

BRIEF REPORT

Minimal Impact of the COVID-19 Pandemic on Disease Activity and Health-Related Quality of Life in Patients With Ankylosing Spondylitis Receiving Bimekizumab: Exploratory Analyses From a Phase 2b Open-Label Extension Study

Philip C. Robinson,¹ Pedro M. Machado,² Nigil Haroon,³ Lianne S. Gensler,⁴ John D. Reveille,⁵ Vanessa Taieb,⁶ Thomas Vaux,⁷ Carmen Fleurinck,⁸ Marga Oortgiesen,⁹ Natasha de Peyrecave,⁸ and Atul Deodhar¹⁰

Objective. The impact of the COVID-19 pandemic on patients with inflammatory rheumatic diseases, such as ankylosing spondylitis (AS), has been variable. Here, we assess disease activity and health-related quality of life (HRQoL) through the pandemic in patients with AS.

Methods. In the open-label extension (OLE) of the phase 2b BE AGILE study, patients with AS received 160 mg of subcutaneous bimekizumab every 4 weeks. We assessed Ankylosing Spondylitis Disease Activity Score with C-reactive protein (ASDAS-CRP), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Ankylosing Spondylitis Quality of Life (ASQoL) scores in the OLE immediately before and during the COVID-19 pandemic (September 2019 to April 2021).

Results. A total of 232 patients remained in the BE AGILE OLE and were included in this post hoc study at the start of the analysis period (September 1, 2019); 12 patients had a COVID-19 treatment-emergent adverse event, and no cases resulted in death. The number of missed bimekizumab doses due to COVID-19 (11 doses) was minimal, and missed assessments remained low ($\leq 5\%$) compared with the prepandemic period. Mean ASDAS-CRP (1.8), BASDAI (2.4), and ASQoL scores (2.8) in the OLE were low at pre-pandemic baseline and remained stable at 1.7 to 1.8, 2.2 to 2.4, and 2.0 to 2.8, respectively, across successive 3-month periods immediately before and during the pandemic. ASDAS-CRP, BASDAI, and ASQoL stability was consistent across major study countries.

Conclusion. Disease activity and HRQoL remained stable during the COVID-19 pandemic in patients with AS receiving bimekizumab in the BE AGILE OLE, with no indication of negative effects on these outcomes.

INTRODUCTION

Ankylosing spondylitis (AS), which is also known as radiographic (r-) axial spondyloarthritis (axSpA), is a chronic

inflammatory disease that predominantly affects the spine and sacroiliac joints (1,2). Chronic pain and functional impairment resulting from AS can severely affect patients' health-related quality of life (HRQoL) (1–3).

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¹Philip C. Robinson, MBChB, PhD: University of Queensland School of Clinical Medicine, Brisbane, Queensland, Australia; ²Pedro M. Machado, FRCP, PhD: University College London, London, UK; ³Nigil Haroon, MD, PhD: Toronto Western Hospital, University of Toronto and Schroeder Arthritis Institute, Toronto, Ontario, Canada; ⁴Lianne S. Gensler, MD: University California, San Francisco; ⁵John D. Reveille, MD: The University of Texas McGovern Medical School, Houston; ⁶Vanessa Taieb, MSc: UCB Pharma, Colombes, France; ⁷Thomas Vaux, MSc: UCB Pharma, Slough, UK; ⁸Carmen Fleurinck, MD, Natasha de Peyrecave, DPhil: UCB Pharma, Brussels, Belgium; ⁹Marga Oortgiesen,

PhD: UCB Pharma, Raleigh, North Carolina; ¹⁰Atul Deodhar, MD: Oregon Health & Science University, Portland.

Data from this article may be requested by qualified researchers 6 months after product approval in the United States and/or Europe, or after global development is discontinued, and 18 months after trial completion. Investigators may request access to anonymized individual patient data and redacted study documents which may include: raw datasets, analysis-ready datasets, the study protocol, a blank case report form, an annotated case report form, a statistical analysis plan, dataset specifications, and a clinical study report. Prior to use of the data, proposals need to be approved by an independent review panel at www.Vivli.org and a signed data sharing agreement will need to be executed. All documents are available in English only, for a pre-specified time, typically 12 months, on a password-protected portal. All the results presented in this article are in aggregate form, and no personally identifiable information was used for this study.

