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Health Technology Briefing
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Deucravacitinib for treating systemic lupus erythematosus

Company/Developer	Bristol-Myers Squibb Pharmaceuticals Ltd

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 27948	NICE ID: Not available	UKPS ID: 675295

Licensing and Market Availability Plans

Currently in phase III clinical trials.

Summary

Deucravacitinib is being developed as a treatment of systemic lupus erythematosus (SLE). SLE is a long-term autoimmune condition (a condition where a person's immune system attacks its own healthy cells) that causes swelling, soreness and inflammation in the body. It affects the whole body including the skin, joints and internal organs and results in long-term ill health. While mild SLE causes skin problems and tiredness, severe SLE is life-threatening because it damages your heart, lungs and kidneys. There is a need for new effective treatment options, as sometimes current treatments do not work well in some patients.

Deucravacitinib is a type of medicine called an immunosuppressant. That means it reduces a person's immune system attacking its own body. Deucravacitinib targets a protein called tyrosine kinase 2 (TYK2) which plays a role in production of chemicals called cytokines and chemokines that cause inflammation leading to reduced inflammation and potential improvement in the SLE symptoms. If licenced, deucravacitinib will provide a new option for the treatment of SLE.

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 systemic lupus erythematosus (SLE).[1]

Technology

Description

Deucravacitinib (SOTYKTU[2], BMS-986165[3]) is a first-in-class, oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor.[4] Deucravacitinib selectively inhibits the TYK2 enzyme (TYK2 belongs to the JAK family). Deucravacitinib binds to the regulatory domain of TYK2, stabilizing an inhibitory interaction between the regulatory and the catalytic domains of the enzyme. This results in allosteric inhibition of receptor-mediated activation of TYK2 and its downstream functions in cells. TYK2 mediates signalling of interleukin-23 (IL-23), interleukin-12 (IL-12), and type I interferons (IFN), which are naturally occurring cytokines involved in inflammatory and immune responses.[2] These key cytokines are involved in the pathophysiology of several autoimmune diseases, including SLE.[5]

Deucravacitinib is currently in clinical development for the treatment of SLE. In ongoing phase III clinical trials (NCT05617677 (POETYK SLE-1), NCT05620407 (POETYK SLE-2)), participants were administered specified doses of deucravacitinib on specified days.[1,3]

Key Innovation

The unpredictable nature of SLE, the burden of treatment-related side effects, and continued disease activity in a subset of patients despite standard therapies, highlight the need for novel targeted treatments that are well tolerated, safe, and effective.[6-8] As a TYK2 intracellular kinase, deucravacitinib has a robust inhibitory effect on an extensive array of cellular responses to a variety of cytokines such as IFN-I, IL-6, IL-12, IL-17, IL-22, and IL-23, all of which play a critical role in the pathogenesis of SLE.[9] Deucravacitinib is taken orally, which may promote convenience and treatment accessibility.[10] If licensed, deucravacitinib would offer a new option for the treatment of SLE.

Regulatory & Development Status

Deucravacitinib currently has Marketing Authorisation in the UK for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[2]

Deucravacitinib is currently in phase II/III clinical trials for the following indications:[11]

- Plaque Psoriasis
- Juvenile Psoriatic Arthritis
- Sjörgen's Syndrome
- SLE
- Discoid Lupus Erythematosus
- Subacute Cutaneous Lupus Erythematosus

Patient Group

Disease Area and Clinical Need

SLE is a chronic multisystem inflammatory autoimmune disease associated with impaired health-related quality of life.[12] The condition can affect any organ system, sequentially or at the same time.[6] In people

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with SLE, cells that have undergone apoptosis are not cleared away properly. The relationship between this and the cause or features of SLE are unclear but researchers suggest that these dead cells may release substances that cause the immune system to react inappropriately and attack the body's tissues, resulting in the signs and symptoms of SLE. SLE may first appear as extreme tiredness (fatigue), a vague feeling of discomfort or illness (malaise), fever, loss of appetite, and weight loss. Most affected individuals also have joint pain, typically affecting the same joints on both sides of the body, and muscle pain and weakness. Skin problems are common in SLE.[13] Mild SLE causes joint and skin problems and tiredness. Moderate SLE causes inflammation of other parts of the skin and body, including the lungs, heart and kidneys. Severe SLE causes life-threatening involvement to the heart, lungs, brain, bone marrow or kidneys and are more likely to cause irreversible damage accrual in the first years of disease.[14] Having lupus also increases the risk of infection, cancer, bone tissue death and pregnancy complications.[15] Many patients experience disease flares, leading to further symptoms that can lead to hospital admissions. This can affect a person's ability to work, complete everyday activities and socialise, causing added stress and anxiety, which can trigger further disease flares.[16] The causes of SLE are unknown but are believed to be linked to environmental, genetic and hormonal factors.[17] Some of the environmental triggers linked to SLE include: air pollution, ultraviolet light, smoking cigarettes and infections.[18] Normal variations (polymorphisms) in many genes can affect the risk of developing SLE and in most cases multiple genetic factors are thought to be involved. In rare cases, SLE is caused by mutations in single genes. Most of the genes associated with SLE are involved in immune system function and variations in these genes likely affect proper targeting and control of the immune response.[13]

