Health Technology Briefing
November 2025

Tapinarof for treating plaque psoriasis

Company/Developer	Organon

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 27425	NICE ID: Not Available	UKPS ID: 675148

Licensing and Market Availability Plans

Currently in phase III clinical trials.

Summary

Tapinarof is being developed for the treatment of plaque psoriasis (PsO) in adults. PsO is a long-term skin condition where the immune system causes inflammation, leading to red, scaly patches on the skin. These patches, called plaques, can appear anywhere on the body but are most common on the elbows, knees, scalp, and lower back. Plaques can be itchy or painful, and in severe cases, the skin around joints may crack and bleed. 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. Hence a need for tolerable treatment with less side effects.

Tapinarof is a medical product in form of a cream that is applied directly on the skin which helps repair the skin barrier by turning on a protein called AhR. This protein enables increased production of important skin-building parts, reduces inflammation, and helps to protect against damage from stress and harmful molecules. Its cream base is specially made to reduce skin irritation and deliver the medicine directly to the affected areas, without too much entering the rest of the body. If approved, tapinarof cream will provide a new treatment option for patients with PsO.

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 plaque psoriasis (PsO) in adults.[1,2]

Technology

Description

Tapinarof cream 1% (VTAMA, DMVT-505) is a first-in-class, non-steroidal, topical aryl hydrocarbon receptor (AhR) agonist to treat PsO in adults.[3] AhR is a widely expressed transcription factor that modulates multiple pathways involved in skin homeostasis and inflammatory responses. Tapinarof binds to and activates AhR to restore skin-barrier function through upregulation of skin-barrier components (filaggrin, loricrin, hornerin, involucrin, and ceramides), downregulation of pro-inflammatory cytokines involved in psoriasis (interleukin [IL]-17A and IL17F) and atopic dermatitis (AD) (IL-4, IL-5, IL-13, and IL-31), and through cytoprotective antioxidant effects that reduce oxidative stress.[4]

Tapinarof cream is currently in clinical development for the treatment of PsO in adults. In the phase III clinical trials (PSOARING 1, NCT03956355; PSOARING 2, NCT03983980) participants are given tapinarof cream 1% applied once daily (QD).[1,2]

Key Innovation

Conventional topical treatments, including corticosteroids, and vitamin A and vitamin D analogues, are used by many patients with psoriasis. Although efficacious for some patients, these topical therapies are commonly associated with restrictions on duration, extent of use, and sites of application, and thus have limitations for managing chronic PsO. In addition, efficacy may not be sustained after withdrawal of treatment, and rebound may be seen with some therapies, particularly corticosteroids.[3] Therefore, there is an unmet need for well-tolerated, effective treatments for PsO. Tapinarof's vehicle is specifically designed to be cosmetically elegant, reduce skin irritation, and optimise the targeted delivery of tapinarof to local sites of disease, with minimal systemic exposure. Tapinarof cream acts locally at application sites, with no-to-minimal systemic absorption even under maximal usage conditions. Tapinarof has no QT interval effects (which means avoid the risk of ventricular arrhythmias especially Torsades de Pointes) and carries no warnings, precautions, limitations on duration or location of use, restrictions, or requirements for dose adjustments in the presence of renal or hepatic dysfunction.[4-6]

If licensed, tapinarof will provide a new treatment option for patients with PsO.

Regulatory & Development Status

Tapinarof does not currently have marketing authorisation in the EU/UK for any indication.

Tapinarof is also in phase II and/or III clinical development for atopic dermatitis.[7]

Patient Group

Disease Area and Clinical Need

Psoriasis is a systemic, immune-mediated, inflammatory skin disease which typically has a chronic relapsing-remitting course, and may have nail and joint (psoriatic arthritis) involvement.[8] PsO (psoriasis vulgaris) is the most common form of psoriasis, affecting 80–90% of people with psoriasis.[8,9] Its symptoms

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are dry skin lesions, known as plaques, covered in scales. They normally appear on the elbows, knees, scalp and lower back, but can appear anywhere on the body. The plaques can be itchy or sore, or both. In severe cases, the skin around the joints may crack and bleed.[9] Psoriasis affects around 2 in 100 people in the UK. It can start at any age, but most often develops in adults between 20 and 30 years old and between 50 and 60 years old. It affects men and women equally. Psoriasis occurs when skin cells are replaced more quickly than usual. It is not known exactly why this happens, but research suggests it is caused by a problem with the immune system.[9] Several factors are associated with the onset or exacerbation of psoriasis, including infection, drugs (including corticosteroid withdrawal), ultraviolet light exposure, trauma, hormonal changes, stress, smoking, and alcohol. Psoriasis may be associated with other conditions such as psoriatic arthritis, metabolic syndrome, inflammatory bowel disease (particularly Crohn's disease), anxiety and depression.[8]