The COVID-19 pandemic has had far-reaching effects, but patients with rheumatic inflammatory diseases such as AS, have been variably affected. Beyond the direct effects of COVID-19, there is concern that pandemic-related restrictions have disrupted patient management and health care systems, subsequently affecting patient health. Restrictions are also likely to have limited patients' physical activity, potentially leading to poorer patient outcomes given that AS symptoms can be exacerbated by reduced exercise. Real-world studies evaluating the implications of the pandemic on disease activity and HRQoL in patients with axSpA have found inconsistent results (4–10).

Bimekizumab, a monoclonal immunoglobulin G1 antibody that selectively inhibits interleukin-17F, in addition to interleukin-17A, to date has demonstrated clinically meaningful and sustained efficacy and was well tolerated in patients with active AS treated for up to 3 years in the phase 2b BE AGILE study and its ongoing open-label extension (OLE) (11–13). At the start of the pandemic in March 2020, patients were in the OLE receiving 160 mg of subcutaneous bimekizumab every 4 weeks (Q4W); most had received more than 3 years of bimekizumab treatment and outcomes were stable. This study's objective was to assess whether the COVID-19 pandemic and associated societal changes negatively affected disease activity and HRQoL in these patients.

PATIENTS AND METHODS

Study design and participants. As reported previously, the BE AGILE study was a 48-week randomized, parallel-group, dose-ranging study double-blind to Week 12, then dose-blind to Week 48 (NCT02963506) (11). It was followed by an OLE study (NCT03355573) with an additional 4 years of bimekizumab treatment. There were 50 study sites across 10 countries (eight European countries, Canada, and USA) in the OLE. Patients with active, moderate to severe AS were eligible; full inclusion and exclusion criteria have been reported previously (11). Patients completing Week 48 of BE AGILE were eligible to enroll in the OLE, in which all patients received 160 mg of subcutaneous bimekizumab Q4W, regardless of prior dosing.

Ethics approval. The BE AGILE study and its OLE were conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonisation Guidance for Good Clinical Practice. Ethical approval was obtained from the relevant institutional review boards at participating sites. All patients provided written informed consent in accordance with

local requirements, with additional written informed consent required for enrollment into the OLE study.

Outcomes. COVID-19 treatment-emergent adverse events (coding to the preferred term “corona virus infection” or “corona-virus test positive” based on MedDRA version 19.0) were recorded, as well as the number of missed bimekizumab doses and missed assessments.

Disease activity was evaluated using the Ankylosing Spondylitis Disease Activity Score with C-reactive protein (ASDAS-CRP) and the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), and HRQoL was evaluated using the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire. ASDAS-CRP and BASDAI assessments were conducted every 12 weeks to Week 252 and at Week 256 and the safety follow-up. ASQoL assessments were conducted every 12 weeks to Week 144, then every 24 weeks to Week 240, and at Week 256 and the safety follow-up.

Statistical analysis. Outcome scores were analyzed for patients from the OLE full analysis set (comprising patients who entered the OLE and had one dose of bimekizumab or more and one valid efficacy variable measurement or more during the OLE) remaining in the study as of September 1, 2019. Data collected from September 2019 to April 2021 were analyzed. Descriptive statistics of outcome scores are reported for 3-month periods before and during the pandemic (observed data). The last data point collected before March 11, 2020 (the World Health Organization–defined start of the COVID-19 pandemic) (14) was used as the prepandemic baseline (ie, the baseline for the study presented here). Changes from this baseline in individual patients' outcome scores are presented for each study visit (observed data) for the pandemic period. Multivariate logistic regression models were run to determine possible predictors of either worsening or improvement during the COVID-19 pandemic in the patient population. All statistical analyses were conducted in System Automation Software (SAS, version 9.3 or later; SAS Institute, Inc).

RESULTS

Patient disposition and characteristics. Outcomes are reported for the 232 patients remaining in the BE AGILE OLE study at the start of the analysis period (September 1, 2019). Baseline demographics and disease characteristics are reported at Week 0 of BE AGILE and at the pre-pandemic baseline for the set of 232 patients. The vast majority of these patients

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Address correspondence to Philip C. Robinson, MBChB, PhD, Department of Rheumatology, Royal Brisbane Hospital, University of

Queensland, Herston 4006 Queensland, Australia. Email: philip.robinson@uq.edu.au.

