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HEALTH TECHNOLOGY BRIEFING SEPTEMBER 2021

Bimekizumab for ankylosing spondylitis

NIHRIO ID	13320	**NICE ID**	10334
Developer/Company	UCB Pharma Ltd	**UKPS ID**	652675

Licensing and market availability plans	Currently in phase III clinical development.

SUMMARY

Bimekizumab is in clinical development for the treatment of adults with ankylosing spondylitis (AS). AS is a long-term condition in which the spine and other areas of the body become inflamed. The inflammation can lead to back pain, fatigue and in serious cases, to severe disability as bones may fuse into a fixed position or joints become progressively damaged. It is not known exactly what causes AS, but in many cases, there seems to be a link with a particular gene known as HLA-B27. Some patients with AS do not respond well to current treatment options, resulting in a clear unmet medical need.

Bimekizumab is a drug administered by subcutaneous injection that neutralises the function of certain proteins that regulate immune responses, namely: interleukin (IL)-17A and IL-17F cytokines. High levels of these interleukins have been shown to be involved in developing inflammatory diseases caused by the immune system. Neutralizing both IL-17A and IL-17F prevents them from interacting with their receptors (targets), which reduces skin and joint inflammation as well as pathological bone formation. Current treatments for AS target IL-17A alone, whereas bimekizumab causes greater reduction of inflammation through targeting both the IL17A and IL17F and results from phase IIB trials suggest bimekizumab may provide a promising therapeutic option for patients with AS.

PROPOSED INDICATION

Adult patients with ankylosing spondylitis.[1]

TECHNOLOGY

DESCRIPTION

Bimekizumab (BKZ,UCB4940) is an investigational novel humanised monoclonal IgG1 antibody that potently and selectively neutralizes both IL-17A and IL-17F, two key cytokines driving inflammatory processes. IL-17A and IL-17F have similar pro-inflammatory functions and independently cooperate with other inflammatory mediators to drive chronic inflammation and damage across multiple tissues. Dual neutralization of both IL-17A and IL-17F may provide a new targeted approach for the treatment of immune-mediated inflammatory diseases. Preclinical results in disease-relevant cells have shown that neutralising IL-17F in addition to IL-17A reduces skin and joint inflammation, as well as pathological bone formation to an extent greater than inhibition of IL-17A alone.[2]

In the phase III trial, NCT03928743, patients were randomized 1:1 to 160 mg every 4 weeks or placebo for 16 weeks (double blind period). After 16 weeks all patients were switched to bimekizumab 160 mg every 4 weeks for 36 further weeks (52 weeks follow-up). Patients in NCT03928743 may continue on treatment beyond 52 weeks by enrolling in the open label extension study, NCT04436640.[3]

INNOVATION AND/OR ADVANTAGES

Current NICE recommended treatments for AS include the use of secukinumab and ixekizumab, which target IL-17A, only if the patient has responded inadequately to conventional therapy (NSAIDS or TNF-α inhibitors).[4]

Bimekizumab targets both the IL17A and IL17F, which results in greater reduction of inflammation than inhibition of IL17A alone.[5] Results from phase IIB trials suggest bimekizumab may provide a promising therapeutic option for patients with AS. Bimekizumab treatment resulted in rapid and sustained improvements across multiple outcomes of disease activity, QoL and function.[6]

DEVELOPMENT STATUS AND/OR REGULATORY DESIGNATIONS

Bimekizumab (Bimzelx) has a marketing authorisation for plaque psoriasis in both the UK and EU.[7]

The most common side effects with bimekizumab are upper respiratory tract infections (nose and throat infection), which may affect more than 1 in 10 people, and oral candidiasis (thrush, a fungal infection in the mouth or throat).[8]

Bimekizumab is in phase III clinical development for psoriatic arthritis, hidradenitis suppurativa and non-radiographic axial spondyloarthritis.[9]