Psoriasis is common, with about 1.3–2.8% of the UK population affected.[8] In England, 2024-25, there were 1,270 finished consultant episodes (FCE) and 1,147 admissions for psoriasis vulgaris (ICD-10 code L40.0) which resulted in 1,343 FCE bed days and 953 day cases.[10]

Recommended Treatment Options

There is no cure for psoriasis, however there are a number of treatments that can control symptoms and the appearance of skin patches.[9]

The National Institute for Health and Care Excellence (NICE) currently recommends the following pharmacological treatment options for moderate to severe PsO in adults:

- Deucravacitinib[11]
- Bimekizumab[12]
- Risankizumab[13]
- Tildrakizumab[14]
- Certolizumab[15]
- Secukinumab[16]
- Guselkumab[17]
- Brodalumab[18]
- Dimethyl fumarate[19]
- Ixekizumab[20]
- Apremilast[21]
- Infliximab[22]

Clinical Trial Information

Trial	**PSOARING 1, DMVT-505-3001;** NCT03956355; A Phase 3 Efficacy and Safety Study of Tapinarof for the Treatment of Plaque Psoriasis in Adults **Phase III** - Completed **Location(s):** USA and Canada **Study completion date:** May 2020
Trial Design	Randomised, parallel assignment, vehicle-controlled, double-blind

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Population	N = 510; participants aged 18 to 75 years with clinical diagnosis of chronic PsO and stable disease for at least 6 months prior to the study; Body Surface Area (BSA) involvement ≥ 3% and ≤ 20%; a Physician Global Assessment (PGA) Score of 2 (Mild), 3 (Moderate) or 4 (Severe) at screening and baseline.
Intervention(s)	Tapinarof cream 1% applied QD
Comparator(s)	Vehicle cream applied QD
Outcome(s)	Primary outcome: Percent of subjects who achieve a PGA score of Clear (0) or Almost Clear (1) with a minimum 2-grade improvement from baseline at week 12. analyses were done using multiple imputation [Time Frame: Baseline to Week 12] See trial record for full list of other outcomes.
Results (efficacy)	A PGA response occurred in 35.4% of the patients in the tapinarof group and in 6.0% of those in the vehicle group (P<0.001 for both comparisons). Results for secondary end points and patient-reported outcomes were generally in the same direction as those for the primary end point.[23]
Results (safety)	Adverse events with tapinarof cream included folliculitis, nasopharyngitis, contact dermatitis, headache, upper respiratory tract infection, and pruritus.[23]
Clinical Trial Information	
Trial	**PSOARING 2, DMVT-505-3002; NCT03983980; A Phase 3 Efficacy and Safety Study of Tapinarof for the Treatment of Plaque Psoriasis in Adults** **Phase III -** Completed **Location(s):** USA and Canada **Study completion date:** May 2020
Trial Design	Randomised, parallel assignment, vehicle-controlled, double-blind
Population	N = 515; participants aged 18 to 75 years with clinical diagnosis of chronic PsO and stable disease for at least 6 months prior to the study; BSA involvement ≥ 3% and ≤ 20%; a PGA Score of 2 (Mild), 3 (Moderate) or 4 (Severe) at screening and baseline.
Intervention(s)	Tapinarof cream 1% applied QD
Comparator(s)	Vehicle cream applied QD
Outcome(s)	Primary outcome: Percent of subjects who achieve a PGA Score of Clear (0) or Almost Clear (1) with a minimum 2-grade improvement from baseline at week 12. analyses were done using multiple imputation [Time Frame: Baseline to Week 12] See trial record for full list of other outcomes.

