

HEALTH TECHNOLOGY BRIEFING AUGUST 2019

Bimekizumab for moderate to severe chronic plaque psoriasis

NIHRIO ID	8725	NICE ID	10125
Developer/Company	UCB Pharma Ltd	UKPS ID	650561

Licensing and market availability plans	Currently in phase III clinical trial
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SUMMARY

Bimekizumab is in clinical development for moderate to severe chronic plaque psoriasis. Plaque psoriasis is a persistent, long lasting chronic inflammatory disease causing red, flaky and itchy patches of skin commonly appearing on the elbows, knees, scalp and lower back. Plaque psoriasis is an autoimmune disease, meaning that the immune cells which usually fight infection attack the body's own tissues instead, in this case, the skin. Treatment is determined by the type and severity of psoriasis, and the area of skin affected, and may include a combination of topical, phototherapy and systemic (oral or injected) therapies.

Bimekizumab is a humanised monoclonal IgG1 antibody which works by selectively neutralising two important proteins (interleukin (IL)-17A and 17F). These proteins promote inflammation and stimulate other chemicals which drive inflammation, and result in multiple tissue damage including the skin. Neutralizing both IL-17F and IL-17A reduces skin and joint inflammation. Early studies have shown that bimekizumab administered by subcutaneous injection has the potential to rapidly resolve symptoms while remaining safe and well-tolerated. If licensed, bimekizumab will offer an additional systemic therapy option for patients with moderate to severe chronic plaque psoriasis.

PROPOSED INDICATION

Moderate to severe chronic plaque psoriasis in adults who are candidates for systemic therapy.¹⁻⁴

TECHNOLOGY

DESCRIPTION

Bimekizumab is a humanised monoclonal IgG1 antibody that was designed to potently and selectively neutralise the biologic functions of both interleukins (IL)-17A and 17F. IL-17F shares a approximately 50% structural homology and overlapping biologic pro-inflammatory function with IL-17A, suggesting it might also play an important role in psoriasis.⁵ IL-17A and IL-17F independently cooperate with other inflammatory mediators to result in chronic inflammation and damage across multiple tissues.⁶ Moreover, in preclinical models, both IL-17A and IL-17F have been shown to cooperate with tumour necrosis factor (TNF) to stimulate production of key proinflammatory cytokines and amplify tissue inflammation. When compared with IL-17A blockade alone, dual neutralisation of IL-17A and IL-17F resulted in lower levels of expression of psoriasis linked genes and cytokines, as well as a greater suppression of disease-relevant immune cell migration.⁵

Bimekizumab is currently in clinical development for the treatment of moderate to severe chronic plaque psoriasis. In the phase III & IIIb clinical trials (NCT03412747; BE SURE, NCT03370133; BE VIVID, NCT03410992; BE READY, NCT03536884; BE RADIANT), participants received different dosage regimen of bimekizumab with treatment duration varying from 16 to 56 weeks.¹⁻⁴ The proposed dosing regimen is 320mg by subcutaneous injection every 4 weeks.^a

INNOVATION AND/OR ADVANTAGES

While targeting TNF-dependent pathways has demonstrated positive responses in patients with psoriasis, greater efficacy has been achieved with drugs that target the IL-23/T-helper 17 immunologic pathway. Despite these advances, achieving completely clear skin and maintaining this level of clearance remains challenging. Treatments that demonstrate greater efficacy and fewer safety issues could provide additional patient benefit.⁵

Previous early phase clinical studies in psoriasis and psoriatic arthritis have suggested that bimekizumab's unique dual neutralization of both IL-17A and IL-17F may provide a new targeted approach for the treatment of immune-mediated inflammatory diseases.⁶ Results from the phase II studies has shown that bimekizumab has the potential to maintain complete or almost complete skin clearance, and to rapidly resolve symptoms while remaining safe and well-tolerated.^{7,8}

DEVELOPMENT STATUS AND/OR REGULATORY DESIGNATIONS

Bimekizumab does not currently have Marketing Authorization in the EU for any indication.