There are approximately 15,000 people in England and Wales with SLE, predominantly women, with a peak incidence at the age of 25-30 years old. The incidence, prevalence and severity of SLE is higher in African-Caribbean, South Asian and Chinese populations compared to European whites. Renal involvement (glomerulonephritis) occurs in up to 40% of cases, has a key role in prognosis, and is associated with a higher mortality rate. It can occur many years after diagnosis, although is usually apparent within 5 years. Approximately 10% of patients with lupus nephritis develop end-stage renal failure requiring dialysis or transplantation.[6] Approximately 20-30% of patients continue to have high disease activity despite standard therapies, or have major organ involvement particularly associated with a worse prognosis (e.g. renal, neuropsychiatric, haematological involvement).[6] In England, in 2024-2025, there were 9,499 finished consultant episodes (FCE) for SLE (ICD10 code M32) which resulted in 6,630 admissions and 8,762 FCE bed days.[19] In 2019, there were 85 deaths from SLE (ICD-10 code M32) in England and Wales.[20]

Recommended Treatment Options

Standard treatment includes non-steroidal anti-inflammatory medicines, hydroxychloroquine and steroids.[16]

The National Institute for Health and Care Excellence (NICE) recommends belimubab as an add-on treatment to standard therapy for treatment of SLE.[16]

Clinical Trial Information

Trial	**POETYK SLE-1; NCT05617677; CTIS 2022-500699-76;** A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Deucravacitinib in Participants With Active Systemic Lupus Erythematosus (SLE) **Phase III**: Active, not recruiting **Locations: 10** EU countries, USA, Canada and other countries

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	Study Completion Date: October 2026
Trial Design	Randomised, parallel assignment, quadruple-blind
Population	N=516 (actual); subjects with Systemic Lupus Erythematosus (SLE) at least 24 weeks before the screening and after at least one SLE background therapy; aged 18-75 years old
Intervention(s)	Oral deucravacitinib[4]
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome: Proportion of participants who achieve Systemic Lupus Erythematosus Responder Index-4 [SRI(4)] response [Time frame: at week 52] See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-
Clinical Trial Information	
Trial	**POETYK SLE-2;** NCT05620407; CTIS 2022-500700-22-00; A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Deucravacitinib in Participants With Active Systemic Lupus Erythematosus (SLE) **Phase III**: Active, not recruiting **Locations:** 7 EU countries, USA and other countries **Primary Completion Date:** October 2026
Trial Design	Randomised, parallel assignment, quadruple-blind
Population	N=513 (actual); subjects with SLE diagnosed at least 24 weeks before the screening; aged 18 to 75 years old
Intervention(s)	Oral deucravacitinib[4]
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome: Proportion of participants who achieve Systemic Lupus Erythematosus Responder Index-4 [SRI(4)] response [Time frame: at week 52] See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-
Clinical Trial Information	
Trial	NCT03920267; EudraCT 2018-003471-35; A Multi-Center Study to Characterize the Long-Term Safety and Efficacy of BMS-986165 in Subjects With Systemic Lupus Erythematosus **Phase II**: Completed **Locations:** 4 EU countries, USA, Canada and other countries

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	Study Completion Date: March 2025
Trial Design	Randomised, parallel assignment, quadruple-blind
Population	N=261 (actual); subjects with SLE who previously completed SLE Study NCT03252587; aged 18 to 75 years old
Intervention(s)	Deucravacitinib in three different doses for each study arm
Comparator(s)	No comparators
Outcome(s)	Primary outcomes: • Number of participants with Adverse Events (AEs) [Time frame: Up to 30 days after last treatment dose (approximately 178 weeks)] • Number of participants with Serious Adverse Events (SAEs) [Time frame: Up to 30 days after last treatment dose (approximately 178 weeks)] • Number of participants with AEs leading to discontinuation [Time frame: Up to 30 days after last treatment dose (approximately 178 weeks)] • Number of participants with abnormal change from baseline in laboratory measurements over time [Time frame: Up to 30 days after last treatment dose (approximately 178 weeks)] • Number of participants with abnormal change from baseline in vital signs over time [Time frame: Up to 30 days after last treatment dose (approximately 178 weeks)]
Results (efficacy)	-
Results (safety)	-
Clinical Trial Information	
Trial	NCT03252587; EudraCT 2017-001203-79; A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Efficacy and Safety of BMS-986165 in Subjects With Systemic Lupus Erythematosus **Phase II**: Completed **Locations:** 5 EU countries, USA, Canada and other countries **Study Completion Date:** June 2021
Trial Design	Randomised, parallel assignment, quadruple-blind
Population	N=363 (actual); subjects with SLE diagnosed at least 24 weeks before the screening; aged 18 to 75 years old
Intervention(s)	Oral deucravacitinib in three different doses for each study arm
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome: Number of participants who meet response criteria for Systemic Lupus Erythematosus (SLE) Responder Index [SRI(4)] [Time frame: at week 32] See trial record for full list of other outcomes
Results (efficacy)	See trial record
Results (safety)	See trial record

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Estimated Cost

Deucravacitinib is currently marketed in the UK; 6mg tablets costs £690 for 28 tablets or £2070 for 84 tablets.[21] The cost of deucravacitinib for treatment of SLE is not yet known.

Relevant Guidance

NICE Guidance

- NICE technology appraisal. Belimumab for treating active autoantibody-positive systemic lupus erythematosus (TA752). December 2021.

NHS England (Policy/Commissioning) Guidance

- NHS England. 2023. Clinical Commissioning Policy: Obinutuzumab for systemic lupus erythematosus with secondary non-response to rituximab (adults and post-pubescent children). 2121.
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Other Guidance

- European League of Associations for Rheumatology (EULAR). EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. 2023.[22]
- British Society for Rheumatology (BSR). Management and treatment of children, young people and adults with systemic lupus erythematosus: British Society for Rheumatology guideline scope. 2023.[23]

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