NIHR | Innovation Observatory

Newcastle University

Health Technology Briefing
March 2025

Risankizumab for moderate to severe plaque psoriasis in children aged 6-17 years

Company/Developer	AbbVie

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 30104	NICE ID: Not available	UKPS ID: Not available

Licensing and Market Availability Plans

Currently in phase III clinical trial

Summary

Risankizumab is in clinical development for the treatment of moderate to severe plaque psoriasis in children aged 6 to 17 years. Psoriasis is a skin condition that causes flaky patches of skin which form scales. Plaque psoriasis is the most common type of psoriasis. It is an autoimmune disease, meaning that the immune cells which usually fight infection attack the body's own tissues instead. The scalp is the most frequent site of onset of psoriasis in children, but the face, groin, armpit and behind the knees can also be affected. The plaques can be itchy or sore, or both. In severe cases, the skin around the joints may crack and bleed. Moderate psoriasis covers between 3%-10% of the body, while severe psoriasis covers more than 10% of the body. The cause of psoriasis is unknown, however certain factors can trigger the symptoms, such as injury, stress, or certain medications. Plaque psoriasis can have a significant negative effect on patients' quality of life, and treatments can result in serious toxicities.

Risankizumab is a drug which is injected beneath the skin (subcutaneous). It is a monoclonal antibody (a type of protein) that is designed to attach to interleukin-23 (IL-23) (another protein of the immune system) and block its activity. IL-23 is involved in causing inflammation that is linked to plaque psoriasis. By blocking the action of IL-23, risankizumab reduces inflammation and other symptoms associated with plaque psoriasis. If licensed, risankizumab will offer an additional treatment option for children with moderate to severe plaque psoriasis.

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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Proposed Indication

Treatment of moderate to severe plaque psoriasis in children aged 6 to 17 years.[1]

Technology

Description

Risankizumab is a humanised immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds with high affinity to the p19 subunit of human interleukin 23 (IL-23) cytokine without binding to IL-12 and inhibits its interaction with the IL-23 receptor complex. IL-23 is a cytokine that is involved in inflammatory and immune responses. By blocking IL-23 from binding to its receptor, risankizumab inhibits IL-23-dependent cell signalling and release of proinflammatory cytokines.[2] IL-23 is thought to be linked to a number of chronic immune-mediated diseases, including psoriasis.[3]

Risankizumab is in phase III clinical development for the treatment of plaque psoriasis in children aged 6 to less than 18 years (NCT04435600, NCT04862286). Risankizumab is administered based on body weight, as a subcutaneous (SC) injection every 12 weeks.[1,4]

Key Innovation

IL-23 inhibitors have emerged as effective options with a well characterised safety profile for the treatment of moderate to severe plaque psoriasis. Selective IL-23 inhibitors require less frequent dosing than IL-17 inhibitors and may possess a more favourable risk profile without an increased risk of candidiasis or inflammatory bowel disease. In addition, IL-23 inhibitors have also been shown to lead to a long duration of remission after withdrawal of the drug.[5] Risankizumab has shown superior efficacy, improved health-related quality of life, as well as being generally well tolerated both in the short and longer term, when compared in head to head trials to currently approved medicines for the treatment of moderate to severe plaque psoriasis.[6]

If licensed, risankizumab will offer an additional treatment option for children with moderate to severe plaque psoriasis.

Regulatory & Development Status

Risankizumab is currently marketed in the EU/UK for the following indications:[2,7]

- Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
- Treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (alone or in combination with methotrexate)
- Treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable.
- Risankizumab is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy.

Patient Group

Disease Area and Clinical Need

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Psoriasis is an inflammatory skin disease that typically follows a relapsing and remitting course. Plaque psoriasis is the most common form of psoriasis. It is characterised by well-delineated red, scaly plaques that vary in extent from a few patches to generalised involvement.[8] They normally appear on the elbows, knees, scalp and lower back, but can appear anywhere on the body. The plaques can be itchy, sore, or both. In severe cases, the skin around the joints may crack and bleed.[9] The scalp is the most frequent site of onset of psoriasis in children, but the face and the flexures may also be affected.[10] Moderate psoriasis covers between 3%-10% of the body, while severe psoriasis covers more than 10% of the body.[11] The cause of psoriasis is unknown. Genetic and environmental factors play a role in the development of psoriasis, and when certain factors trigger the immune system, it becomes more active. This leads to a chronic inflammation that causes the skin cells to reproduce too quickly. Triggers can include infections, certain medications, ultraviolet light, low-grade inflammation, smoking, stress and excessive alcohol consumption.[12]