Bimekizumab is currently in development for the treatment of ankylosing spondylitis, non-radiographic axial spondyloarthritis, psoriatic arthritis, and hidradenitis suppurativa.⁹

^a Information provided by UCB Pharma Ltd on the UK PharmaScan

PATIENT GROUP

DISEASE BACKGROUND

Plaque psoriasis is the most common type of psoriasis¹⁰ and follows a relapsing-remitting course which is characterised by dry red skin lesions (called plaques) covered in silver scales which commonly appear on the elbows, knees, scalp and lower back. The plaques can be itchy and sore, and in severe cases, the skin may crack and bleed.¹¹

Psoriasis is a skin condition that speeds up the life cycle of skin cells. It causes cells to build up rapidly on the surface of the skin. The cause of psoriasis is not yet fully understood, but is thought to be related to an immune system problem with T cells and other white blood cells, called neutrophils, in the body. Overactive T cells also trigger increased production of healthy skin cells, more T cells and other white blood cells, especially neutrophils. These travel into the skin causing redness. Dilated blood vessels in psoriasis-affected areas create warmth and redness in the skin lesions.¹²

What first triggers the inflammatory process is currently not known and is thought to be a complex mix of factors including: genetic susceptibility, skin injury, excessive alcohol consumption, smoking, stress, hormonal changes (e.g. puberty or menopause), certain medicines (e.g. lithium, antimalarial medicines, anti-inflammatory medicines, ACE inhibitors and beta blockers), throat infections and other immune disorders.¹³ Psoriasis is associated with several comorbidities, including cardiovascular disease, lymphoma, and depression, with up to 40% of patients developing conditions such as Psoriatic Arthritis.¹⁴

For most people, plaque psoriasis is managed in primary care but up to 60% of people will require a specialist referral at some point.¹⁰ For many people with plaque psoriasis, there can be functional, psychological and social impacts resulting from reduced employment and income, problems related to treatments, psoriatic arthritis and the stigma attached to having a visible skin disease.¹⁰

CLINICAL NEED AND BURDEN OF DISEASE

Psoriasis affects around 2% of people in the UK. It can start at any age but most often develops in adults under 35 years old, and affects men and women equally.¹⁵ Approximately 20% of those affected with psoriasis have moderate to severe psoriasis.¹⁶ Based on the population estimates for England and Wales (Mid-2018), the number expected of patients diagnosed with moderate to severe psoriasis would be 236,463 patients.¹⁷

In 2017-18 there were 1,324 admissions (of which 807 were day cases) for psoriasis vulgaris (ICD-10 code L40.0) in England which resulted in 1,419 finished consultant episodes (FCE) and 2,302 FCE bed days.¹⁸

PATIENT TREATMENT PATHWAY

TREATMENT PATHWAY

When the symptoms are particularly severe or patients not responding well to treatment, they may be referred to a skin specialist (dermatologist). Treatments are determined by the type and severity of psoriasis, and the area of skin affected. In general, a mild treatment such as topical creams applied to the skin is initiated, and probably progress to a stronger treatments if necessary.¹⁹

Treatment falls into 3 categories:^{19,20}

- Topical – creams and ointments applied to the skin
- Phototherapy – the skin is exposed to certain types of ultraviolet light
- Systemic – oral and injected medications that work throughout the entire body

Different types of treatment are often used in combination.

CURRENT TREATMENT OPTIONS

There are 2 main types of systemic treatment, non-biological and biological for patients with moderate to severe psoriasis.^{19,20}

The non-biological medications include methotrexate, ciclosporin, acitretin, apremilast, and dimethyl fumarate.^{19,20}

Biological treatments are indicated for severe psoriasis and include: etanercept, adalimumab, infliximab, ustekinumab, brodalumab, certolizumab pegol, guselkumab, ixekizumab, secukinumab, tildrakizumab and risankizumab.^{19,20}

PLACE OF TECHNOLOGY

If licensed, bimekizumab will offer an additional treatment option for patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy.

CLINICAL TRIAL INFORMATION

Trial	BE SURE, NCT03412747 , PS0008, EudraCT 2016-003392-22 ; aged ≥18 years old; bimekizumab vs adalimumab both in addition to placebo; phase III
Sponsor	UCB Biopharma SPRL
Status	Ongoing
Source of Information	Trial registry; ^{1,21} Company
Location	EU countries (not including the UK), USA, Canada and other countries
Design	Randomised, active comparator-controlled, double-blind; parallel assignment
Participants	N=478 aged 18 years and older; chronic plaque psoriasis (PSO) for at least 6 months prior to the screening visit; Psoriasis Area Severity Index (PASI) ≥12 and body surface area (BSA) affected by PSO ≥10% and Investigator's Global Assessment (IGA) score ≥3 on a 5-point scale.
Schedule	Participants were randomised to one of the treatment arms: 1. Arm 1: Subjects received bimekizumab dose regimen 1 for 56 weeks. Subjects received placebo at pre-specified time-points to maintain the blinding. 2. Arm 2: Subjects received bimekizumab dose regimen 1 for 16 weeks and proceed with bimekizumab dose regimen 2 until week 56. Subjects received placebo at pre-specified time-points to maintain the blinding.

