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HEALTH TECHNOLOGY BRIEFING SEPTEMBER 2021

Bimekizumab for active psoriatic arthritis

NIHRIO ID	10607	**NICE ID**	10397
Developer/Company	UCB Pharma Ltd	**UKPS ID**	652673

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

SUMMARY

Bimekizumab is in clinical development for the treatment of adults with psoriatic arthritis which is a type of chronic inflammatory arthritis affecting the joints and connective tissue and is associated with psoriasis of the skin or nails. Although the exact cause of the disease remains unknown, it is thought to occur as a result of the immune system mistakenly attacking healthy tissues around the joint and bones. Psoriatic arthritis can get progressively worse and may lead to the joints becoming permanently damaged or deformed. There is a need for further treatments for psoriatic arthritis which demonstrate clinically meaningful improvements in both musculoskeletal and skin outcomes.

Bimekizumab works by specifically targeting chemical messengers (cytokines) called interleukin 17A (IL17A) and interleukin 17F (IL17F). IL17A and IL17F amplify inflammatory responses. By neutralising these, bimekizumab reduces inflammation. Bimekizumab is administered by an injection under the skin (subcutaneous) every four weeks. If licenced bimekizumab will offer an additional treatment option for patients with active psoriatic arthritis.

PROPOSED INDICATION

Treatment of adults with active psoriatic arthritis (PsA).[1-6]

TECHNOLOGY

DESCRIPTION

Bimekizumab (Bimzelx®) is a monoclonal antibody that selectively neutralises interleukin 17A (IL17A) and interleukin 17F (IL17F). In vitro, IL17A and IL17F are only moderate signal activators, but they cooperate with other proinflammatory cytokines, including tumour necrosis factor (TNF), to amplify inflammatory responses. This dual neutralisation of IL17A and IL17F has shown to more effectively reduce expression of genes linked to inflammation and pro-inflammatory cytokines, and suppress immune cell migration in dermal fibroblasts and synoviocytes from patients with PsA.[7]

Bimekizumab is currently in clinical development for the treatment of PsA in adults. In phase III and II clinical trials (NCT04009499, BE VITAL; NCT03895203, BE OPTIMAL; NCT03896581, BE COMPLETE; NCT04109976; NCT02969525, BE ACTIVE; NCT03347110, BE ACTIVE 2) participants received different dosage regimens of bimekizumab with the treatment varying from 4 to 120 weeks The proposed dosage regimen is 160mg every four weeks by subcutaneous (SC) injection.[1-6]

INNOVATION AND/OR ADVANTAGES

Existing technologies target only IL17A, but bimekizumab targets both IL17A and IL17F. The dual neutralisation of IL17A and IL17F is a potential novel therapeutic approach. Bimekizumab had a significant improvement on American College of Rheumatology (ACR) 50 response, based on a 50% or greater improvement relative to baseline. In addition to this, bimekizumab had fewer treatment-emergent adverse events (TEAEs) compared to a placebo, most of which were mild to moderate.[7]

DEVELOPMENT STATUS AND/OR REGULATORY DESIGNATIONS

Bimekizumab has a marketing authorisation for plaque psoriasis in both the UK and EU.[8]

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

PATIENT GROUP

DISEASE BACKGROUND

Psoriatic arthritis (PsA) is a type of chronic, multi-organ inflammatory disease that causes irreversible structural damage to the joints over time and can worsen the patient's quality of life (QoL).[10,11] Although the aetiology of PsA remains unconfirmed, multiple immune system cell types and cytokines have been implicated in PsA disease activity. The synovial fluid of

joints affected by PsA shows increased levels of T-cells and cytokines such as TNF, interleukin 6 (IL6), interleukin 12/23 (IL12/IL23), and interleukin 17 (IL17). Together, these cytokines drive joint inflammation and other downstream biological effects, such as osteoblast and osteoclast activation, which further contributes to joint damage.[12]