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Table 1. Baseline demographics and disease characteristics at BE AGILE baseline and at the start of the COVID-19 pandemic

	BE AGILE baseline (N = 232)	Pre-pandemic baseline (N = 232)
Age, years, mean (SD)	41.6 (11.0)	-
Sex, male, n (%)	198 (85.3)	-
HLA-B27 positive, n (%)	212 (91.4) ^a	-
Age at first diagnosis, years, mean (SD)	34.2 (9.7)	-
Symptom duration, years, median (minimum to maximum)	12.3 (0.2-47.2)	-
Disease duration, years, median (minimum to maximum)	4.8 (0.0-37.3)	-
Prior TNFi therapy, n (%)	28 (12.1)	-
Region, n (%)		
Eastern Europe	208 (89.7)	-
North America	8 (3.4)	-
Western Europe	16 (6.9)	-
Country, n (%)		
Poland	81 (34.9)	-
Czech Republic	60 (25.9)	-
Russia	31 (13.4)	-
Ukraine	20 (8.6)	-
Bulgaria	9 (3.9)	-
Germany	8 (3.4)	-
Spain	8 (3.4)	-
Hungary	7 (3.0)	-
USA	6 (2.6)	-
Canada	2 (0.9)	-
ASDAS-CRP, mean (SD)	3.9 (0.8)	1.8 (0.9) ^b
BASDAI, mean (SD)	6.4 (1.4)	2.4 (1.8)
ASQoL, mean (SD)	8.5 (4.3)	2.8 (3.5)
BASFI, mean (SD)	5.7 (2.0)	2.6 (2.2)
Total spinal pain, mean (SD)	7.0 (1.8)	2.5 (2.1)
PGADA, mean (SD)	6.9 (1.7)	2.6 (2.0)
hs-CRP, mg/L		
Mean (SD)	19.9 (21.9) ^c	6.3 (16.2)
Median (minimum to maximum)	13.0 (0.4-130.1) ^c	2.8 (0.1-183.9)
Concomitant treatment, n (%)		
NSAIDs	210 (90.5)	-
csDMARDs	62 (26.7)	-
Corticosteroids	23 (9.9)	-

Note: Patients from the safety set who remained in the study on September 1, 2019 (N = 232). The prepandemic baseline is defined as the last visit before March 11, 2020. All patients received 160 mg of bimekizumab Q4W during the OLE.

Abbreviations: ASDAS, Ankylosing Spondylitis Disease Activity Score; ASQoL, Ankylosing Spondylitis Quality of Life; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; CRP, C-reactive protein; csDMARD, conventional synthetic disease-modifying antirheumatic drug; HLA, human leukocyte antigen; hs-CRP, high-sensitivity C-reactive protein; NSAID, nonsteroidal anti-inflammatory drug; OLE, open-label extension; PGADA, patient's global assessment of disease activity; Q4W, every four weeks; SD, standard deviation; TNFi, tumor necrosis factor inhibitor.

^aThe HLA-B27 status of 5 (2.2%) patients was unknown.

^bn = 228.

^cn = 231.

