  - In clinical trials, Assessment of SpondyloArthritis international Society ≥40% improvement (ASAS40) is a stringent outcome used to assess efficacy.[2]
  - In clinical practice, focus is on Axial Spondyloarthritis Disease Activity Score (ASDAS) low disease activity (LDA; <2.1) or Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) <2. While ASDAS is the preferred instrument for assessing disease activity, BASDAI is historically more widely used by healthcare professionals.[1]
- BKZ is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- BKZ has demonstrated sustained clinical efficacy to 3 years in patients across the full disease spectrum of axSpA (i.e., non-radiographic [nr-] and radiographic [r-]axSpA) in the BE MOBILE 1 and 2 studies and their combined OLE.[3]

Methods

- BE MOBILE 1 (NCT03928704; nr-axSpA) and 2 (NCT03928743; r-axSpA) study designs have been previously reported.[2] From Week 16, all patients received BKZ 160 mg every 4 weeks. At Week 52, eligible patients could enrol in the OLE, BE MOVING (NCT04436640), and continue receiving BKZ for a further 112 weeks.
- Among BKZ-randomised patients who achieved ASAS40 and ASDAS LDA at Week 16 (non-responder imputation; NRI), the proportion of patients achieving each respective outcome to Week 164 (modified non-responder imputation [mNRI]/ observed case [OC]) was assessed.
- In BKZ-randomised patients who achieved ASDAS LDA at Week 16 and entered the OLE:
  - The proportion of patients who maintained ASDAS LDA at ≥75% of subsequent visits (≥9 out of 12 visits) to Week 164, including those who never lost ASDAS LDA from Week 16 to Week 164 (12 visits), is presented.
  - For patients who demonstrated a loss of ASDAS LDA status at ≥1 visit after Week 16, the proportion of patients who achieved ASDAS major improvement (ASDAS-MI; ≥2.0-unit reduction from baseline) or clinically important improvement (ASDAS-CII; ≥1.1-unit reduction from baseline) is reported.
  - Baseline characteristics for patients who achieved ASDAS LDA at Week 16 and never lost ASDAS LDA, or lost ASDAS LDA at ≥1 visit, are also reported.
- In BKZ-randomised patients who achieved BASDAI <2 at Week 16 and entered the OLE, the proportion of patients who maintained BASDAI <2 at ≥75% of subsequent visits to Week 164, including those who never lost BASDAI <2 from Week 16 to Week 164 (12 visits), is reported.
- Data are presented pooled across studies.
  - Heatmap data indicate ASDAS status over time at the individual patient level, and are reported as observed.

Results

- Overall, 128 and 221 patients were randomised to BKZ across BE MOBILE 1 and 2, respectively (N=349).
- The majority of patients who achieved a response at Week 16 maintained their response at Week 164 (**Figure 1**).
  - Of 160 patients (45.8%; NRI) who achieved **ASAS40** at Week 16, **80.4% maintained their response** at Week 164 (mNRI; **Figure 1A**).
  - Of 152 patients (43.6%; NRI) who achieved **ASDAS LDA** at Week 16, **78.8% maintained ASDAS LDA** at Week 164 (mNRI; **Figure 1B**).
- **Figure 2** summarises the individual patient ASDAS disease status at each timepoint to Week 164 for the 133 BKZ-randomised patients who achieved ASDAS LDA at Week 16 and entered the OLE.
  - Of these 133 patients, **85.0% maintained ASDAS LDA** at **≥75% of subsequent visits** to Week 164, and **41.4% never lost ASDAS LDA** from Week 16 to Week 164 (12 visits; **Figure 2**).
  - In patients who had an observed ASDAS ≥2.1 at least once (42.1%), **the majority still achieved ASDAS-MI or ASDAS-CII** at Weeks 52, 104 and 164 (87.5%, 78.6% and 71.4%, respectively; **Figure 2**).
- Baseline characteristics were similar between those who maintained ASDAS LDA to Week 164 at all visits (n=55) and those who lost ASDAS LDA at least once (n=78), with slight differences by race, current tobacco use, prior tumour necrosis factor inhibitor exposure and human leukocyte antigen B27 status (**Table**).
- Of the 82 patients who achieved BASDAI <2 at Week 16 and entered the OLE, **60 (73.2%) maintained BASDAI <2** at **≥75% of subsequent visits** to Week 164, including **35 (42.7%)** who **never lost BASDAI <2** (**Figure 3**).

