Health Technology Briefing
January 2024

Secukinumab biosimilar for treating plaque psoriasis

Company/Developer	Bio-Thera Solutions

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 35136	NICE ID: Not available	UKPS ID: Not available

Licensing and Market Availability Plans

Currently in phase III clinical trials

Summary

Secukinumab biosimilar is in clinical development for the treatment of moderate to severe plaque psoriasis in adults. Plaque psoriasis is a long-lasting autoimmune disease that causes skin cells to reproduce very quickly. Plaque psoriasis is characterised by thick, scaly patches called plaques on the skin. These plaques most commonly effect elbows, the back, knees, and scalp. In more severe cases, plaques can appear on the entire body including the face, feet, and genitals. Plaque psoriasis is most common in people that are white, drink alcohol, live stressful lifestyles, experience depression, are obese and who smoke tobacco. Biosimilar medicines are biological therapies which have no clinically meaningful differences in efficacy, quality, and safety compared to the reference biologic product. Biosimilars are competitively priced to compete with the original medicinal product allowing them to be more widely available to the patients who need them.

Secukinumab biosimilar is a monoclonal antibody (protein), that can recognise, attach to and block the function of messenger molecules/ targets in the immune system: interleukin 17A (IL-17A) and interleukin 17A/F (IL-17A/F). These targets are involved in inflammation and other processes that are important in psoriasis. Secukinumab biosimilar can therefore reduce the activity of the immune system and the symptoms of plaque psoriasis. If licenced, secukinumab biosimilar would offer clinicians and patients an additional and potentially cheaper alternative to the reference medicine treatment option for patients with moderate to severe plaque psoriasis.

Proposed Indication

Treatment of adults with moderate to severe plaque psoriasis.[1]

Technology

Description

Secukinumab biosimilar (BAT2306) targets Interleukin 17A (IL-17A) and 17A/F (IL-17A/F).[2,3] These IL are mainly by a subset of T helper cells, neutrophils and mast cells, which promotes the expression of other pro-inflammatory cytokines and effector proteins, leading to the activation of neutrophils and macrophages as well as epithelial cells and fibroblasts. This cascade is suggested to play an important role in the pathophysiology of many autoimmune diseases, including psoriasis. Secukinumab biosimilar mechanism of action offers greater specificity and selectivity in targeting the specific downstream cytokine.[2]

Secukinumab biosimilar is currently in phase III clinical development for patients with moderate to severe plaque psoriasis. In the phase III clinical trial (NCT05377944) secukinumab biosimilar is administered via subcutaneous injection (2 injections of 150 mg/1 ml) at weeks 0, 1, 2, 3, and 4 followed by dosing every 4 weeks, thereafter up to Week 40.[1]

Key Innovation

Currently, there is no biosimilars secukinumab approved globally.[4] Biological medicines are currently the largest cost and cost growth areas in the NHS medicines budget. By making biosimilar medicines more quickly available, the NHS could potentially save up to £300m each year. Additionally, it could enable more patients to have access to other lifesaving and life-enhancing treatments.[5] Therefore if licensed, secukinumab biosimilar will offer an additional, more affordable treatment option for patients with moderate to severe plaque psoriasis.

Regulatory & Development Status

Secukinumab biosimilar does not currently have marketing authorisation in the EU/UK for any indication.

Patient Group

Disease Area and Clinical Need

Psoriasis is a chronic, immune-mediated inflammatory skin disease. Severity ranges from a few scattered red, scaly plaques to almost the entire body surface. It may progressively worsen with age, or improve and decline over time in its severity; the degree of severity depends on inheritance and environmental factors.[6] The terms moderate to severe for psoriasis describe how much of your body is covered in red, scaly psoriasis patches. Moderate psoriasis covers 3% to 10% of your body, while severe psoriasis covers more than 10% of your body or is on sensitive areas like your face, palms, soles, or skin folds.[7,8] Plaque psoriasis is the most common form of psoriasis. Its symptoms are dry skin lesions, known as plaques, covered in scales.[9] Psoriasis can occur at any age, although is uncommon in children (0.71%) and most cases occur before 35 years.[10] The cause of plaque psoriasis is thought to be an immune system problem where infection-fighting cells attack healthy skin cells by mistake. Researchers believe that both genetics and environmental factors play a role. Possible triggers of plaque psoriasis include infections, such as strep throat or skin infections, weather, especially cold, dry conditions, injury to the skin, smoking and exposure to second-hand smoke and heavy alcohol consumption.[11] Psoriasis affects about 1 in every 50 people.[12]

The prevalence of psoriasis is estimated to be around 1.3% to 2.2% in the UK. In England (2022/23) there were 6,590 admissions and 7,492 finished consultant episodes (FCE) for psoriasis (ICD-10 code L40.0), resulting in 9,063 FCE bed days and 5,207 day cases.[13]

