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Health Technology Briefing
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Deucravacitinib for treating active psoriatic arthritis

Company/Developer	Bristol-Myers Squibb Pharmaceuticals Ltd

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 27949	NICE ID: Not available	UKPS ID: 655170

Licensing and Market Availability Plans

Currently in Phase II/III clinical development.

Summary

Deucravacitinib is in clinical development for the treatment of active psoriatic arthritis (PsA). PsA is a long-term disabling condition causing stiff, inflamed, or painful joints (especially the small joints of hands and feet). The severity of symptoms tends to fluctuate. Characteristic symptoms include one or more swollen toes or fingers, perhaps with damaged nails, and joint pain that eases with exercise. PsA is caused when the immune system attacks the body's own cells, called an inflammatory response or autoimmune reaction. Most cases of PsA involve inflammation of the skin as well as the joints, with red or dark flaky skin patches. PsA is a progressive form of arthritis that can lead to bone damage if not treated successfully. Damage to the eyes, stomach, lungs, kidneys, or liver is rare but can be permanent. PsA is a varied disease in which existing treatments do not work for everyone.

Deucravacitinib is taken orally. It suppresses the part of the immune response that leads to the PsA symptoms of inflammation, skin, and joint damage. It targets a protein found in cells called tyrosine kinase (TYK2) that plays a role triggering production of chemicals called cytokines that cause inflammation. Deucravacitinib recognises TYK2 and binds on to it, making it unable to signal for more inflammation. Deucravacitinib is the first medicinal product to target TYK2 and one of only a few targeted treatments for PsA that do not need injections or intravenous infusion (drips). If licensed, deucravacitinib will provide a new option for the treatment of PsA.

Proposed Indication

Treatment of active psoriatic arthritis (PsA).[1]

Technology

Description

Deucravacitinib (BMS-986165, Sotyktu) is a small-molecule immunosuppressant.[2,3] Deucravacitinib selectively inhibits the TYK2 enzyme (TYK2 belongs to the JAK family). Deucravacitinib binds to the regulatory domain of TYK2, stabilising 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. Deucravacitinib inhibits the release of proinflammatory cytokines and chemokines.

Deucravacitinib is currently in phase III clinical development for the treatment of PsA in adults with either (i) no prior exposure to biologic treatment or (ii) failed treatment with an interferon (INF)-inhibitor (through either inefficacy or intolerance).[1,4,5] In the completed phase II clinical trial (NCT03881059), participants were administered doses of 6mg daily and 12mg daily.[1]

Key Innovation

Deucravacitinib is a first-in-class therapeutic product, a TYK2 inhibitor.[6] As patients often need to test different therapies to find one that their PsA responds to, the introduction of TYK2 inhibition as a novel therapeutic target has potential to improve personalisation of PsA treatments.[2,7,8] Deucravacitinib is taken daily in tablet(s), whereas the majority of targeted therapies recommended by the National Institute for Health and Care Excellence (NICE) for PsA (after non-response to standard disease modifying antirheumatic drugs (DMARDs)) are administered by injection or intravenous infusion.[9] Only a few oral therapies are currently recommended for PsA including Janus kinase (JAK) inhibitors (tofacitinib and upadacitinib) and a phosphodiesterase 4 (PDE4) inhibitor (apremilast).[9]

If licensed, deucravacitinib will offer a new option for the treatment of PsA. Additionally, it will add a new class of therapeutic target (TYK2 inhibitor) to the available treatment options.

Regulatory & Development Status

Deucravacitinib currently has Marketing Authorisation in the EU/UK for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[10]

Deucravacitinib also is in phase II/III clinical development for over 20 indications including:[11]

- lichen planopilaris
- plaque psoriasis (paediatric patients)
- hidradenitis suppurativa
- alopecia areata
- active Sjögren's Syndrome
- active systemic lupus erythematosus
- Crohn's disease
- Ulcerative colitis
- psoriasis (including pustular and erythrodermic subtypes)[6]