PATIENT GROUP

DISEASE BACKGROUND

AS is a rheumatological autoimmune disease that may be axial, affecting sacroiliac joints and spine, or peripheral. It not only affects joints but also soft tissues such as tendons and ligaments. There are extra-articular manifestations such as anterior uveitis, psoriasis, and inflammatory bowel disease.[10] In more advanced cases, this inflammation can lead to fibrosis and calcification, resulting in the loss of flexibility and the fusion of the spine, resembling "bamboo" with an immobile position.[11]

AS is around twice as common in men as women. It most often begins between 20 and 30 years of age.[10] While the cause of AS remains unclear, it is thought to be an interplay of genetic and environmental factors. The prevalence of AS has a clear correlation with the human leukocyte antigen (HLA)-B27 positive rate in specific populations. Studies have revealed that in HLAB27-positive populations, the prevalence rate of AS is approximately 5%–6%. Microbial infection can act as a triggering factor of the host innate immune system and AS development.[11]

The symptoms of AS usually develop slowly over several months or years. The symptoms may come and go, and improve or get worse, over many years. The main clinical manifestations include chronic back pain and progressive spinal rigidity as well as inflammation of the hips, shoulders, peripheral joints and fingers/toes, arthritis, enthesitis (inflammation of the tendons and ligaments) and fatigue.[11,12]

CLINICAL NEED AND BURDEN OF DISEASE

In line with previous NICE technology appraisals, the company estimates the UK patient population range to be between 238 and 500 per 100,000.[13,14] Approximately 1 out of every 10 people with AS have a severe form of the disease and may become quite disabled over time.[15] About a third of people with AS may be unable to work altogether, and a further 15% report some changes to their working lives.[16]

Hospital Episode Statistics show that in 2019-20 there were 3,892 Finished Consultant Episodes (FCE), 3,822 admissions and 1,406 FCE bed days with the primary diagnosis AS (ICD10 code M45) in England.[17] In 2020, there were 21 deaths with AS as the underlying cause of death (ICD10 code M45) in England and Wales.[18]

PATIENT TREATMENT PATHWAY

TREATMENT PATHWAY

There is no cure for AS, but treatment is available to help relieve the symptoms.[19] Conventional therapy for AS includes NSAIDs and physiotherapy.[20] NSAIDs are first line treatment but different painkillers such as paracetamol or codeine may be recommended if NSAIDs are not suitable.[19] Biological DMARDs, which includes TNF-alpha inhibitors, are typically used when the disease has not responded adequately to conventional therapy.[20] Interleukin 17 inhibitors are also licenced by MHRA and approved by NICE for treating AS. Corticosteroids have a powerful anti-inflammatory effect and can be taken as tablets or injections by people with AS. Joint replacement surgery may be recommended to improve pain and movement in the affected joint if the joint has become severely damaged. Regular follow up is recommend as symptoms tend to come and go.[19]

CURRENT TREATMENT OPTIONS

Biological disease-modifying antirheumatic drugs which are recommended for the treatment of severe AS in adults whose disease has responded inadequately to, or who cannot tolerate NSAIDs, include:[21]

- Adalimumab
- Certolizumab pegol
- Etanercept
- Golimumab
- Infliximab

Secukinumab is recommended as an option for treating active AS in adults whose disease has responded inadequately to conventional therapy (NSAIDs or TNF-alpha inhibitors).[21]

Ixekizumab is recommended as an option for treating active AS that is not controlled well enough with conventional therapy, or active non-radiographic axial spondyloarthritis with objective signs of inflammation only if tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough.[4]

PLACE OF TECHNOLOGY

If licensed, bimekizumab will provide an additional targeted treatment option for adults with AS.

