Bimekizumab Improved Physical Function and Health-Related Quality of Life in Patients with Axial Spondyloarthritis: 52-Week Results from Two Phase 3 Studies

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Week 0 Week 4 Week 8 Week 12 Week 16 Week 24 Week 36 Week 52

(n=128) (n=128) (n=126) (n=126) (n=127) (n=123) (n=117) (n=110)

76.6% 46.1% 36.5% 34.9% 31.5% 26.0% 23.1% 22.7%

61.7% 38.3% 32.5% 34.1% 32.3% 25.2% 19.7% 26.4%

 59.4%
 35.9%
 28.6%
 23.8%
 17.3%
 17.9%
 12.0%
 13.6%

45.3% 27.3% 23.8% 15.1% 16.5% 15.4% 12.0% 12.7%

40.6% 25.8% 19.8% 19.0% 16.5% 13.0% 12.0% 11.8%

32.8% 23.4% 17.5% 19.0% 15.7% 13.0% 10.3% 12.7%

31.3% 27.3% 19.8% 19.8% 18.9% 16.3% 11.1% 16.4%

25.0% 14.8% 11.9% 10.3% 8.7% 10.6% 9.4% 9.1%

Week 0 Week 4 Week 8 Week 12 Week 16 Week 24 Week 36 Week 52

(n=221) (n=217) (n=211) (n=213) (n=210) (n=201) (n=197) (n=196)

6.1% 47.5% 37.0% 32.4% 29.0% 26.9% 25.4% 26

56.1% 21.7% 16.6% 13.1% 12.9% 9.0% 8.6% 9.2%

40.7% | **26.7%** | **21.3%** | 19.7% | 17.6% | 14.4% | 11.2% | 9.7%

39.8% | **22.1%** | 13.7% | 16.0% | 12.9% | 12.9% | 13.2% | 13.3%

34.4% | **24.9%** | 17.1% | 16.9% | 14.3% | 12.9% | 16.2% | 15.3%

31.2% | 16.1% | 10.4% | 11.3% | 11.9% | 9.5% | 9.1% | 9.2%

30.8% | 14.3% | 14.2% | 11.3% | 11.0% | 10.4% | 10.7% | 9.2%

42.4% 37.0% 31.9% 29.5% 29.4% 26.9% 26.5%

32.7% | 24.2% | 22.5% | 21.4% | 18.9% | 15.7% | 14.8%

34.6% | 31.8% | 29.1% | 28.6% | 24.9% | 24.9% | 24.5%

29.5% | 26.1% | 24.9% | 23.8% | 16.4% | 17.8% | 14.3%

20.6%

37.5% 21.9% 19.0% 17.5%

44.4% 42.1% 33.9% 30.1% 28.2% 20.9%

44.4% 42.9% 41.7% 40.7% 35.9% 39.1%

41.3% 31.7% 31.5% 26.8% 24.8% 25.5%

18.3% 18.1% 13.0% 13.7% 12.7%

19.8% 18.9% 13.8% 17.9% 17.3%

11.1% 14.2% 9.8% 5.1% 8.2%

42.2% 34.7% 33.8% 30.8% 27.9% 27.0%

51.2% | 43.2% | 43.3% | 40.3% | 38.6% | 37.2%

47.4% | 44.1% | 41.4% | 41.3% | 35.5% | 34.7%

Objective

To report the impact of bimekizumab (BKZ) on physical function and health-related quality of life (HRQoL) in patients across the full disease spectrum of axial spondyloarthritis (axSpA).

Background

- AxSpA severely impairs physical function and HRQoL.¹
- BKZ, a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F and IL-17A, was well tolerated and demonstrated sustained efficacy up to Week 52 in patients with active non-radiographic (nr-) and radiographic (r-) axSpA (i.e., ankylosing spondylitis)² in the phase 3 studies BE MOBILE 1 and 2.³