PsA tends to affect more adults than young people.[13] Men and women are equally likely to develop psoriatic arthritis with the peak onset being between the ages of 30 and 50 years.[14,15] Almost 1 in 3 people with psoriasis develop PsA.[16] Like psoriasis, PsA is thought to occur as a result of the immune system mistakenly attacking healthy tissue. However, it is not clear why some people with psoriasis develop psoriatic arthritis and others do not.[16] Symptoms of PsA can include a red, scaly rash (psoriasis), swollen, stiff and painful joints, sausage-like swelling of fingers or toes (dactylitis), thickening, discolouration and pitting of the nails, pain and swelling at the back of the heel, and fatigue.[13] Common effects on QoL include disruption in participating in social activities, day-to-day life, fatigue and sleep disturbances.[11] Patients with PsA have a poorer quality of life compared to patients with psoriasis alone.[10]

The severity of psoriatic arthritis can range from mild to severe and despite improvement on conventional synthetic disease-modifying anti-rheumatic drug (DMARD) medication, up to 47% people will develop joint damage which is visible on radiograph by 2 years. People with psoriatic arthritis also have 60% higher risk of mortality and a 3 year decreased life expectancy compared to the general population.[17]

CLINICAL NEED AND BURDEN OF DISEASE

Almost 1 in 3 people with psoriasis develop PsA, and a large number of people with PsA have psoriasis to some extent.[15,16] Based on the UK PsA prevalence of 0.19% in adults, using the Office for National Statistics (ONS) mid-2020 population estimates, there are an estimated 100,491 adults with PsA in the UK.[18,19]

In England, 2019-20, there were 3,869 finished consultant episodes (FCE) for arthropathic psoriasis (ICD-10 code L40.5), of which there were 1,497 FCE bed days and 3,308 day cases.[20]

PATIENT TREATMENT PATHWAY

TREATMENT PATHWAY

The main aims of treatment will be to relieve the symptoms, slow the progression of disease and improve quality of life. The healthcare management of symptoms related to the disease can be delivered by a multidisciplinary team formed by the general practitioner (GP), rheumatologist, specialist nurse, dermatologist, physiotherapist, occupational therapist, and psychologist.

In addition to this, change of habits such as having a balance between rest and regular physical activity, losing weight, not smoking and only drinking a moderate amount of alcohol may help to ease the symptoms.[16]

CURRENT TREATMENT OPTIONS

There are several therapeutic treatment approaches according to different disease severity and include:[16]

- Non-steroidal antiinflammatory drugs (NSAIDs) may be used to help relieve pain and reduce inflammation. There are two types of NSAIDs, the traditional NSAIDs, such as ibuprofen and naproxen or diclofenac, and the COX-2 inhibitors (also called coxibs), such as celecoxib or etoricoxib.
- Like NSAIDs, corticosteroids can help reduce pain and swelling.
- DMARDs are medications that work by tackling the underlying causes of the inflammation in your joints. Leflunomide is often the first drug given for psoriatic arthritis, although sulfasalazine or methotrexate may be considered as alternatives.
- Biological treatment may be offered for patients who have not responded to at least two different types of DMARD or are not able to be treated with at least two different types of DMARD. The biological medicines that may be offered include TNF alpha inhibitors (adalimumab, infliximab, certolizumab pegol, etanercept, golimumab), IL-17A inhibitors (ixekizumab, secukinumab), apremilast, tofacitinib, ustekinumab, and guselkumab.

PLACE OF TECHNOLOGY

If licenced bimekizumab will offer an additional treatment option for adult patients with active psoriatic arthritis.

CLINICAL TRIAL INFORMATION

Trial	**BE VITAL;** NCT04009499**;** 2018-004725-86**;** A Multicenter, Open-Label Extension Study to Assess the Long-Term Safety, Tolerability, and Efficacy of Bimekizumab in the Treatment of Subjects With Active Psoriatic Arthritis **Phase III** – Enrolling by invitation **Location(s):** 8 EU countries, United Kingdom, Canada, United States and other countries **Primary completion date:** May 2025
Trial design	Single group, open label assignment.
Population	N=1045 (planned); adults with active psoriatic arthritis; previously completed NCT03895203 or NCT03896581 without meeting any withdrawal criteria.
Intervention(s)	Subjects will receive 160 mg bimekizumab every 4 weeks by subcutaneous injection.
Comparator(s)	No comparator
Outcome(s)	• Incidence of treatment-emergent adverse events (TEAEs) during the study [Time frame: from PA0012 entry visit until safety follow-up (up to week 160)]. • Incidence of treatment-emergent serious adverse events (SAEs) during the study [Time frame: from PA0012 entry visit until safety follow-up (up to week 160)]. See trial record for full list of other outcomes.