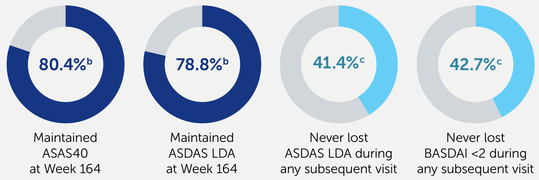
Conclusions

Across the full disease spectrum of axSpA, the majority of bimekizumab-randomised patients who achieved stringent clinical outcomes at Week 16 maintained their response to Week 164, with many never losing ASDAS LDA status or BASDAI <2 at every subsequent visit. These findings build on previous evidence that bimekizumab improves outcomes impacting patients' daily lives over the long-term.[4]

Summary

This analysis examined the **maintenance of stringent clinical responses** through **3 years** of treatment with **bimekizumab** in patients with **axSpA** across two phase 3 trials and their open-label extension.

Among bimekizumab-randomised patients who achieved each respective efficacy outcome at Week 16:[a]

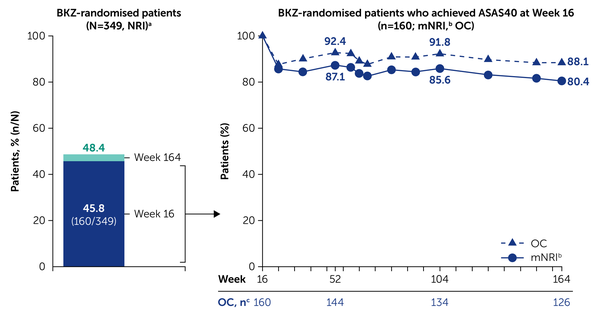


Bimekizumab provided **robust maintenance of clinical responses**, including **low levels of disease activity**, from Week 16 to Week 164 across the full disease spectrum of axSpA.

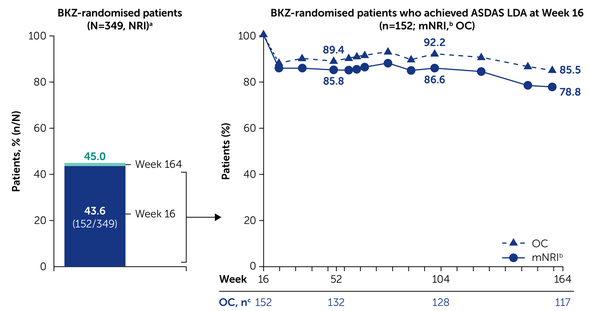
[a] Never lost response was analysed in bimekizumab-randomised patients who entered the OLE; **[b]** Data imputed using mNRI; **[c]** Patients who had missing ASDAS LDA/BASDAI <2 data at any visit after Week 16 were considered non-responders.

Figure 1 Maintenance of ASAS40 and ASDAS LDA to Week 164 among bimekizumab-randomised patients who achieved each respective outcome at Week 16

A) Maintenance of ASAS40 response to Week 164



B) Maintenance of ASDAS LDA status to Week 164



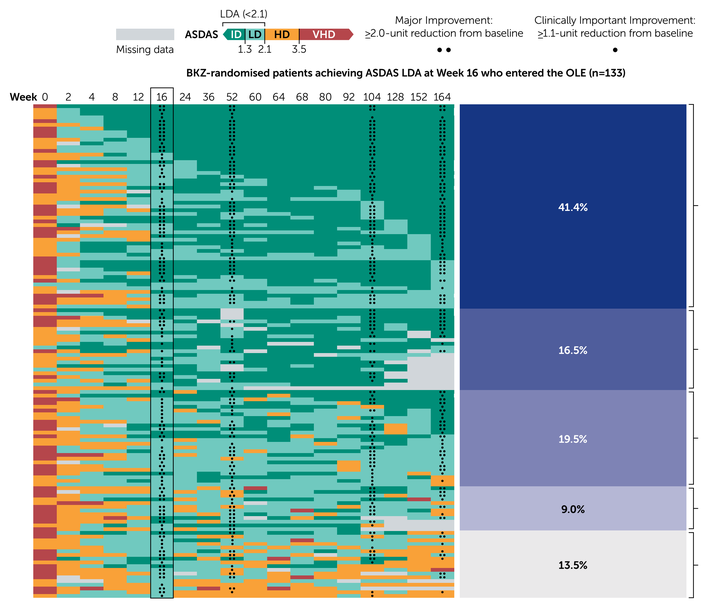
Pooled randomised set. Only patients randomised to BKZ at baseline were included in this analysis. **[a]** Number of patients achieving ASAS40 or ASDAS LDA at Week 16 and Week 164 in patients randomised to BKZ at baseline; **[b]** mNRI considered all visits following discontinuation of study treatment due to adverse events or lack of efficacy as a non-response; all other missing data were imputed with MI and the response derived from the imputed values; **[c]** n represents the total number of patients with a non-missing assessment for the outcome measured, at the given week.

