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HEALTH TECHNOLOGY BRIEFING
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Secukinumab for moderate to severe plaque psoriasis in children aged 6 to less than 18 years old

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Developer/Company	Novartis General Medicines	**UKPS ID**	644578

Licensing and market availability plans	Currently in phase III clinical trials

SUMMARY

Secukinumab as subcutaneous injection is in clinical development for the treatment of chronic plaque psoriasis in children and adolescents. Plaque psoriasis, is the most common type of psoriasis and is an inflammatory skin disease that typically follows a relapsing and remitting course. Plaque psoriasis 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.

Secukinumab is a monoclonal antibody, a type of protein, designed to recognise and attach to a messenger molecule in the immune system called interleukin 17A. This molecule is involved in the inflammation and other immune system processes that cause psoriasis. By attaching to and blocking the action of interleukin 17A, secukinumab reduces the activity of the immune system and the symptoms of the disease. If licensed, secukinumab will offer a first-line systemic treatment option in children and adolescents with moderate to severe plaque psoriasis in patients who are candidates for systemic therapy.

PROPOSED INDICATION

Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescents aged 6 years to less than 18 years who are candidates for systemic therapy – first-line.[a]

TECHNOLOGY

DESCRIPTION

Secukinumab (Cosentyx) is a fully human IgG1/κ monoclonal antibody that selectively binds to and neutralises the proinflammatory cytokine interleukin-17A (IL-17A). Secukinumab works by targeting IL-17A and inhibiting its interaction with the IL-17 receptor, which is expressed on various cell types including keratinocytes. As a result, secukinumab inhibits the release of proinflammatory cytokines, chemokines and mediators of tissue damage and reduces IL-17A-mediated contributions to autoimmune and inflammatory diseases. Clinically relevant levels of secukinumab reach the skin and reduce local inflammatory markers. As a direct consequence, treatment with secukinumab reduces erythema, induration and desquamation present in plaque psoriasis lesions. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. IL-17A plays a key role in the pathogenesis of plaque psoriasis, psoriatic arthritis and ankylosing spondylitis and is up-regulated in lesional skin in contrast to non-lesional skin of plaque psoriasis patients and in synovial tissue of psoriatic arthritis patients. The frequency of IL-17-producing cells was also significantly higher in the subchondral bone marrow of facet joints from patients with ankylosing spondylitis.[1]

Secukinumab is currently in development for the treatment of moderate to severe plaque psoriasis in children and adolescents aged 6 years to less than 18 years. In the phase III trial (NCT02471144), secukinumab low dose (75 mg if weighing less than 50 kg or 150 mg if weighing 50 kg or more) or secukinumab high dose (75 mg if weighing less than 25 kg; 150 mg if weighing between 25 and less than 50 kg; or 300 mg if weighing more than 50 kg) will be administered subcutaneously at randomisation, weeks 1, 2, 3, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, and 48 during the blinded phase of the study, thereafter at week 52 and every 4 weeks during the extension treatment period until week 232.[2]

INNOVATION AND/OR ADVANTAGES

Effective options for first-line treatment of severe paediatric psoriasis are limited and there is limited evidence of effectiveness in the paediatric population.[3] If approved for this indication, secukinumab will provide an additional treatment option that involves a different mechanism of action to the other NICE-recommended biological treatments. Secukinumab could potentially be used as an add-on therapy or as a substitute therapy to existing treatment options.[a] In adults, up to the end of December 2018, secukinumab had been studied in over 30 psoriasis studies involving over 11,000 patients as well as widely in non-interventional studies, including registries, with positive results. The efficacy of secukinumab in children aged 6 to 18 is currently being studied at phase III.[b]

DEVELOPMENT STATUS AND/OR REGULATORY DESIGNATIONS

Secukinumab is currently available in the UK as a ready-to-use solution in a pre-filled syringe or pen injector for the following therapeutics indications:[1]

- moderate to severe plaque psoriasis in adults who are candidates for systemic therapy

[a] Information provided by Novartis General Medicines on UK Pharma Scan
[b] Information provided by Novartis General Medicines

- active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate (alone or in combination with methotrexate)
- active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.