Results (efficacy)	-
Results (safety)	-

Trial	**BE OPTIMAL; NCT03895203; 2017-002322-20;** A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Active Reference (Adalimumab) Study Evaluating the Efficacy and Safety of Bimekizumab in the Treatment of Subjects With Active Psoriatic Arthritis **Phase III –** Active, not recruiting **Location(s):** 8 EU countries, United Kingdom, Canada, United States and other countries **Primary completion date:** August 2021
Trial design	Randomised, triple-masked, parallel assignment.
Population	N=852 (actual); adults with active psoriatic arthritis that are naïve to biological disease-modifying rheumatic drugs.
Intervention(s)	Subjects will receive 160 mg bimekizumab every 4 weeks by subcutaneous injection.
Comparator(s)	Active comparator (adalimumab) or placebo
Outcome(s)	American College of Rheumatology (ACR) 50 response at week 16 [Time frame: week 16]. The ACR50 response rate is based on a 50% or greater improvement of arthritis relative to baseline. See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	**BE COMPLETE; NCT03896581; 2017-002804-29;** A Multicenter, Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Bimekizumab in the Treatment of Subjects With Active Psoriatic Arthritis **Phase III –** Active, not recruiting **Location(s):** 5 EU countries, United Kingdom, Canada, United States and other countries **Primary completion date:** August 2021
Trial design	Randomised, triple-masked, parallel assignment.
Population	N=400 (actual); adults with active psoriatic arthritis and history of inadequate response or intolerance to TNF alpha inhibitors.
Intervention(s)	Subjects will receive 160 mg bimekizumab by subcutaneous injection every 4 weeks.
Comparator(s)	Matched placebo
Outcome(s)	ACR50 response at week 16 [time frame: week 16] The ACR50 response rate is based on a 50% or greater improvement of arthritis relative to baseline. See trial record for full list of other outcomes.
Results (efficacy)	-

Results (safety)	-

Trial	NCT04109976; 2018-004725-86; A Multicenter, Randomized, Open-Label Study to Evaluate the Safe and Effective Use of the Prefilled Safety Syringe or Auto-Injector for the Subcutaneous Self-Injection of Bimekizumab Solution by Subjects With Active Psoriatic Arthritis **Phase III –** Completed **Location(s):** 4 EU countries, United States and Russia **Study completion date:** November 2020
Trial design	Randomised, open label, parallel assignment.
Population	N=215 (actual); adults with active psoriatic arthritis.
Intervention(s)	Study participants will receive 160 mg bimekizumab every 4 weeks either in a prefilled safety syringe or auto-injector.
Comparator(s)	No comparator
Outcome(s)	Percentage of participants able to self-administer safe and effective injections using the bimekizumab safety syringe or the bimekizumab auto-injector at week 4 [time frame: week 4]. See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	**BE ACTIVE;** NCT02969525; 2016-001103-23; A Multicenter, Phase 2B, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Study to Evaluate the Efficacy and Safety of Bimekizumab in Active Psoriatic Arthritis **Phase II –** Completed **Location(s):** 4 EU countries, United States and Russia **Study completion date:** July 2018	**BE ACTIVE 2;** NCT03347110; 2017-001003-74; A Multicenter, Open-Label, Follow-Up Study to Evaluate the Long-Term Safety and Efficacy of Bimekizumab in Subjects With Psoriatic Arthritis **Phase II –** Completed **Location(s):** 4 EU countries, United States and Russia **Study completion date:** October 2020
Trial design	Randomised, quadruple-masked, parallel assignment.	Open label, single group assignment.
Population	N=206 (actual); adults with active psoriatic arthritis.	N=184 (actual); adults with active psoriatic arthritis; previously completed NCT02969525 without meeting any withdrawal criteria.
Intervention(s)	• Bimekizumab dosage regimen 1: 16mg bimekizumab subucutaneous (SC) injection every 4 weeks for 12 weeks • Bimekizumab dosage regimen 2: 160mg bimekizumab SC injection every 4 weeks for 12 weeks	160mg bimekizumab SC injection every four weeks.[21]