Patient Group

Disease Area and Clinical Need

PsA is an autoimmune condition, with flares and remissions, which is heterogeneous in nature.[12] It is a type of arthritis that develops in some people with the skin condition psoriasis, and it typically causes affected joints to become inflamed (swollen), stiff and painful. In most cases, people will experience problems with their skin before they notice any symptoms affecting their joints. Like psoriasis, PsA is thought to be a result of the immune system mistakenly attacking healthy tissue. The pain, swelling and stiffness associated with PsA can affect any joint in the body, but the condition often affects areas such as the hands, feet, knees, elbows, neck and spine. Some people may have severe problems affecting many joints, whereas others may only notice mild symptoms in one or two joints.[7] Other common symptoms are one or more tender, swollen or stiff joints, that ease with exercise, swollen sausage-like finger(s) or toe(s), nail changes, tenderness, pain and swelling over tendons, a reduced range of movement and general tiredness.[13] Active PsA means that there are three or more tender joints and three or more swollen joints.[14] Severe PsA can cause long-term damage to joints, bones and other tissue in the body.[15] It causes chronic pain and disability and has a substantial associated personal and societal cost.[16]

PsA occurs in around 25% of patients with psoriasis; but estimates range from 6-42%.[17,18] It affects men and women similarly, but with geographic variability.[19] A 2018 meta-analysis estimated pooled PsA prevalence and incidence rates respectively as 133 every 100,000 subjects (95% CI, 107-164 every 100,000 subjects) and 83 every 100,000 person-years (PY) (95% CI, 41-167 every 100,000 PY). Prevalence was higher in North Europe (12 of 28 studies) at 172 per 100,000 (95% CI 143-206).[19] The UK incidence estimated from primary care records was 17.2 every 100,000 PY in 2019, and the Psoriasis (PsO) and PsA Alliance quote a 0.5% prevalence in the UK population, or about 325,000 patients.[16,20] In England, 2022-23, there were 3,486 finished consultant episodes (FCE) for arthropathic psoriasis (ICD-10 code L40.5), of which there were 1,913 FCE bed days and 2,918 day cases.[21] Seven deaths attributed to PsA were registered in England and Wales in 2021.[22]

Recommended Treatment Options

NICE currently recommends systemic therapies for people with active PsA and any type of PsO fulfilling the criteria for systemic therapy.[9]

NICE recommends the following treatment options when standard DMARDs have failed to adequately treat active PsA:

- Bimekizumab, alone or with methotrexate when tumour necrosis (TNF)-alpha inhibitors are contraindicated.[14]
- Upadacitinib, alone or with methotrexate when TNF-alpha inhibitors are contraindicated but would otherwise be considered.[23]
- Guselkumab, alone or with methotrexate when TNF-alpha inhibitors are contraindicated but would otherwise be considered.[24]
- Risankizumab, alone or with methotrexate when patients have peripheral arthritis with 3 or more tender and swollen joints, moderate to severe PsO (at least 3% of the body surface area is affected by plaque PsO).[25]
- Ixekizumab, alone or with methotrexate when the person has had a TNF-alpha inhibitor but their disease has not responded or has stopped responding.[26]
- Aprelimast, alone or with DMARDs when the patient has peripheral arthritis with 3 or more tender and swollen joints, and their disease has not responded to at least 2 standard DMARDs (alone or in combination).[27]

- Certolizumab pegol, alone or with methotrexate when the person has had a TNF-alpha inhibitor but their disease has stopped responding.[28]
- Secukinumab, alone or with methotrexate the person has had a TNF-alpha inhibitor but their disease has not responded or has stopped responding, or TNF-alpha inhibitors are contraindicated.[28]
- Ustekinumab, alone or with methotrexate when treatment for TNF-alpha inhibitors are contraindicated or the person has had treatment with 1 or more TNF-alpha inhibitors.[29]
- Golimumab when it used as described for other TNF inhibitor treatments in NICE technology appraisal TA199.[30]
- Etanercept, Infliximab or adalimumab when the person has peripheral arthritis with 3 or more tender and swollen joints, and have not responded to at least two standard DMARDs individually or in combination.[31]

Clinical Trial Information	
Trial	NCT04908202; EudraCT 2020-005097-10; A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Deucravacitinib in Participants With Active Psoriatic Arthritis Who Are Naïve to Biologic Disease-modifying Anti-rheumatic Drugs **Phase III** - recruiting **Locations**: 10 EU countries, UK, US, and other countries. **Primary completion date**: September 2024
Trial Design	Randomised, parallel assignment, quadruple masked
Population	N=650 (estimated); adult; diagnosed to have PsA of at least 3 months duration at screening; active plaque psoriatic skin lesion(s) or documented medical history of plaque psoriasis at screening; active arthritis; PsA hand and/or foot joint erosion during screening period
Intervention(s)	Deucravacitinib
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome: proportion of participants meeting American College of Rheumatology improvement of 20% (ACR20) [Time Frame: At week 16] See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-
Clinical Trial Information	
Trial	NCT04908189; EudraCT 2020-005099-36 A Multi-center, Randomized, Double-blind, Placebo-controlled Phase 3 Study to Evaluate the Efficacy and Safety of Deucravacitinib in Participants With Active Psoriatic Arthritis (PsA) Who Are Naïve to Biologic Disease Modifying Anti-rheumatic Drugs or Had Previously Received TNFα Inhibitor Treatment **Phase III** – active, not recruiting. **Locations**: Seven EU countries, UK, USA, Canada and other countries. **Estimated primary completion date**: December 2023