Plaque psoriasis accounts for about 90% of all psoriasis cases. The prevalence of psoriasis is estimated to be about 1.3-2.2% in the UK, with the highest prevalence being in white people.[8,13] The estimated prevalence of psoriasis in children is between 0-1.37%.[14,15] In England, in 2023-24, there were 916 finished consultant episodes (FCE) and 813 admissions for plaque psoriasis (ICD-10 code L40.0) which resulted in 1,487 FCE bed days and 598 day cases.[16]

Recommended Treatment Options

The National Institute for Health and Care Excellence (NICE) recommends the following treatment options for severe plaque psoriasis, as defined by a total psoriasis area and severity index of 10 or more, in children and young people:

- Secukinumab (6 to 17 years)[17]
- Adalimumab (4 years and older)[18]
- Etanercept (6 years and older)[18]
- Ustekinumab (12 years and older).[18]

Clinical Trial Information

Trial	**OptIMMize-1;M19-977;NCT04435600, 2023-504156-10-00**; A randomised, active-controlled, efficacy assessor-blinded study to evaluate pharmacokinetics, safety and efficacy of risankizumab in patients from 6 to less than 18 years of age with moderate to severe plaque psoriasis **Phase III-** Completed **Locations:** Three EU countries, UK, USA, Canada, and Japan **Study completion date:** October 2024	**OptIMMize-2; M19-973; NCT04862286, 2022-500408-22-00;** OptIMMize-2: A phase 3 multicenter, single-arm, open-label extension study to assess the safety, tolerability, and efficacy of risankizumab in subjects with moderate to severe plaque psoriasis who have completed participation in study M19-977 (OptIMMize-1) **Phase III-** Enrolling by invitation **Locations:** Three EU countries, UK, USA, Canada, and Japan **Primary completion date:** February 2029
Trial Design	Randomised, sequential assignment, single masking	Single group assignment, open label
Population	N= 150 (actual); Participants with moderate to severe plaque psoriasis for	N= 132 (estimated); Participants who have completed participation in study M19-977

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	at least 6 months before the baseline visit, aged 6 to less than 18 years	and who meet all eligibility criteria for participation in Study M19-973
Intervention(s)	• Risankizumab SC injection • Ustekinumab SC injection	Risankizumab SC injection every 12 weeks
Comparator(s)	No comparator	No comparator
Outcome(s)	Primary outcome measures: • Percentage of participants achieving Psoriasis Area Severity Index (PASI) 75 (defined as at least 75% improvement in PASI) [Time frame: Baseline (Week 0) to Week 16 of each part of the study (Parts 1-4)] • Percentage of participants achieving static Physician's Global Assessment (sPGA) clear or almost clear [Time frame: At Week 16 of each part of the study (Parts 1-4)] • US Only: Percentage of participants achieving static Physician's Global Assessment (sPGA) clear or almost clear and with at least 2 grade improvement from baseline [At Week 16 of each part of the study (Parts 1-4)] See trial record for full list of other outcomes	Primary outcome measure: Number of participants with adverse events [Time frame: Up to approximately 224 weeks]
Results (efficacy)	-	-
Results (safety)	-	-

Estimated Cost

A 150mg/ml solution for injection pre-filled syringe costs £3,326.09.[19]

Relevant Guidance

NICE Guidance

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- NICE technology appraisal. Secukinumab for treating moderate to severe plaque psoriasis in children and young people (TA734). Published October 2021.
- NICE technology appraisal. Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people (TA455). Published July 2017.
- NICE Clinical guideline. Psoriasis: assessment and management (CG153). September 2017.
- 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

- National Health Service (NHS), Lancashire & South Cumbria Medicines Management Group. Guidelines for the Management of Psoriasis in Primary Care. May 2024.[20]
- European Guidelines Dermatology (EuroGuiDerm). EuroGuiDerm guideline on the systemic treatment of Psoriasis vulgaris Part 2: specific clinical and comorbid situations. February 2021.[21]
- EuroGuiDerm. EuroGuiDerm guideline on the systemic treatment of Psoriasis vulgaris Part 1: treatment and monitoring recommendations. December 2020.[22]

Additional Information

AbbVie 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.

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