	• Bimekizumab dosage regimen 3: 160mg bimekizumab SC injection every 4 weeks for 12 weeks, with a one-off loading dose of 320mg bimekizumab • Bimekizumab dosage regimen 4: 320mg bimekizumab SC injection every 4 weeks for 12 weeks After 12 weeks patients assigned to placebo or 16mg bimekizumab (regimen 1) were randomly assigned (1:1) to either 160mg or 320mg bimekizumab, all other patients remained on their originally assigned initial dose up to 48 weeks.[7]	
Comparator(s)	Matched placebo	No comparator
Outcome(s)	ACR50 response at week 12 [time frame: week 12] The ACR50 response rate was based on 50% improvement relative to baseline in the following measures: • Tender Joint Count (TJC) based on 78 joints • Swollen Joint Count (SJC) based on 76 joints See trial record for full list of other outcomes.	• Incidence of TEAEs during the study [time frame: from entry visit of PA0009 until safety follow-up visit (up to week 120)] • Incidence of treatment-emergent SAEs during the study [time frame: from entry visit of PA0009 until safety follow-up visit (up to week 120)] See trial record for full list of other outcomes.
Results (efficacy)	At 12 weeks, compared with the placebo group, significantly more patients in the 16 mg bimekizumab (odds ratio [OR] 4·2 [95% CI 1·1-15·2]; p=0·032), 160 mg bimekizumab (8·1 [2·3-28·7]; p=0·0012), and 160 mg (loading dose) bimekizumab (9·7 [2·7-34·3]; p=0·0004) groups achieved an ACR50 response.[7]	Bimekizumab leads to long-term efficacy for skin/joint manifestations of PsA, with >50% pts achieving high thresholds of disease control (ACR50, BSA 0%, MDA) after 108 wks' treatment.[21] Week 152 results are consistent with 108 week results.[22]
Results (safety)	At 12 weeks, 24 (57%) of 42 patients in the placebo group and 68 (41%) of the 164 patients in the bimekizumab groups reported treatment-emergent adverse events. Most of these adverse events were mild or moderate. Serious treatment-emergent adverse events were rare, occurring in nine patients, eight of whom were receiving bimekizumab. No deaths or cases	The safety profile reflects previous observations.[21]

	of inflammatory bowel disease were reported.[7]	

ESTIMATED COST

The cost of bimekizumab is not yet known.

RELEVANT GUIDANCE

NICE GUIDANCE

- NICE technology appraisal in development. Risankizumab for previously treated active psoriatic arthritis (ID1399). Expected date of issue to be confirmed.
- NICE technology appraisal in development. Upadacitinib for treating active psoriatic arthritis after inadequate response to DMARDs (ID2690). Expected date of issue to be confirmed.
- NICE technology appraisal. Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs (TA711). June 2021.
- NICE technology appraisal. Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs (TA543). October 2018.
- NICE technology appraisal. Ixekizumab for treating active psoriatic arthritis after inadequate response to DMARDs (TA537). August 2018.
- NICE technology appraisal. Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs (TA445). May 2017.
- NICE technology appraisal. Ustekinumab for treating active psoriatic arthritis (TA340). March 2017.
- NICE technology appraisal. Apremilast for treating active psoriatic arthritis (TA433). February 2017.
- NICE technology appraisal. Golimumab for the treatment of psoriatic arthritis (TA220). April 2011.
- NICE technology appraisal. Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (TA199). August 2010.
- NICE clinical guideline. Psoriasis: assessment and management (CG153). October 2012.

NHS ENGLAND (POLICY/COMMISSIONING) GUIDANCE

- NHS England. 2013/14 NHS Standard Contract for Specialised Rheumatology Services (Adult). A13/S/a.
- NHS England. 2013/14 NHS Standard Contract for Specialised Dermatology Services (All Ages). A12/S/a.

OTHER GUIDANCE

- European League Against Rheumatism (EULAR). European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. December 2015.[23]

- British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR). The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics. October 2013.[24]
- Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of psoriasis and psoriatic arthritis in adults: a national clinical guideline (SIGN 121). October 2010.[25]

ADDITIONAL INFORMATION

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