Methods

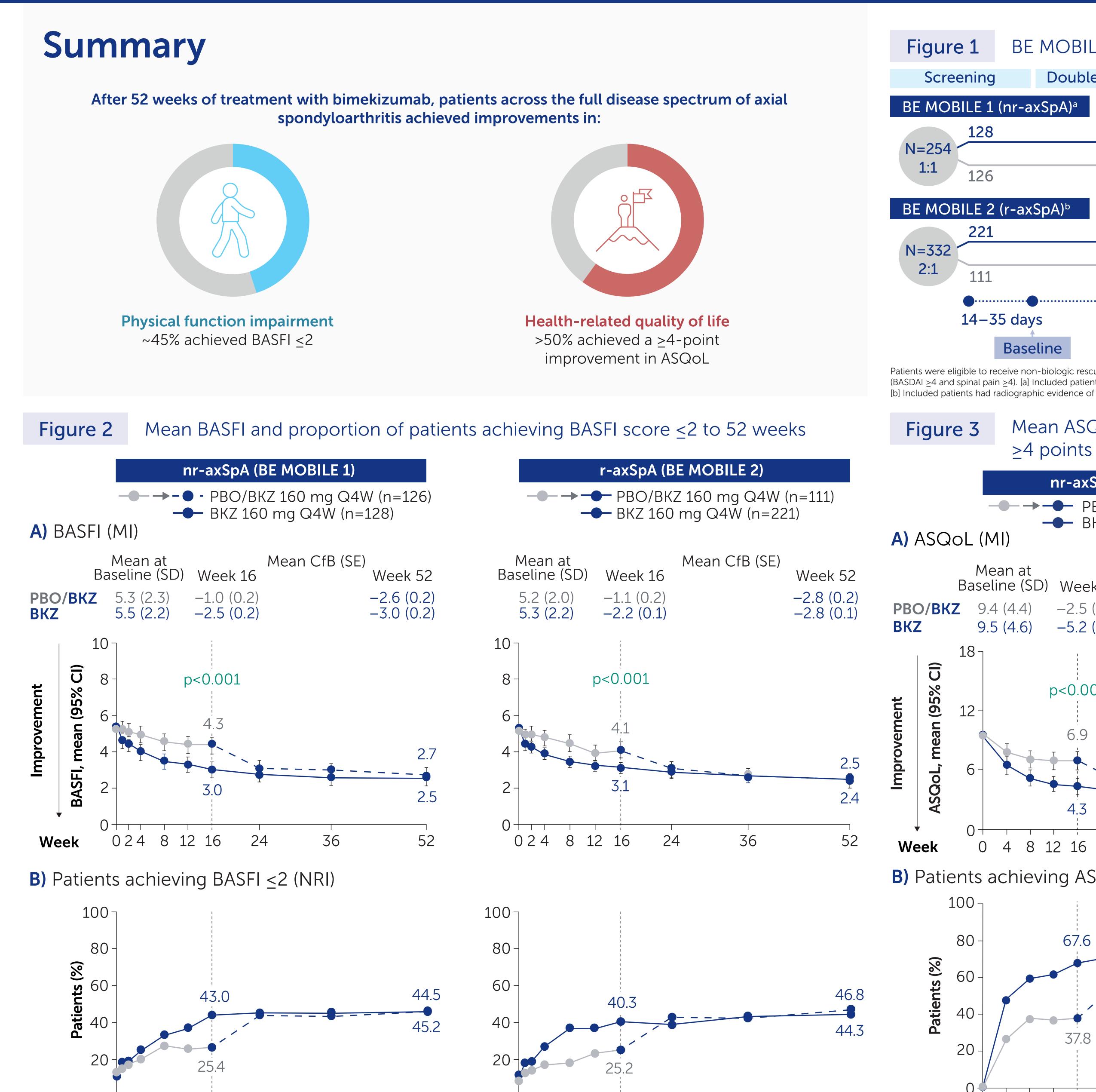
- BE MOBILE 1 (NCT03928704) and 2 (NCT03928743) were conducted in parallel and comprised a 16-week double-blind period followed by a 36-week maintenance period (**Figure 1**).³
- We report, to Week 52, mean scores in physical function using the Bath Ankylosing Spondylitis Functional Index (BASFI) and HRQoL with the Ankylosing Spondylitis Quality of Life questionnaire (ASQoL) using multiple imputation (MI).
- The proportion of patients achieving the following are also reported using non-responder imputation (NRI): BASFI ≤2
- Clinically relevant ASQoL improvement (≥4-point reduction from baseline).⁴
- The proportion of BKZ-randomized patients impacted by each ASQoL item (i.e., responded "yes") over time is reported as observed (OC).

