

Health Technology Briefing

July 2022

Ustekinumab biosimilar for treating moderate to severe plaque psoriasis

Company/Developer

Celltrion Healthcare

New Active Substance

Significant Licence Extension (SLE)

NIHRI ID: 30947

NICE ID: 11773

UKPS ID: Not Available

Licensing and Market Availability Plans

Currently in phase III clinical trials.

Summary

Ustekinumab biosimilar is in clinical development for adults with moderate to severe plaque psoriasis. Plaque psoriasis, which is the most common type of psoriasis, is a long-lasting 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 part of the body's own immune system becomes overactive and attacks normal tissues in the body, in this case, the skin. Treatment for moderate to severe psoriasis usually involves the administration of biologic systemic (oral or injected) therapies which alter the immune system in a way that disrupts the disease cycle and improves symptoms and signs of disease, however these types of drugs are expensive.

Ustekinumab biosimilar is a biologic product developed and proven to be biologically identical to the previously approved biologic (ustekinumab). Ustekinumab is a monoclonal antibody, a type of protein, that acts by binding to and neutralising molecules in the immune system related to the inflammatory response and production of plaques. It is administered under the skin (subcutaneous injection). If licensed, ustekinumab biosimilar would offer an additional and affordable treatment option for adult patients with moderate to severe plaque psoriasis.

Proposed Indication

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.

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Adults (aged 18 to 80 years) with moderate to severe plaque psoriasis.¹

Technology

Description

Ustekinumab biosimilar (CT-P43) contains the active ingredient ustekinumab, which is a human IgG1k monoclonal antibody.¹ Ustekinumab binds to and neutralises the p40 subunit common to interleukin-12 (IL-12) and interleukin-23 (IL-23) and prevents their interaction with the IL-12 receptor β 1 subunit of the IL-12 and IL-23 receptor complexes. Gene expression levels of IL-12 and IL-23 are elevated in psoriasis skin lesions. IL-12 exacerbates psoriasis, whereas its inhibition reduces the disease severity.²

Ustekinumab biosimilar is in clinical development for adults with moderate to severe plaque psoriasis. In the phase III clinical trial (NCT04673786), ustekinumab biosimilar is administered by subcutaneous injection in a 45mg or 90mg dose from day 1 (week 0) until week 40.¹

Key Innovation

Ustekinumab biosimilar is a high quality and affordable biologic product developed and proven to be biologically identical to the previously approved biologic (ustekinumab).³ Clinical observations of ustekinumab in psoriasis have supported its first-in-class status and confirmed the fundamental role of IL-12 or IL-23 in psoriasis pathogenesis. Ustekinumab exhibits a long biologic half-life and low immune response rate, which translates into 12-week dosing intervals for treatment of moderate-to-severe psoriasis. The positive clinical results of ustekinumab observed in psoriasis and other immune-mediated disorders, indicate that IL-12 and IL-23 (cytokines that modulate lymphocyte function, including T-helper (Th) 1 and Th17 cell subsets) play a critical role in the underlying pathologic processes of these immune disorders.²

If licensed, ustekinumab biosimilar would offer an additional treatment option for adult patients with moderate to severe psoriasis.

Regulatory & Development Status

Ustekinumab biosimilar does not currently have Marketing Authorisation in the EU/UK for any indication.

Patient Group

Disease Area and Clinical Need

Psoriasis follows a relapsing-remitting course, characterised by dry red skin lesions (called plaques) covered in silver scales, which commonly appear on the elbows, knees, scalp and lower back.^{4,5} The plaques can be itchy and sore, and in severe cases, the skin around the joints may crack and bleed.⁵ Psoriasis speeds up the life cycle of skin cells, due to an overactive immune system. Normal skin cells will grow and shed in a month, whereas the skin cells of a person with psoriasis do this in three to four days. This can lead to a build-up of skin cells on the surface causing plaques which itch, burn and sting.⁶ Plaque psoriasis is the most common type of psoriasis, which is a skin condition that causes flaky patches of skin that form scales.⁷ It is not known what exactly triggers the inflammatory process, although certain genes and environmental triggers may play a role.⁸ Psoriasis is associated with several comorbidities, including cardiovascular disease, lymphoma, and depression, with up to 40% of patients developing conditions such as psoriatic arthritis.^{9,10} For many people with plaque psoriasis, there can be functional, psychological and social

impacts resulting from reduced employment and income. Factors that contribute to this include symptoms related to the skin, problems related to treatments, psoriatic arthritis and the stigma attached to having a visible skin disease.⁴