	3. Arm 3 – Active comparator: Subjects received adalimumab for 24 weeks and then received bimekizumab dose regimen 1 until week 56. Subjects received placebo at pre-specified time-points to maintain the blinding.
Follow-up	up to 72 weeks
Primary Outcomes	Time frame 16 weeks: <ul style="list-style-type: none"> • PASI90 response. • Investigator's Global Assessment (IGA 0/1) response (clear or almost clear with at least a 2-category improvement from baseline)
Secondary Outcomes	Time frame 4 weeks: <ul style="list-style-type: none"> • PASI75 response at Week 4. Time frame 16 weeks: <ul style="list-style-type: none"> • PASI100 response. Time frame 24 weeks: <ul style="list-style-type: none"> • PASI90 response. • IGA response. • PASI100 response. Time frame 56 weeks: <ul style="list-style-type: none"> • PASI90 response. • IGA response. Time frame 72 weeks: <ul style="list-style-type: none"> • Incidence of Treatment Emergent Adverse Events (TEAEs) adjusted by duration of subject exposure to study treatment. • Incidence of Serious Adverse Events (SAEs) adjusted by duration of subject exposure to study treatment. • Incidence of TEAEs leading to withdrawal adjusted by duration of subject exposure to study treatment.
Key Results	-
Adverse effects (AEs)	-
Expected reporting date	Estimated study completion date in March 2020.

Trial	BE VIVID, NCT03370133 , PS0009, EudraCT 2016-003425-42 ; aged ≥18 years old; bimekizumab vs placebo and ustekinumab (active comparator); phase III
Sponsor	UCB Biopharma SPRL
Status	Ongoing
Source of Information	Trial registry ^{2,22} Company
Location	EU countries (incl the UK), USA, Canada and other countries
Design	Randomised, placebo and active comparator-controlled, double-blind study
Participants	N=568 aged ≥ 18 years older; PSO for at least 6 months prior to the screening visit; PASI ≥12 and BSA affected by PSO ≥10% and IGA score ≥3 on a 5-point scale.
Schedule	Participants were randomised to one of the treatment arms:

	<ul style="list-style-type: none"> • Arm 1: Subjects received bimekizumab for 52 weeks. • Arm 2: Subjects received ustekinumab (dose 1 or dose 2 depending on subjects weight) for 52 weeks. Placebo was administered at pre-specified time points to maintain the blinding. • Arm 3: Subjects received placebo up to week 16 and bimekizumab starting at week 16 through week 52.
Follow-up	up to 68 weeks
Primary Outcomes	Time frame 16 weeks: <ul style="list-style-type: none"> • PASI90 response. • IGA response (0/1) (clear or almost clear with at least a 2-category improvement from baseline).
Secondary Outcomes	Time frame 4 weeks: <ul style="list-style-type: none"> • PASI75 response at week 4. Time frame 12 weeks: <ul style="list-style-type: none"> • PASI90 response. • IGA response. Time frame 16 weeks: <ul style="list-style-type: none"> • PASI100 response. • Patient symptom diary response for itch. • Patient symptom diary response for pain. • Patient symptom diary response for scaling. • Scalp IGA response (clear or almost clear with at least a 2-category improvement from baseline) at week 16 for subjects with scalp PSO at baseline. Time frame 52 weeks: <ul style="list-style-type: none"> • PASI90 response. • IGA response. Time frame 68 weeks: <ul style="list-style-type: none"> • Incidence of TEAEs adjusted by duration of subject exposure to study treatment. • Incidence of SAEs adjusted by duration of subject exposure to study treatment. • Incidence of TEAEs leading to withdrawal adjusted by duration of subject exposure to study treatment.
Key Results	-
Adverse effects (AEs)	-
Expected reporting date	Estimated study completion date in January 2020.

Trial	BE READY, NCT03410992 , PS00013, EudraCT 2016-003426-16 ; aged ≥18 years old; bimekizumab vs placebo; phase III
Sponsor	UCB Biopharma SPRL
Status	Ongoing
Source of Information	Trial registry ^{3,23} Company
Location	EU countries (incl the UK), USA, Canada and other countries