CLINICAL TRIAL INFORMATION

Trial	**BE MOBILE 2;** NCT03928743, 2017-003065-95; A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Bimekizumab in Subjects With Active Ankylosing Spondylitis **Phase III** - Ongoing **Location(s):** 9 EU countries, UK, USA, Turkey, Japan and China **Primary completion date:** August 2021	**BE MOVING**; NCT04436640, 2019-004163-47; A Multicenter, Open-Label Extension Study to Assess the Long-Term Safety, Tolerability, and Efficacy of Bimekizumab in the Treatment of Study Participants With Active Axial Spondyloarthritis, Ankylosing Spondylitis, and Nonradiographic Axial Spondyloarthritis **Phase III** - Enrolling by invitation **Location(s):** 9 EU countries, UK, USA, Turkey and Japan **Primary completion date:** July 2024
Trial design	Randomised, parallel assignment, placebo-controlled, quadruple masked.	Open label, single group assignment
Population	N=332 (actual), Subjects with ankylosing spondylitis, moderate-to-severe active disease, who have either failed to respond to 2 different nonsteroidal anti-inflammatory drugs (NSAIDs) given at the maximum tolerated dose for a total of 4 weeks or have a history of intolerance to or a	N=485 (planned), Study participants who completed NCT03928704 or NCT0392874; aged 18 years and older

	contraindication to NSAID therapy; aged 18 years and older	
Intervention(s)	Bimekizumab, at pre-specified time-points.	Bimekizumab at prespecified time-points.
Comparator(s)	Placebo during the double-blind treatment period, and bimekizumab during the maintenance period.	No comparator.
Outcome(s)	Primary outcome measures: - Assessment of SpondyloArthritis International Society 40% response criteria (ASAS40) response at Week 16 [Time Frame: Week 16] See trial record for full list of other outcomes.	Primary outcome measures; • Percentage of participants with treatment-emergent adverse events (TEAEs) during the study [Time Frame: From Baseline (Day 1) until Safety Follow-Up (up to Week 128)] See trial record for full list of other outcomes.
Results (efficacy)	-	-
Results (safety)	-	

Trial	**BE AGILE;** NCT02963506, 2016-001102-42; A Multicenter, Phase 2B, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Study to Evaluate the Efficacy and Safety of Bimekizumab in Subjects With Active Ankylosing Spondylitis **Phase IIB** - Completed **Location(s):** 6 EU countries, USA, Canada, Russia and Ukraine **Study completion date:** August 2018	**BE AGILE 2;** NCT03355573, 2017-001002-15; A Multicenter, Open-Label Extension Study to Evaluate the Long Term Safety and Efficacy of Bimekizumab in Subjects With Ankylosing Spondylitis **Phase II** - Ongoing **Location(s):** 6 EU countries, USA, Canada, Russia and Ukraine **Primary completion date:** November 2022
Trial design	Randomised, parallel assignment and double-blind	Open label, single group assignment
Population	N=303 (actual); Subjects with ankylosing spondylitis, moderate-to-severe active disease, inadequate response to NSAIDs; aged 18 years and older	N=256 (actual); Subjects completed NCT0296 3506 without meeting any withdrawal criteria; aged 18 years and older
Intervention(s)	Bimekizumab in different dosages.	Bimekizumab at a prespecified dose.
Comparator(s)	Placebo and then bimekizumab	None.
Outcome(s)	Primary outcome measures: - Percentage of Participants With Axial Spondyloarthritis International Society 40% Response Criteria	Primary outcome measures; • Incidence of treatment-emergent adverse events (TEAEs) during the study [Time Frame: From Entry