Results

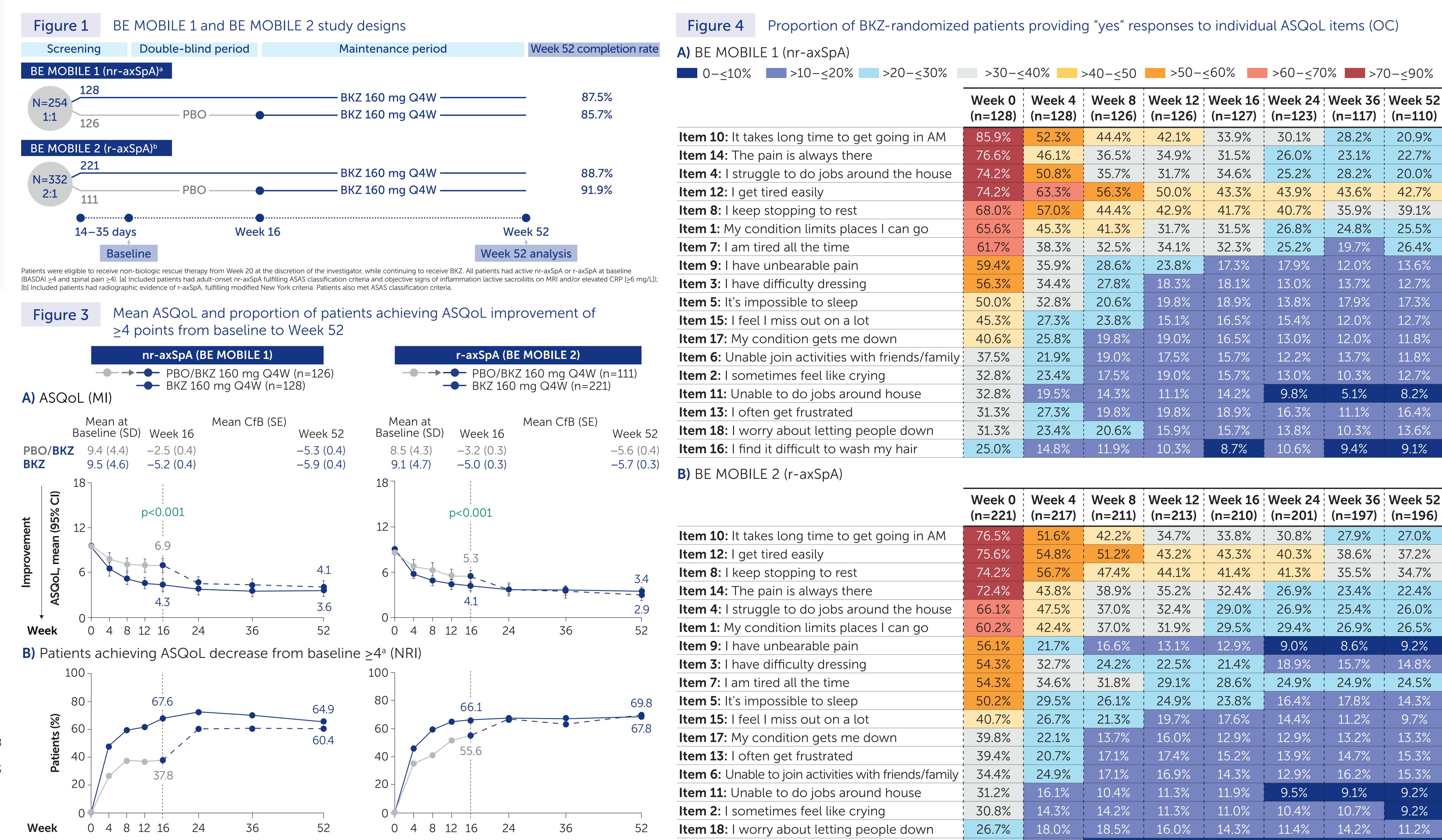
- 254 patients with nr-axSpA (BKZ: 128; placebo: 126) and 332 with r-axSpA (BKZ: 221; placebo: 111) were randomized; 86.6% (220/254) and 89.8% (298/332) patients completed to Week 52, respectively.
- Mean baseline BASFI and ASQoL indicated impaired physical function and HRQoL (Figure 2A, Figure 3B).
- At Week 16, significantly greater reductions from baseline (i.e., improvement) in BASFI and ASQoL were observed in BKZ-treated patients vs placebo (p<0.001).
- Mean scores remained low or decreased at Week 52 in BKZ-randomized patients and patients switching from placebo to bimekizumab at Week 16 (placebo/BKZ; Figure 2A, Figure 3A).
- A higher proportion of BKZ- vs placebo-treated patients also achieved BASFI <2, and ≥4 ASQoL reduction from baseline at Week 16.
- These proportions were sustained or increased to Week 52, and were similar among BKZ-randomized and placebo/BKZ patients (Figure 2B, Figure 3B).
- ASQoL items impacting at least two-thirds of BKZ-randomized patients with nr-axSpA and r-axSpA at baseline were (**Figure 4**):
- 10: 'It takes long time to get going in AM' (85.9% and 76.5%)
- 14: 'The pain is always there' (76.6% and 72.4%)
- 12: 'I get tired easily' (74.2% and 75.6%)
- 4: 'I struggle to do jobs around the house' (74.2% and 66.1%)
- 8: 'I keep stopping to rest' (68.0% and 74.2%).
- Profound reductions from baseline were seen in the proportion of patients responding "yes" to each ASQoL item through 52 weeks of BKZ treatment; the greatest reductions at Week 52 were in items 10 (–65.0% and –49.5%) and 14 (-53.9% and -50.0%; **Figure 4**).