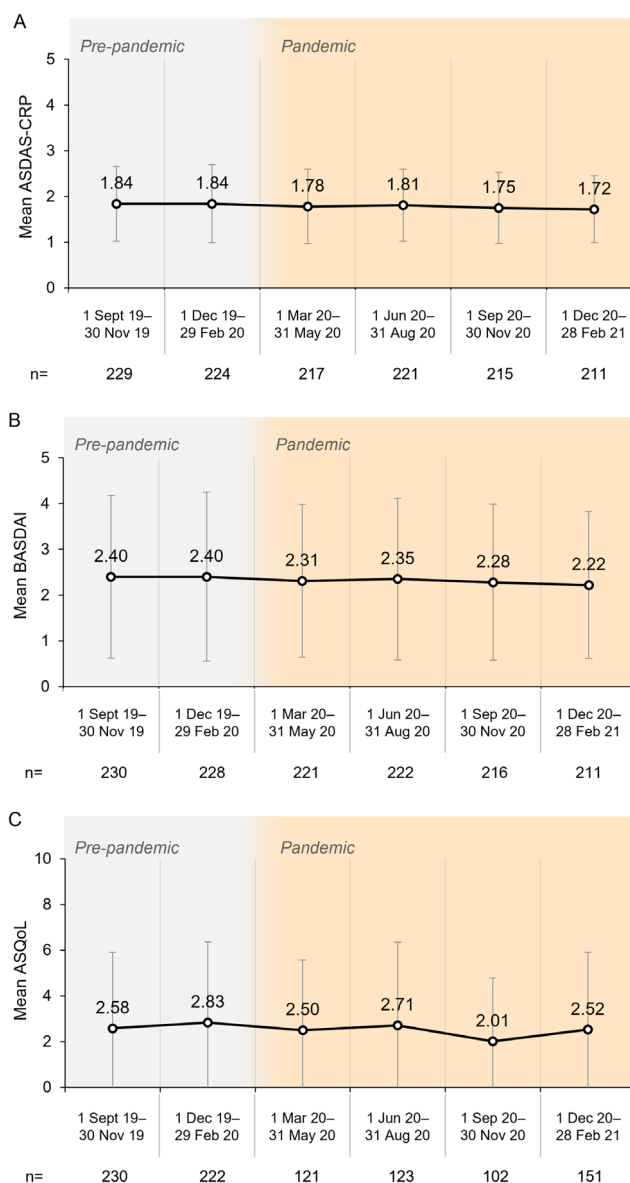


Figure 1. Mean Ankylosing Spondylitis Disease Activity Score with C-reactive protein (ASDAS-CRP) (A), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) (B) and Ankylosing Spondylitis Quality of Life (ASQoL) (C) scores during the prepandemic and pandemic periods in patients receiving 160 mg of bimekizumab every 4 weeks (observed data). Patients from the open-label extension full analysis set who remained in the study on September 1, 2019, with a recorded outcome assessment. Error bars show SD. The mean score from each period of measurement was calculated using the last recorded measurement from each patient within the specified time period. Patient numbers appear lower for ASQoL than ASDAS-CRP and BASDAI during the four pandemic periods because ASQoL assessments were conducted every 24 weeks from Week 156, whereas ASDAS-CRP and BASDAI assessments were conducted every 12 weeks. Data for the period of March 1, 2021, to April 30, 2021, are not shown because data were only available for a limited number of patients at the time of the analyses.