Recommended Treatment Options

- The National Institute for Health and Care Excellence (NICE) currently recommends the following treatment options: [14-29]
- Deucravacitinib
- Bimekizumab
- Risankizumab
- Tildrakizumab
- Certolizumab pegol
- Guselkumab
- Brodalumab
- Dimethyl fumarate
- Ixekizumab
- Apremilast
- Secukinumab
- Ustekinumab
- Adalimumab
- Infliximab
- Etanercept

Clinical Trial Information

Trial	NCT05377944; A Multicenter, Randomized, Double-Blind, Parallel-Arm, Phase 3 Study to Compare Efficacy and Safety of BAT2306 With Cosentyx® in Patients with Moderate to Severe Plaque Psoriasis **Phase III** – Active, not recruiting **Location:** China **Primary completion date:** July 2024
Trial Design	Randomised, parallel assignment, double masking
Population	N=502 (actual); adult patients with moderate to severe plaque-type psoriasis
Intervention(s)	Patients will receive subcutaneous treatment of 300 mg secukinumab biosimilar (2 injections of 150 mg/1 ml) via PFS at weeks 0, 1, 2, 3, and 4 followed by dosing every 4 weeks, thereafter up to Week 40.
Comparator(s)	Patients will receive subcutaneous treatment of 300 mg EU-approved Cosentyx (2 injections of 150 mg/1 ml) at weeks 0, 1, 2, 3, and 4 followed by dosing every 4 weeks, thereafter up to Week 40.
Outcome(s)	The primary outcome is the psoriasis area and severity index (PASI), specifically: • Percent change from baseline in Psoriasis Area and Severity Index (PASI) score to Week 8

	• Percent change from baseline in PASI score to Week 12 See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-

Estimated Cost

The cost of secukinumab biosimilar is not yet known.

Relevant Guidance

NICE Guidance

- NICE technology appraisal. Deucravacitinib for treating moderate to severe plaque psoriasis (TA907). June 2023.
- NICE technology appraisal. Bimekizumab for treating moderate to severe plaque psoriasis (TA723). September 2021.
- NICE technology appraisal. Risankizumab for treating moderate to severe plaque psoriasis (TA596). August 2019.
- NICE technology appraisal. Tildrakizumab for treating moderate to severe plaque psoriasis (TA575). April 2019.
- NICE technology appraisal. Certolizumab pegol for treating moderate to severe plaque psoriasis (TA574). April 2019.
- NICE technology appraisal. Guselkumab for treating moderate to severe plaque psoriasis (TA521). June 2018.
- NICE technology appraisal. Brodalumab for treating moderate to severe plaque psoriasis (TA511). March 2018.
- NICE technology appraisal. Dimethyl fumarate for treating moderate to severe plaque psoriasis (TA475). September 2017.
- NICE technology appraisal. Ixekizumab for treating moderate to severe plaque psoriasis (TA442). April 2017.
- NICE technology appraisal. Apremilast for treating moderate to severe plaque psoriasis (TA419). November 2016.
- NICE technology appraisal. Secukinumab for treating moderate to severe plaque psoriasis (TA350). July 2015.
- NICE technology appraisal. Ustekinumab for the treatment of adults with moderate to severe psoriasis (TA180) September 2009.
- NICE technology appraisal. Adalimumab for the treatment of adults with psoriasis (TA146) June 2008.
- NICE technology appraisal. Infliximab for the treatment of adults with psoriasis (TA134) January 2008.
- NICE technology appraisal. Etanercept and efalizumab for the treatment of adults with psoriasis (TA103) July 2006.
- NICE clinical guideline. Psoriasis: assessment and management (CG153) October 2012.
- NICE quality standard. Psoriasis (QS40) August 2013.

NHS England (Policy/Commissioning) Guidance

- NHS England. 2013/14 NHS Standard Contact for Specialised Dermatology Services (All ages). A12/S/a.

Other Guidance

- British Association of Dermatologists. Guidelines for biologic therapy for psoriasis. April 2017.[30]
- American Academy of Dermatology Association. Psoriasis Clinical Guideline. April 2019.[31]
- Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. 2020.[32]

Additional Information

Bio-Thera Solutions did not enter information about this technology onto the UK PharmaScan database; the primary source of information for UK horizon scanning organisations on new medicines in development. As a result, the NIHR Innovation Observatory has had to obtain data from other sources. UK PharmaScan is an essential tool to support effective NHS forward planning; allowing more effective decision making and faster uptake of innovative new medicines for patients who could benefit. We urge pharmaceutical companies to use UK PharmaScan so that we can be assured of up-to-date, accurate and comprehensive information on new medicines.

References

1 ClinicalTrials.gov. *A Multicenter, Randomized, Double-Blind, Parallel-Arm, Phase 3 Study to Compare Efficacy and Safety of BAT2306 With Cosentyx® in Patients With Moderate to Severe Plaque Psoriasis*. *Trial ID: NCT05377944*. Available from: https://clinicaltrials.gov/study/NCT05377944?term=NCT05377944&rank=1 [Accessed 21st November 2023].

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