	(ASAS40) at Week 12 [Time Frame: Week 12] See trial record for full list of other outcomes.	Visit (Visit 1) until Last Visit (up to Week 208)] • Incidence of serious adverse event (SAE) during the study [Time Frame: From Entry Visit (Visit 1) until Last Visit (up to Week 208)] See trial record for full list of other outcomes.
Results (efficacy)	At week 12, significantly more bimekizumab-treated patients achieved ASAS40 vs placebo (non-responder imputation (NRI): 29.5%–46.7% vs 13.3%; p<0.05 all comparisons; OR vs placebo 2.6–5.5 (95% CI 1.0 to 12.9)). A significant dose-response was observed (p<0.001). The primary end point was supported by all secondary efficacy outcomes. At week 48, 58.6% and 62.3% of patients receiving bimekizumab 160 and 320 mg throughout the study achieved ASAS40, respectively (NRI); similar ASAS40 response rates were observed in re-randomised patients.[6]	Efficacy demonstrated at Week 48 in BE AGILE was maintained or improved up to Week 156. Mean Ankylosing Spondylitis Disease Activity Score (ASDAS) improved from 3.9 at BE AGILE baseline to 2.0 and 1.8 at Weeks 48 and 156 respectively (by multiple imputation (MI)). At Week 156 in the NRI analyses, ASAS40 and ASAS partial remission were achieved by 62.6% (observed case (OC): 72.6%) and 32.7% (OC: 37.9%) patients respectively. ASDAS inactive disease and ASDAS <2.1 responder rates (NRI) were maintained or continued to increase from Week 48, and by Week 156, responses were achieved by 28.0% (OC: 33.0%) and 57.1% (OC: 67.4%) patients respectively. ASDAS major improvement responder rates (NRI) continued to increase from 44.9% at Week 48 to 46.5% at Week 156 (OC: 52.9%).[22]
Results (safety)	During the double-blind period, treatment-emergent adverse events occurred in 26/60 (43.3%) patients receiving placebo and 92/243 (37.9%) receiving bimekizumab.[6]	Over the 156 weeks, the exposure-adjusted incidence rate (EAIR) per 100 patient-years (PY) of TEAEs was 143.5, with an EAIR of 5.8 for serious TEAEs, 1.3 for serious infections, and 3.8 for Candida infections. All Candida infections were mild or moderate; none were systemic or led to study discontinuation. Over 156 weeks, the EAIR of inflammatory bowel disease (1.2), anterior uveitis (0.8), and injection site reactions (0.5) remained low.[22]

Trial	NCT03215277, 2017-000957-37; A Multicenter, Phase 2A, Randomized, Investigator-Blind, Subject-Blind, Parallel-Group Study to Evaluate the Efficacy and Safety of Bimekizumab and Certolizumab Pegol in Subjects With Active Ankylosing Spondylitis **Phase IIA** - Completed **Location(s):** 6 EU countries, USA and Russia

	Study completion date: May 2020
Trial design	Randomised, parallel assignment and double-blind
Population	N=76; Subjects with active adult-onset ankylosing spondylitis, moderate to severe disease, inadequate response to NSAIDs; aged 18 years and older
Intervention(s)	Subjects will receive several bimekizumab administrations on pre-defined time points.
Comparator(s)	Subjects will receive several certolizumab pegol administrations on pre-defined time points.
Outcome(s)	Primary outcome measures: - Change from Baseline in Ankylosing Spondylitis Disease Activity Score (ASDAS) at Week 12 [Time Frame: From Baseline to Week 12] - Incidence of adverse events (AE) during the study conduct [Time Frame: From Screening until Safety Follow-Up Visit (up to Week 64)] - Incidence of serious adverse events (SAEs) during the study conduct [Time Frame: From Screening until Safety Follow-Up Visit (up to Week 64)] - Number of subjects who withdrew due to an adverse event (AE) during the study conduct [Time Frame: From Screening until Safety Follow-Up Visit (up to Week 64)] See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

ESTIMATED COST

The cost of bimekizumab is not yet known.

RELEVANT GUIDANCE

NICE GUIDANCE

- NICE technology appraisal in development. Tofacitinib for treating active ankylosing spondylitis (ID3865). Expected publication date: To Be Confirmed.
- NICE technology appraisal in development. Upadacitinib for treating active ankylosing spondylitis (ID3848). Expected publication date: To Be Confirmed.
- NICE technology appraisal. Ixekizumab for treating axial spondyloarthritis after NSAIDs (TA718). July 2021
- NICE technology appraisal. Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors (TA407). September 2016.
- NICE technology appraisal. TNF-alpha inhibitors for ankylosing spondylitis and nonradiographic axial spondyloarthritis (TA383). February 2016.
- NICE guideline. Spondyloarthritis in over 16s: diagnosis and management (NG65). February 2017. Last updated June 2017.
- NICE quality standard. Spondyloarthritis (QS170). June 2018.

NHS ENGLAND (POLICY/COMMISSIONING) GUIDANCE

- NHS England. 2013/14 NHS Standard Contract for Specialised Rheumatology Services (Adult). A13/S/a.

OTHER GUIDANCE

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ADDITIONAL INFORMATION

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