Psoriasis affects around 2% of people in the UK, approximately 20% of those affected with psoriasis have moderate to severe psoriasis.^{7,11} Around 90% of people with psoriasis have plaque psoriasis.¹² Based on the mid-year (2020) population estimates for the UK, the estimated number of patients diagnosed with moderate to severe psoriasis would be 268,324 patients.¹³ In England in 2020-21, there were 924 finished consultant episodes (FCE) for psoriasis vulgaris (ICD-10 code L40.0), which resulted in 847 FCE bed days and 741 day cases.¹⁴

Recommended Treatment Options

NICE recommends the following treatment options for moderate to severe psoriasis:¹⁵

- Brodalumab
- Ustekinumab
- Tildrakizumab
- Dimethyl fumarate
- Certolizumab pegol
- Bimekizumab
- Risankizumab
- Guselkumab
- Secukinumab
- Apremilast
- Ixekizumab

Clinical Trial Information

Trial	NCT04673786 ; EudraCT 2020-001045-39 ; A Randomized, Active-Controlled, Double-Blind, Phase 3 Study to Compare the Efficacy and Safety of CT-P43 to Stelara in Patients With Moderate to Severe Plaque Psoriasis Phase III - Completed Location(s): Estonia Study completion date: May 2022
Trial Design	Quadruple-blind, randomised, parallel assignment, active-controlled
Population	N=509 (actual); Subjects aged 18 to 80 years with a diagnosis of plaque-type psoriasis for at least 24 weeks
Intervention(s)	Patients initially randomised to the ustekinumab biosimilar group on day 1 (week 0) continued their treatment with ustekinumab biosimilar (45mg or 90mg by subcutaneous injection) until week 40
Comparator(s)	Patients initially randomised to stelara group (ustekinumab) on day 1 (week 0) were randomised again in a ratio of 1:1 to either continue stelara (45mg or 90mg by subcutaneous injection) or undergo transition to ustekinumab biosimilar prior to dosing at week 16. Thereafter, patients continued their treatment until week 40
Outcome(s)	Demonstrate efficacy equivalence [Time Frame: from baseline to Week 12]

Results (efficacy)	-
Results (safety)	-

Estimated Cost

The cost of ustekinumab biosimilar is not yet known.

Relevant Guidance

NICE Guidance

- NICE technology appraisal guidance in development. Deucravacitinib for treating moderate to severe plaque psoriasis (ID3859). Expected date of issue to be confirmed.
- NICE technology appraisal guidance. Bimekizumab for treating moderate to severe plaque psoriasis (TA723). September 2021.
- NICE technology appraisal guidance. Risankizumab for treating moderate to severe plaque psoriasis (TA596). August 2019.
- NICE technology appraisal guidance. Certolizumab pegol for treating moderate to severe plaque psoriasis (TA574). April 2019.
- NICE technology appraisal guidance. Tildrakizumab for treating moderate to severe plaque psoriasis (TA575). April 2019.
- NICE technology appraisal guidance. Guselkumab for treating moderate to severe plaque psoriasis (TA521). June 2018.
- NICE technology appraisal guidance. Brodalumab for treating moderate to severe plaque psoriasis (TA511). March 2018.
- NICE technology appraisal guidance. Dimethyl fumarate for treating moderate to severe plaque psoriasis (TA475). September 2017.
- NICE technology appraisal guidance. Ixekizumab for treating moderate to severe plaque psoriasis (TA442). April 2017.
- NICE technology appraisal guidance. Apremilast for treating moderate to severe plaque psoriasis (TA419). November 2016.
- NICE technology appraisal guidance. Secukinumab for treating moderate to severe plaque psoriasis (TA350). July 2015.
- NICE technology appraisal guidance. Ustekinumab for the treatment of adults with moderate to severe psoriasis (TA180). September 2009.
- NICE technology appraisal guidance. Adalimumab for the treatment of adults with psoriasis (TA146). June 2008.
- 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 Contract for Specialised Dermatology Services (All ages). A12/S/a.

Other Guidance

- British Association of Dermatologists. British Association of Dermatologists guidelines for biologic therapy for psoriasis. 2020.¹⁶
- Menter A et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. 2019.¹⁷

Additional Information

Celltrion Healthcare 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

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