In 2018, the European Medicines Agency (EMA) accepted a modification of an agreed paediatric investigation plan for secukinumab (P/0372/2018).[4]

The most common side effects with secukinumab (which may affect more than 1 in 10 people) are upper respiratory tract infections (colds) with inflammation of the nose and throat (nasopharyngitis) and blocked or runny nose (rhinitis). Most of the side effects are mild to moderate in severity. Because secukinumab may increase the risk of infection, it must not be given to patients with serious active infections such as tuberculosis.[5]

Secukinumab is currently in phase III development for the following indications:[6,7]

- Hidradenitis suppurativa
- Non-radiographic axial spondyloarthritis
- Juvenile PSA / enthesitis-related arthritis

Secukinumab is currently in phase II development for the following indications:[8-10]

- Giant cell arteritis
- Atopic dermatitis
- Tendinopathy

PATIENT GROUP

DISEASE BACKGROUND

Psoriasis is an inflammatory skin disease that typically follows a relapsing and remitting course. Plaque psoriasis is the most common type of psoriasis, making up approximately 90% of cases. The disease 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]

Plaque psoriasis is thought to occur when skin cells are replaced more quickly than usual, resulting in the build-up of immature skin cells on the surface of the skin (causing the development of plaques). The cause of this overproduction of skin cells is thought to have an autoimmune origin when T-cells attack healthy skin cells instead of pathogens, causing the deep skin layers to produce new skin cells more quickly than usual. This in turn further triggers the immune system to produce more T-cells and so perpetuates a cycle of inflammation.[12]

The first triggers to the inflammatory process is currently unknown 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 inflections and other immune disorders.[13]

Psoriasis for many people results in profound functional, psychological, and social morbidity, with consequent reduced levels of employment and income. Factors that contribute to this include symptoms related to the skin (for example, chronic itch, bleeding, scaling and nail involvement), problems related to treatments, psoriatic arthritis, and the effect of living with a highly visible,

stigmatising skin disease. Even people with minimal involvement state that psoriasis has a major effect on their life. Several studies have also reported that people with psoriasis, particularly those with severe disease, may be at increased risk of cardiovascular disease, lymphoma and non-melanoma skin cancer.[11]

CLINICAL NEED AND BURDEN OF DISEASE

There are no validated diagnostic criteria for psoriasis, so it is difficult to obtain an accurate figure for its prevalence. In the UK, the prevalence is greatest in white people. Men and women are equally affected. It can occur at any age, but the majority of cases occur before the age of 35 years.[11,14] Data from a longitudinal cohort study based on the UK Clinical Practice Research Datalink (CPRD) between 1999 and 2013 reports an increased rate of psoriasis prevalence from 2.3% (2,297 cases per 100,000) in 1999 to 2.8% (2,815 per 100,000) in 2013.[15] This same study reported that the overall, adjusted psoriasis incidence declined from 159 cases per 100,000 person years (95% CI 155–164) in 1999 to 129 per 100,000 person years (95% CI 126–133) in 2013. The risk of all-cause mortality for patients with psoriasis remains elevated compared with people without psoriasis (hazard ratio 1.21; 95% confidence interval 1.13–1.3).[15]

Psoriasis begins in childhood in almost one-third of the cases.[16] Children suffering from psoriasis also have a higher prevalence of comorbidities, including obesity, diabetes mellitus, hypertension, rheumatoid arthritis, Crohn's disease and psychiatric disorders, compared with children without psoriasis.[13,17,18] Although paediatric psoriasis is not uncommon, limited epidemiology data are available to date. It is estimated that approximately 30–50 % of adults with psoriasis developed psoriasis before 20 years of age.[16] One UK study reported prevalence of childhood psoriasis in the UK to be about 0.55 % in children aged 0–9 years and 1.37 % in children aged 10–19 years. [16]No study was identified which reported incidence of psoriasis in children in the UK. A population-based US study of under 18 year olds diagnosed with psoriasis between 1970 and 1999, reported an overall age- and sex-adjusted annual incidence of paediatric psoriasis of 40.8 per 100,000.[19]