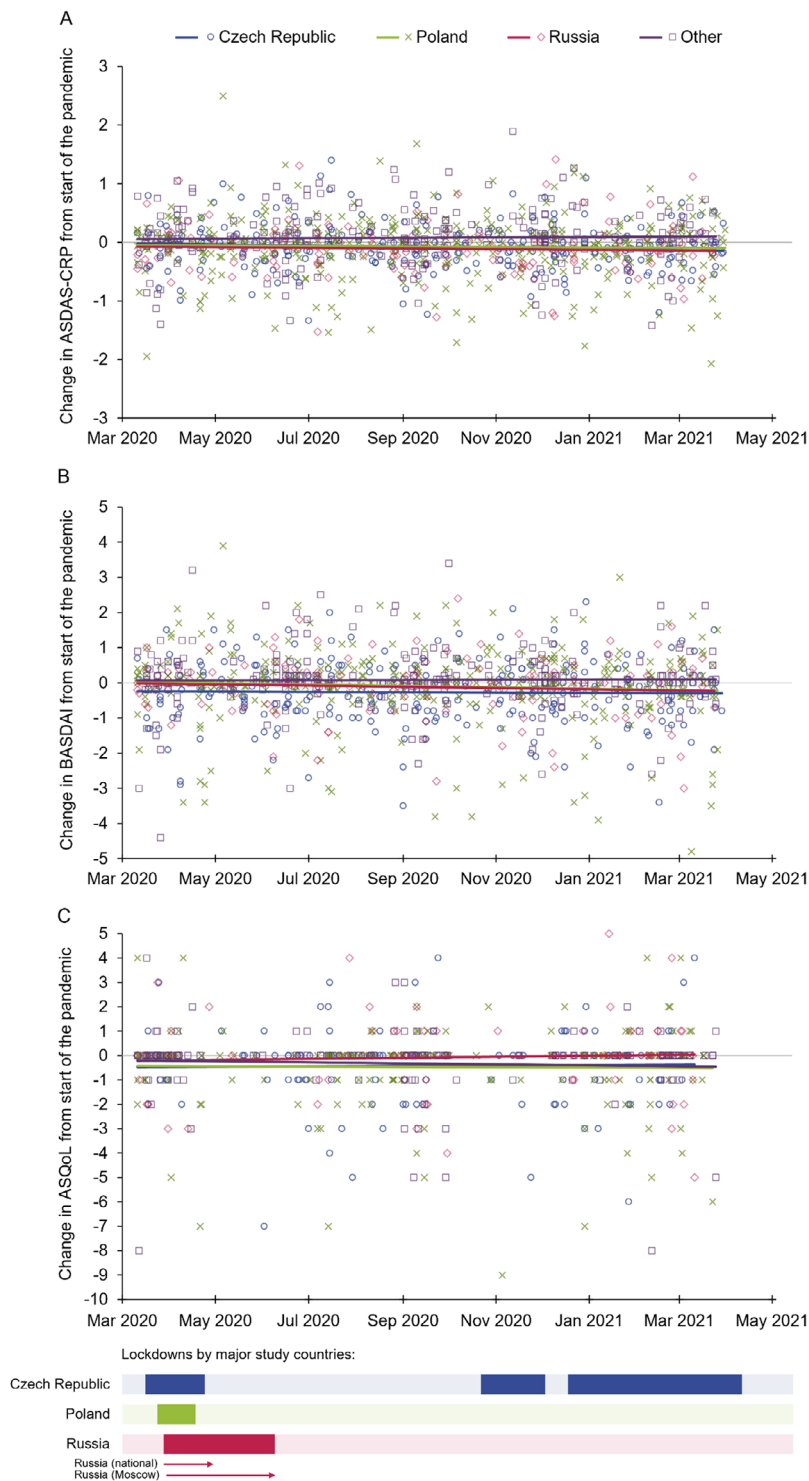


Figure 2. Change in Ankylosing Spondylitis Disease Activity Score C-reactive protein (ASDAS-CRP) (A), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) (B), and Ankylosing Spondylitis Quality of Life (ASQoL) (C) score since the start of the pandemic in patients receiving 160 mg of bimekizumab every 4 weeks (observed data). Patients from the open-label extension full analysis set who remained in the study on September 1, 2019, with a recorded outcome assessment. Using the last data point collected before March 11, 2020, as prepandemic baseline, changes from this baseline in individual patients' outcome scores are presented for each study visit. Each marker represents a single patient visit; linear trendlines for each of the countries/regions are shown. Patient numbers appear lower for ASQoL than ASDAS-CRP and BASDAI during the pandemic period because ASQoL assessments were conducted every 24 weeks from Week 156, whereas ASDAS-CRP and BASDAI assessments were conducted every 12 weeks. Lockdowns (national, unless otherwise indicated) for the major study countries are shown by dark-colored bars. ASDAS-CRP, Ankylosing Spondylitis Disease Activity Score C-reactive protein; ASQoL, Ankylosing Spondylitis Quality of Life; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; OLE, open-label extension; Q4W, every four weeks; SD, standard deviation.

(n = 208, 89.7%) were based in Eastern Europe (Table 1). The top three countries by patient number were Poland (n = 81, 34.9%), Czech Republic (n = 60, 25.9%) and Russia (n = 31, 13.4%) (Table 1).

Disease characteristics of the study population (N = 232) at baseline of BE AGILE and at pre-pandemic baseline are shown in Table 1. At baseline of BE AGILE, patients had mean (SD) ASDAS-CRP, BASDAI and ASQoL scores of 3.9 (0.8), 6.4 (1.4), and 8.5 (4.3), respectively. At the pre-pandemic baseline, patients' mean ASDAS-CRP, BASDAI and ASQoL scores had reduced to 1.8 (0.9), 2.4 (1.8), and 2.8 (3.5), respectively (Table 1).

Between September 2019 and February 2021, 12 of 232 (5.2%) patients enrolled in the OLE had a COVID-19 treatment-emergent adverse event. Of these, cases in three patients were classified as serious adverse events because of hospitalization, but none led to death or admittance to an intensive care unit. During the pandemic period, very few bimekizumab doses were missed because of COVID-19 (11 doses) and the number of missed assessments remained low ($\leq 5\%$) (Supplementary Table 1).