Trial Design	Randomised, parallel assignment, quadruple masked
Population	N=700 (estimated); adult; diagnosed to have PsA of at least 3 months duration at screening; active plaque psoriatic skin lesion(s) or documented medical history of plaque psoriasis at screening; active arthritis
Intervention(s)	Deucravacitinib
Comparator(s)	• Matched placebo • Apremilast
Outcome(s)	Primary outcome: Proportion of participants meeting American College of Rheumatology improvement of 20% (ACR20) [Time Frame: At week 16] See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-
Clinical Trial Information	
Trial	NCT03881059; EudraCT 2018-004293-10; A Randomized, Placebo-Controlled, Double-blind, Multicenter Study to Assess the Efficacy and Safety of Multiple Doses of BMS-986165 in Subjects With Active Psoriatic Arthritis (PsA). **Phase II** – completed. **Locations:** 6 EU countries, UK, USA and Russian Federation. **Actual study completion date**: January 2021
Trial Design	Randomised, parallel assignment, double-masked
Population	N=203 (actual); adults diagnosed with PsA for at least 6 months; at least one lesion of plaque psoriasis (>=2cm) at screening; active arthritis at screening and day 1. Patients either (i) cannot have prior exposure to biologics (biologic-naïve) or (ii) have failed or been intolerant to 1 tumour necrosis factor inhibitor (TNFi) (TNFi-experienced)
Intervention(s)	Deucravacitinib 6 mg once a day or 12 mg once a day[32]
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome: Percentage of Participants Achieving the American College of Rheumatology (ACR) 20 Response at Week 16 [Time frame: 16 weeks after first dose] See trial record for full list of other outcomes
Results (efficacy)	See trial record
Results (safety)	See trial record

Estimated Cost

Deucravacitinib is currently marketed in the UK for the treatment of moderate to severe plaque psoriasis in adults. 6mg tablets costs £690 for 28 tablets or £2070 for 84 tablets.[33]

Relevant Guidance

NICE Guidance

- NICE technology appraisal. Bimekizumab for treating active psoriatic arthritis (TA916). October 2023.
- NICE technology appraisal. Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs (TA815). August 2022.
- NICE technology appraisal. Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs (TA803). July 2022.
- NICE technology appraisal. Upadacitinib for treating active psoriatic arthritis after inadequate response to DMARDs (TA768). February 2022.
- NICE technology appraisal. Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs (TA543). October 2018.
- NICE technology appraisal. Ixekizumab for treating active psoriatic arthritis after inadequate response to DMARDs (TA537). August 2018.
- NICE technology appraisal. Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs (TA445). May 2017.
- NICE technology appraisal. Ustekinumab for treating active psoriatic arthritis (TA340). June 2015. Last updated: March 2017
- NICE technology appraisal. Apremilast for treating active psoriatic arthritis (TA433). February 2017.
- NICE technology appraisal. Golimumab for the treatment of psoriatic arthritis (TA220). April 2011.
- NICE technology appraisal. Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (TA199). August 2010.
- NICE guideline. Spondyloarthritis in over 16s: diagnosis and management. (NG65). February 2017, updated June 2017.
- NICE quality standard. Spondyloarthritis (QS170). June 2018.

NHS England (Policy/Commissioning) Guidance

- NHS England. 2013/14 NHS Standard Contract for Specialised Rheumatology Services (Adult). A13/S/a.
- NHS England. 2013/14 NHS Standard Contract for Specialised Dermatology Services (All Ages). A12/S/a.

Other Guidance

- The 2022 British Society for Rheumatology guideline for the treatment of psoriatic arthritis with biologic and targeted synthetic DMARDs. May 2022.[34]
- Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. June 2022.[35]
- European League Against Rheumatism (EULAR). EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. May 2020.[36]
- BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. February 2017. [37]

Additional Information

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