Design	Randomised, placebo controlled, double-blind study
Participants	N=435 aged \geq 18 years older; chronic PSO for at least 6 months prior to the screening visit; PASI \geq 12 and BSA affected by PSO \geq 10% and IGA score \geq 3 on a 5-point scale.
Schedule	Participants were randomised to one of the treatment arms: <ul style="list-style-type: none"> • Arm 1: Subjects received bimekizumab for 16 weeks. Subjects who achieve certain predefined response criteria were re-randomised to either receive bimekizumab or placebo until week 56. Subjects who do not achieve predefined response criteria entered the bimekizumab escape arm. • Arm 2: Subjects received placebo for 16 weeks. Subjects who achieve certain predefined response criteria were proceeded with placebo until week 56. Subjects who do not achieve certain predefined response criteria entered the bimekizumab escape arm.
Follow-up	up to 68 weeks
Primary Outcomes	Time frame 16 weeks: <ul style="list-style-type: none"> • PASI90 response. • IGA response (0/1)(clear or almost clear with at least a 2-category improvement from baseline).
Secondary Outcomes	Time frame 4 weeks: <ul style="list-style-type: none"> • PASI75 response at Week 4. Time frame 16 weeks: <ul style="list-style-type: none"> • PASI100 response. • Patient symptom diary response for itch. • Patient symptom diary response for pain. • Patient symptom diary response for scaling. • Scalp IGA response (clear or almost clear) at week 16 for subjects with scalp PSO at baseline. Time frame 56 weeks: <ul style="list-style-type: none"> • PASI90 response. Time frame 68 weeks: <ul style="list-style-type: none"> • Incidence of TEAEs adjusted by duration of subject exposure to study treatment. • Incidence of SAEs adjusted by duration of subject exposure to study treatment. • Incidence of TEAEs leading to withdrawal adjusted by duration of subject exposure to study treatment.
Key Results	-
Adverse effects (AEs)	-
Expected reporting date	Estimated study completion date in January 2020.

Trial	BE RADIANT, NCT03536884 , PS00015, EudraCT 2017-003784-35 ; aged \geq 18 years old; bimekizumab vs secukinumab; phase III
Sponsor	UCB Biopharma SPRL
Status	Ongoing

Source of Information	Trial registry ^{4,24}
Location	EU countries (incl the UK), USA, Canada and other countries
Design	Randomised, active comparator-controlled, double-blind study
Participants	N=700; aged ≥ 18 years older; chronic PSO for at least 6 months prior to the screening visit; PASI ≥12 and BSA affected by PSO ≥10% and IGA score ≥3 on a 5-point scale.
Schedule	<p>Participants were randomised to one of the treatment arms:</p> <ul style="list-style-type: none"> • Arm 1: Subjects randomised to this arm received bimekizumab dosage regimen 1. At week 16 subjects were re-randomised and continue to receive bimekizumab regimen 1. Placebo was administered at pre-specified time-points to maintain the blinding over the treatment period. • Arm 2: Subjects randomized to this arm received bimekizumab dosage regimen 2 starting at week 16 after initial treatment on bimekizumab regimen 1 for 16 weeks. Placebo was administered at pre-specified time-points to maintain the blinding over the treatment period. • Arm 3 - active comparator: Subjects received secukinumab.
Follow-up	up to 64 weeks
Primary Outcomes	<p>Time frame 16 weeks:</p> <ul style="list-style-type: none"> • PASI100 response.
Secondary Outcomes	<p>Time frame 4 weeks:</p> <ul style="list-style-type: none"> • PASI75 response at Week 4. <p>Time frame 16 weeks:</p> <ul style="list-style-type: none"> • PASI90 response. • IGA response (0/1) with at least a 2-category improvement from baseline <p>Time frame 48 weeks:</p> <ul style="list-style-type: none"> • PASI100 response. <p>Time frame 64 weeks:</p> <ul style="list-style-type: none"> • Incidence of TEAEs adjusted by duration of subject exposure to study treatment. • Incidence of SAEs adjusted by duration of subject exposure to study treatment. • Incidence of TEAEs leading to withdrawal adjusted by duration of subject exposure to study treatment.
Key Results	-
Adverse effects (AEs)	-
Expected reporting date	Estimated study primary outcome completion date in August 2020. Final open label extension completion date, August 2022.

ESTIMATED COST

The cost of bimekizumab is not known yet.

RELEVANT GUIDANCE

NICE GUIDANCE

- NICE technology appraisal guidance in development. Risankizumab for treating moderate to severe plaque psoriasis (ID1398). Expected publication: October 2019.
- NICE technology appraisal guidance. Tildrakizumab for treating moderate to severe plaque psoriasis (TA575). April 2019.
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- NICE technology appraisal guidance. Guselkumab for treating moderate to severe plaque psoriasis (TA521). June 2018.
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- NICE technology appraisal guidance. Ixekizumab for treating moderate to severe plaque psoriasis (TA442). April 2017.
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- NICE technology appraisal guidance. Apremilast for treating moderate to severe plaque psoriasis (TA419). November 2016.
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NHS ENGLAND (POLICY/COMMISSIONING) GUIDANCE

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OTHER GUIDANCE

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ADDITIONAL INFORMATION

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