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Results (efficacy)	A PGA response occurred in 40.2% of the patients in the tapinarof group and in 6.3% of those in the vehicle group (P<0.001 for both comparisons). Results for secondary end points and patient-reported outcomes were generally in the same direction as those for the primary end point.[23]
Results (safety)	Adverse events with tapinarof cream included folliculitis, nasopharyngitis, contact dermatitis, headache, upper respiratory tract infection, and pruritus.[23]
Clinical Trial Information	
Trial	**PSOARING 3, DMVT-505-3003; NCT04053387;** A Long-Term, Open-Label, Extension Study to Evaluate the Safety and Efficacy of Tapinarof Cream, 1% for the Treatment of Plaque Psoriasis in Adults **Phase III -** Completed **Location(s):** USA and Canada **Study completion date:** April 2021
Trial Design	Randomised, single group assignment, vehicle-controlled, open-label
Population	N = 763; participants has completed the 12-week treatment period in 1 of the 2 parent studies (Study DMVT-505-3001 or Study DMVT-505-3002); aged 18 to 75 years.
Intervention(s)	Intermittent use of Tapinarof cream 1% applied QD according to PGA score
Comparator(s)	Not applicable
Outcome(s)	Primary outcomes: • Number of subjects with Adverse Events (AEs) and Serious Adverse Events (SAEs) [Time frame: Baseline to 44 weeks] • Frequency of AEs and SAEs [Time frame: Baseline to 44 weeks] • Number of subjects with clinically meaningful changes from baseline in clinical laboratory values and vital signs [Time frame: Baseline to 40 weeks] • Remittive effect of treatment success in pivotal: median time to first worsening (PGA ≥ 2) while off therapy for subjects who entered LTE PGA = 0 (Clear) [Time frame: Baseline to 44 weeks] • Complete disease clearance during LTE: number of subjects achieving disease clearance PGA = 0 (Clear) while on therapy for subjects entered LTE PGA ≥ 1 (Almost Clear) [Time frame: Baseline to 44 weeks] • Response during LTE: Number of subjects achieving PGA = 0 or 1 (Clear or Almost Clear) while on therapy for subjects who entered LTE with PGA ≥ 2 (Mild) [Time frame: Baseline to 44 weeks] • Remittive effect of treatment success: number of subjects experiencing worsening (PGA ≥ 2) while off therapy for

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	subjects who entered LTE with a PGA = 0 (Clear) [Time frame: Baseline to 44 weeks] • Change from baseline in %BSA affected [Time frame: Baseline to 40 weeks] • Percent change from baseline in %BSA affected [Time frame: Baseline to 40 weeks] • Mean duration (days) of treatment course [Time frame: Baseline to 40 weeks] • Change from baseline in Psoriasis Area and Severity Index (PASI) Score [Time frame: Baseline to 40 weeks] • Percent change from baseline in PASI Score [Time frame: Baseline to 40 weeks] • Change from baseline in disease impact on daily activities, as measured by the Dermatology Life Quality Index (DLQI) [Time frame: Baseline to 40 weeks] • Percent change from baseline in disease impact on daily activities, as measured by the DLQI [Time frame: Baseline to 40 weeks] See trial record for full list of other outcomes.
Results (efficacy)	The majority of eligible patients (92%, n = 763/833) elected to enroll in PSOARING 3, the long-term extension trial. Efficacy continued to improve beyond the 12-week trials with a high rate (40.9%; n = 312/763) of complete disease clearance (PGA = 0), an approximately 4-month remittive effect off therapy (maintenance of PGA = 0 or 1) after first achieving PGA = 0, and durability of response both on or with intermittent therapy for up to 52 weeks. For the 312 patients who achieved a PGA score of 0 at any time during PSOARING 3, the mean total duration of remittive effect off therapy was approximately 4 months.[3]
Results (safety)	Incidence and severity of folliculitis and contact dermatitis AESIs were generally mild or moderate, localized to the site of application, and associated with low discontinuation rates.[3]

Estimated Cost

The cost of tapinarof is not yet known.

Relevant Guidance

NICE Guidance

- NICE technology appraisal awaiting development. Icotrokinra for treating moderate to severe plaque psoriasis in people 12 years and over [ID6579] (GID-TA11780). Expected date of issue to be confirmed.
- NICE technology appraisal. Deucravacitinib for treating moderate to severe plaque psoriasis (TA907). June 2023.

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- NICE technology appraisal. Bimekizumab for treating moderate to severe plaque psoriasis (TA723). September 2021.
- NICE technology appraisal. Risankizumab for treating moderate to severe plaque psoriasis (TA596). August 2019.
- NICE technology appraisal. Tildrakizumab for treating moderate to severe plaque psoriasis (TA575). April 2019.
- NICE technology appraisal. Certolizumab pegol for treating moderate to severe plaque psoriasis (TA574). April 2019.
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- NICE technology appraisal. Brodalumab for treating moderate to severe plaque psoriasis (TA511). March 2018.
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- NICE technology appraisal. Secukinumab for treating moderate to severe plaque psoriasis (TA350). July 2015.
- NICE clinical guideline. Psoriasis: assessment and management (CG153). October 2012. Last updated 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

- European Guidelines Dermatology (EuroGuiDerm). Living EuroGuiDerm Guideline for the systemic treatment of psoriasis vulgaris. 2025.[24]
- British Association of Dermatologists. Guidelines for biologic therapy for psoriasis 2023: a pragmatic update. 2024.[25]
- NHS Lancashire & South Cumbria Medicines Management Group. Guidelines for the Management of Psoriasis in Primary Care. 2024.[26]
- American Academy of Dermatology Association. Psoriasis Clinical Guideline. 2021.[27]

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