Patient outcomes through the pandemic. In the patients receiving 160 mg of bimekizumab Q4W during the analysis period, mean ASDAS-CRP, BASDAI, and ASQoL scores were stable across successive 3-month periods before and during the pandemic (Figure 1). The mean ASDAS-CRP remained stable at 1.8 during the two pre-pandemic periods (a 6-month period) and ranged from 1.7 to 1.8 in the four pandemic periods (a total of 12 months) (Figure 1A). Similarly, the mean BASDAI score remained stable at 2.4 during the prepandemic periods and ranged between 2.2 and 2.4 during the pandemic periods (Figure 1B). Stable mean ASQoL scores, ranging between 2.6 and 2.8 in the pre-pandemic periods and 2.0 and 2.7 during the pandemic, were also observed (Figure 1C).

Furthermore, when we evaluated change from prepandemic baseline (last visit before March 11, 2020) in individual patients' outcome scores during the pandemic period, there were no notable changes in ASDAS-CRP, BASDAI, or ASQoL scores (Figure 2). The stability of patient outcomes was consistent across major study countries, as demonstrated by the horizontal linear trendlines (Figure 2). Because of the stability of outcomes, multinomial models did not converge, preventing evaluation of potential predictors of outcome worsening or improvement during the COVID-19 pandemic.

DISCUSSION

Following more than 3 years of bimekizumab treatment in most patients with active AS enrolled in the BE AGILE OLE, disease activity (ASDAS-CRP and BASDAI) and HRQoL (ASQoL) at pre-pandemic baseline were substantially improved relative to study baseline, with mean values indicating low disease activity at the onset of the pandemic. Our analysis showed that, at a group level,

disease activity and HRQoL remained stable through the COVID-19 pandemic. This was consistent with the sustained and stable efficacy of bimekizumab reported for up to 3 years of treatment (12,15), which followed the improvements in efficacy outcomes achieved in the first 12 and 48 weeks (11). We also found that there were no notable increases in missed study assessments during the pandemic. For the top three countries by patient number (analyzed individually to account for their differing restrictions during the pandemic), assessed outcomes also remained stable.

Our findings differ from some real-world studies evaluating the implications of the pandemic on patients with rheumatic disease, which may reflect the clinical trial setting of this study and differences in patient populations, study design approaches, and use of alternative outcome measures (4,6,7,9,10). For example, disease activity in this study population at the start of the pandemic was low overall and patients may have been less susceptible to pandemic-related effects as a result. Most studies published to date suggest that the pandemic has negatively affected stress and anxiety levels (which were not specifically measured in this study), wellbeing and access to healthcare services in patients with axSpA (4,6,7,10). Conversely, other studies have found no major consequences of delayed or interrupted treatment caused by reduced access to healthcare services during the pandemic, with more patients communicating with rheumatologists electronically than through in-person appointments and most continuing their antirheumatic medication as prescribed (5,9,16). It is possible that the patients in this study may have benefited from the clinical trial context, even during the pandemic.

Study limitations include the fact that multiple factors could have influenced outcomes, including geographic heterogeneity in COVID-19 infections and societal impacts, which could not be fully accounted for. Pandemic conditions are also likely to have varied across patients in the study because of variation in their individual circumstances. Additionally, most patients were White and based in Eastern Europe; social and ethnocultural characteristics of this population may have affected patients' responses to the pandemic, and our findings may therefore not be fully representative of different demographics.

Despite these limitations, the observation of stable disease control and HRQoL during the COVID-19 pandemic in patients with AS receiving bimekizumab in this ongoing OLE study is encouraging. Although monitoring should be continued for the remainder of this and subsequent studies to evaluate potential long-term effects of the pandemic, findings indicate that the COVID-19 pandemic did not have a significant adverse effect on disease control or preservation of quality of life in patients with AS treated with bimekizumab.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Taieb and Vaux had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study design and conception. Robinson, Machado, Haroon, Gensler, Reveille, Taieb, Vaux, Fleurinck, Oortgiesen, de Peyrecave, Deodhar.

Acquisition of data. Gensler, Deodhar.

Analysis and interpretation of data. Robinson, Machado, Haroon, Gensler, Reveille, Taieb, Vaux, Fleurinck, Oortgiesen, de Peyrecave, Deodhar.

ROLE OF THE STUDY SPONSOR

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