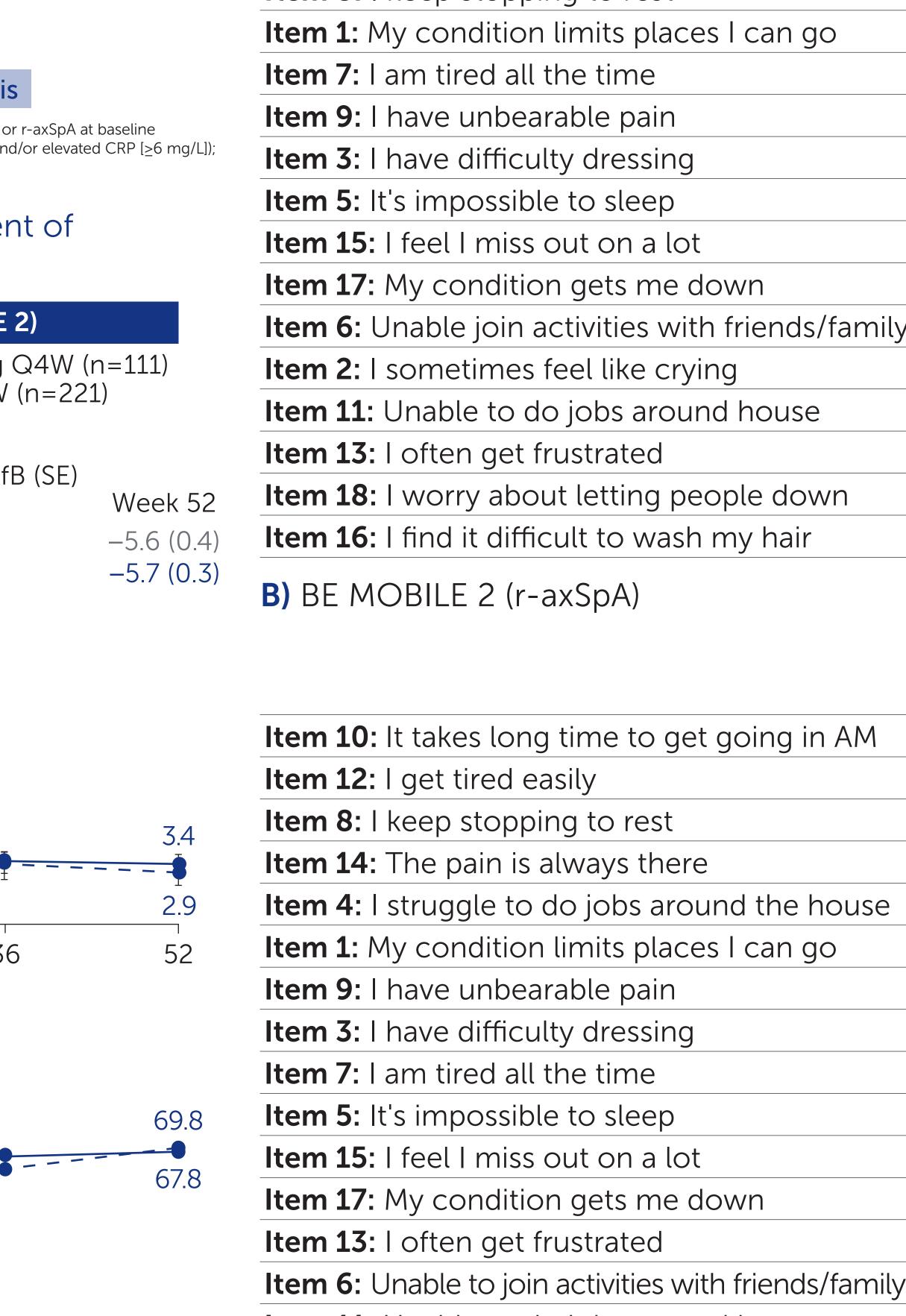
Conclusions

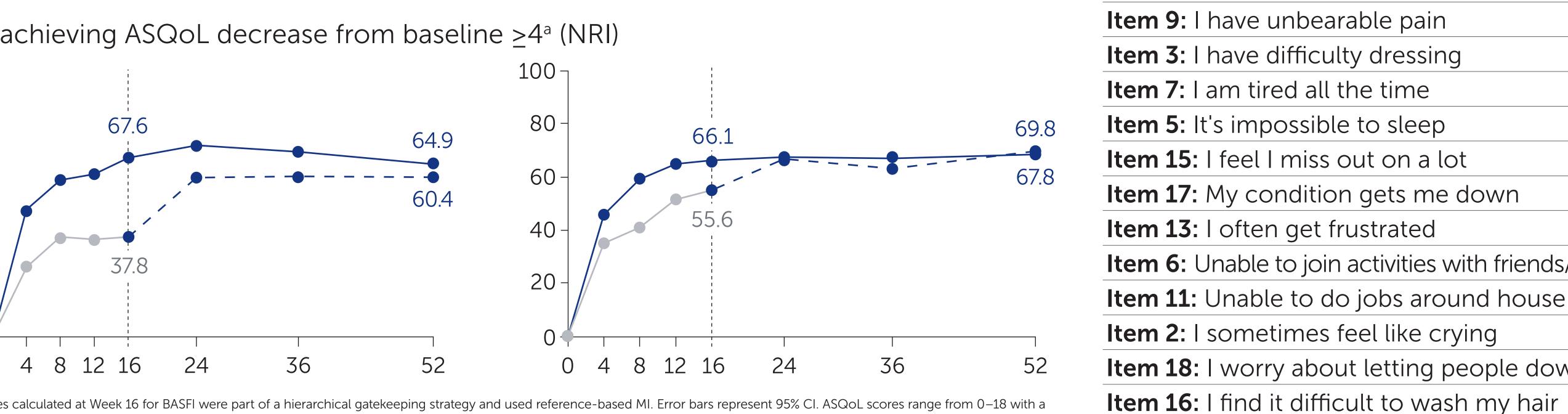
High proportions of patients across the full disease spectrum of axSpA achieved and sustained meaningful improvements in physical function and HRQoL over 52 weeks of bimekizumab treatment.



higher score reflecting greater impact on physical function (i.e., higher functional impairment).

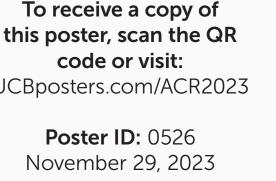






higher score reflecting greater impact on HRQoL (i.e., poorer quality of life). [a] Reported for patients with baseline ASQoL score >4. BE MOBILE 1: PBO/BKZ 160 mg Q4W n=111, BKZ 160 mg Q4W n=111 **BE MOBILE 2:** PBO/BKZ 160 mg Q4W n=90, BKZ 160 mg Q4W n=192.

Randomized set. Items are ordered by decreasing frequency of "yes" responses at baseline tine like in the lik





tilly, Janssen, Moonlake, Novartis, Pfizer, and UCB Pharma; Pfizer, and UCB Pharma; Pfizer, and UCB Pharma; VT: Employees of UCB Pharma; VT: Employee and shareholder of UCB Pharma; Abvie, BMS, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, BMS, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Abvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, BMS, Celgene, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, Janssen, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, MoonLake, Novartis, Pfizer, and UCB Pharma; Grant/research support from Abbvie, Eli Lilly, MoonLake, MoonLake, MoonLake, MoonLake, MoonLake, MoonLake, MoonLake, MoonLake, M