Based on UK studies, the company has estimated a psoriasis prevalence of 0.4% in the UK population aged under 19 years old. A study suggests that referral patterns to secondary care for psoriasis equal to approximately 18% of adult psoriasis patients. The company has assumed the same rate for children. Only 19% of paediatric secondary care patients are eligible for systemic therapy.[20-23]

The Hospital Episode Statistics for England 2017/18 recorded a total of 10,304 finished consultant episodes and 9,625 admissions for primary diagnosis Psoriasis (ICD-10 code L40) of which 329 cases were recorded in patients aged 5 to 17 years old, in the same period, amongst patients admitted to hospital for all diagnoses, those recorded to have Psoriasis (ICD-10 code L40) aged between 5 and 17 were a total of 1,452.[24]

PATIENT TREATMENT PATHWAY

TREATMENT PATHWAY

For most people in the UK, psoriasis is managed in primary care, with specialist referral being needed at some point for up to 60% of people. Supra-specialist (level 4) tertiary care is required in the very small minority with especially complex, treatment resistant and/or rare manifestations of psoriasis.[11,25]

CURRENT TREATMENT OPTIONS

Current first-line treatment options for people with mild to moderate psoriasis include topical therapies (such as corticosteroids, vitamin D3 analogues, dithranol and tar preparations).[11,14]
In paediatric severe psoriasis and under certain conditions including when first-line therapies have failed or cannot be used, the British Association of Dermatologist (BAD) recommend to offer adalimumab (>=4 years), etanercept (>= 6 years) or ustekinumab (>=12 years) to children and young people who fulfil the criteria for biologic therapy.[26]

PLACE OF TECHNOLOGY

If licensed, secukinumab will offer an additional first-line systemic treatment option for children aged 6 to less than 18 years with plaque psoriasis who have experienced inadequate control of symptoms with topical treatment, or failed to respond to or tolerate previous systemic treatment and/or UV therapy.

CLINICAL TRIAL INFORMATION

Trial	**NCT02471144, EudraCT2014-005663-32; children aged 6-17 years; Secukinumab vs Etanercept or placebo; phase III**
Sponsor	Novartis Pharmaceuticals
Status	Ongoing
Source of Information	Trial registry[2],[27]
Location	11 EU (incl UK), USA, Canada and other countries
Design	Randomised, placebo- and active-controlled
Participants	n=162; aged 6-17 years; plaque-type psoriasis history for at least 3 months
Schedule	Randomised to: • Subcutaneous secukinumab low dose injection (75 mg if weighing less than 50 kg; or 150 mg if weighing 50 kg or more) at randomisation, weeks 1, 2, 3, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, and 48 during the blinded phase of the study, thereafter at week 52 and every 4 weeks during the extension treatment period until week 232; • Subcutaneous secukinumab high dose injection (75 mg if weighing less than 25 kg; 150 mg if weighing between 25 and less than 50 kg; or 300 mg if weighing more than 50 kg) at randomisation, weeks 1, 2, 3, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, and 48 during the blinded phase of the study, thereafter at week 52 and every 4 weeks during the extension treatment period until week 232; • Subcutaneous etanercept 0.8 mg/kg (one or two injections per dose) once per week, for 51 weeks administered at home (self-injected or by caregiver) or at the study site; • Secukinumab placebo
Follow-up	The study consists of 5 periods: screening (up to 4 weeks), induction (of 12 weeks), maintenance (of 40 weeks), extension treatment epoch (open-label of 184 weeks) and post- treatment follow-up epoch (of 16 weeks). Overall follow-up for 232 weeks.
Primary Outcomes	Percentage of participants achieving a 75% improvement from baseline in Psoriasis Area and Severity Index (PASI) score at week 12.