Table Baseline characteristics for bimekizumab-randomised patients who achieved ASDAS LDA at Week 16 and entered the OLE, stratified by maintenance of ASDAS LDA status to Week 164

	BKZ 160 mg Q4W	
Mean (SD), unless otherwise stated	Maintenance of ASDAS LDA status to Week 164 at all visits (n=55)	Loss of ASDAS LDA status at any timepoint to Week 164[a] (n=78)
Age, years	37.2 (10.7)	35.7 (8.4)
Male, n (%)	41 (74.5)	63 (80.8)
Race, n (%)[b]		
White	49 (89.1)	60 (76.9)
Asian	3 (5.5)	17 (21.8)
BMI, kg/m^2	25.6 (3.8)	25.8 (4.6)
Current tobacco use, yes, n (%)	19 (34.5)	12 (15.4)
Time since first symptoms of axSpA, years	10.5 (8.3)	8.5 (6.8)
HLA-B27, positive, n (%)	45 (81.8)	71 (91.0)
hs-CRP		
mg/L, geometric mean (geometric CV [%])	5.8 (232.1)	5.2 (290.9)
≤5 mg/L, n (%)	24 (43.6)	34 (43.6)
ASDAS	3.7 (1.0)	3.5 (0.8)
BASDAI	6.5 (1.3)	6.3 (1.3)
Prior TNFi exposure, yes, n (%)	2 (3.6)	7 (9.0)

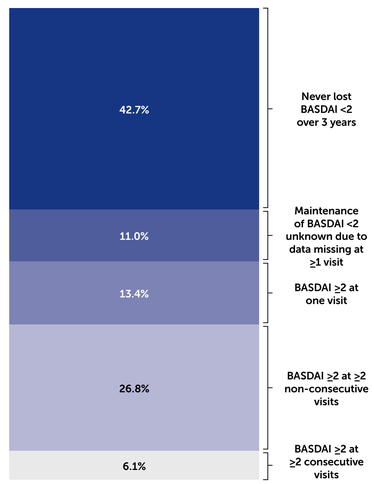
Includes all BKZ-randomised patients who achieved ASDAS LDA at Week 16 and entered the OLE (n=133). Population with "Loss of ASDAS LDA status at any timepoint to Week 164" excluded BKZ-randomised patients who did not enter the OLE (19 patients). **[a]** Includes patients who had missing ASDAS LDA data at any visit after Week 16, regardless of whether they had an observed loss of response; **[b]** 2 patients (3.6%) who maintained ASDAS LDA were other/mixed, 1 patient (1.8%) was black. 1 patient (1.3%) who lost ASDAS LDA status by Week 164 had missing data at baseline for race.

Figure 2 Patient-level ASDAS status by visit among bimekizumab-randomised patients who achieved ASDAS LDA (<2.1) at Week 16 and entered the OLE



Pooled randomised set. Only patients randomised to BKZ at baseline were included in this analysis. Patients were excluded if they did not enter the OLE. Never lost response was defined as patients who achieved ASDAS LDA at Week 16 and at every subsequent visit from Week 16 to Week 164. 101 patients had ASDAS LDA at Week 16, and also had an available ASDAS measurement at every visit up to and including Week 164.

Figure 3 BASDAI <2 at Week 164 for bimekizumab-randomised patients who achieved BASDAI <2 at Week 16 and entered the OLE (n=82)



Pooled randomised set. Only patients randomised to BKZ at baseline were included in this analysis. Patients were excluded if they did not enter the OLE. Never lost response was defined as patients who achieved BASDAI <2 at Week 16 and at every subsequent visit from Week 16 to Week 164. 67 patients had BASDAI <2 at Week 16, and also had an available BASDAI measurement at every visit up to and including Week 164.

ASAS40: Assessment of SpondyloArthritis international Society 40% response; **ASDAS:** Axial Spondyloarthritis Disease Activity Score; **ASDAS-CII:** ASDAS clinically important improvement; **ASDAS-MI:** ASDAS major improvement; **axSpA:** axial spondyloarthritis; **BASDAI:** Bath Ankylosing Spondylitis Disease Activity Index; **BKZ:** bimekizumab; **BMI:** body mass index; **CV:** coefficient of variation; **HD:** high disease activity; **HLA-B27:** human leukocyte antigen B27; **hs-CRP:** high-sensitivity C-reactive protein; **ID:** inactive disease; **IL:** interleukin; **LD:** low disease; **LDA:** low disease activity; **MI:** multiple imputation; **mNRI:** modified non-responder imputation; **nr-axSpA:** non-radiographic axial spondyloarthritis; **NRI:** non-responder imputation; **OC:** observed case; **OLE:** open-label extension; **Q4W:** every 4 weeks; **r-axSpA:** radiographic axial spondyloarthritis; **SD:** standard deviation; **TNFi:** tumour necrosis factor inhibitor; **VHD:** very high disease activity.

References: [1]Ramiro S. Ann Rheum Dis 2023;82:19–34; [2]Baraliakos X. Ann Rheum Dis 2024;83:199–213; [3]Baraliakos X. Ann Rheum Dis 2025;84(suppl 1):947–8; [4]Marzo-Ortega H. RMD Open 2025;11:e006013.

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