Secondary Outcomes	• Percentage of participants achieving a 90% improvement from baseline in PASI score at week 12 • Percentage of participants achieving a 50%, 100% improvement from baseline in PASI score at week 12 • Percentage of participants achieving a 50%, 75%, 90% or 100% improvement from baseline in PASI Score and an Investigator's Global Assessment (IGA) mod 2011 score of 0 or 1 at week 1, 2, 3, 4, 6, 8,12,13,14,15 ,16, 20, 24,28,32,36,40,44,48,and Week 52 • Percent of participants achieving PASI score and IGA mod 2011 0 or 1 score over time at week 12 and 52 • Change from baseline in Children's Dermatology Life Quality Index (cDLQI) score up to week 52 • Percentage of participants achieving a cDLQI score of 0 or 1 at each visit up to week 52 • Composite clinical safety and tolerability as assessed by growth, weight gain, tolerability of s.c. injections, vital signs, clinical laboratory variables, ECGs, and adverse events monitoring • Percentage of participants with clinically important reduction in disability as evaluated by CHAQ questionnaire over time at Week 12 and Week 52
Key Results	Not reported
Adverse effects (AEs)	-
Expected reporting date	Study primary completion date reported as December 2018

Trial	**NCT03668613, EudraCT2017-004515-39; children aged 6-17 years; secukinumab; phase III**
Sponsor	Novartis Pharmaceuticals
Status	Ongoing
Source of Information	Trial registry[28],[29]
Location	EU (not incl UK), USA, Russia and other countries
Design	Randomised, open-label
Participants	n=80; aged 6 to <18 years; moderate to severe plaque psoriasis, defined as a PASI score ≥ 12, and IGA mod 2011 score of ≥ 3, and BSA involvement of ≥10%, at randomization
Schedule	Randomised to: • secukinumab low dose (dose depends on the weight group) • secukinumab high dose (dose depends on the weight group)
Follow-up	Active intervention up to 12 weeks. Overall follow-up up to week 224.
Primary Outcomes	1. Number of participants with PASI 75 response [Time Frame: week 12] 2. Number of participants with IGA mod 2011 0 or 1 response [Time Frame: week 12]
Secondary Outcomes	1. Number of participants with PASI 90 response [Time Frame: week 12] 2. Number of Participants with Adverse Events [Time Frame: up to week 224]

	3. Secukinumab concentration in serum [Time Frame: up to week 224]
Key Results	-
Adverse effects (AEs)	-
Expected reporting date	Study primary completion date reported as September 2019

ESTIMATED COST

Secukinumab is already marketed in the UK for the treatment of adult patients with ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. The NHS indicative price of 2 pre-filled disposable pens of secukinumab 150mg/1ml solution for injection is £1,218.78.[18]

ADDITIONAL INFORMATION

RELEVANT GUIDANCE

NICE GUIDANCE

- NICE technology appraisal guidance. Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people (TA455). July 2017.
- NICE clinical guideline. Psoriasis: assessment and management (CG153). October 2012, last updated September 2017.
- NICE interventional procedures guidance. Grenz rays therapy for inflammatory skin conditions (IPG236). November 2007.
- NICE quality standards. Psoriasis (QS40). August 2013.

NHS ENGLAND (POLICY/COMMISSIONING) GUIDANCE

- NHS England. 2017. Commissioning Medicines for Children in Specialised Services. 170001/P
- NHS England. 2013/14 NHS Standard Contract for Specialised Dermatology Services (All ages). A12/S/a.

OTHER GUIDANCE

- Joint American Academy of Dermatology and National Psoriasis Foundation. Guidelines of care for the management and treatment of psoriasis with biologics. 2019.[30]
- European S3-Guideline on the systemic treatment of psoriasis vulgaris – Update Apremilast and Secukinumab – EDF in cooperation with EADV and IPC. 2017.[31]
- British Association of Dermatologists. Guidelines for biologic therapy for psoriasis. April 2017.[25]
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