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Health Technology Briefing
April 2025

Deuruxolitinib for treating alopecia areata in adults

Company/Developer	Sun Pharmaceutical Industries Ltd.

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 20545	NICE ID: Not Available	UKPS ID: 675103

Licensing and Market Availability Plans

Currently in Phase III clinical trials

Summary

Deuruxolitinib is in clinical development for the treatment of alopecia areata in adults. Alopecia areata is an autoimmune condition of uncertain origins that produces spot baldness, most commonly on the affected person's scalp; this is often accompanied with depression and anxiety, making it hard to carry out daily activities. Internally, immune cells called T cells mistakenly attack the hair follicles, causing inflammation and preventing the growth of any more hair from the follicle. There is currently no standard treatment option for alopecia areata.

Deuruxolitinib is a type of immunotherapy caked a Janus kinase (JAK) inhibitor, that is taken orally and suppresses proteins called JAK1 and JAK2, both of which are involved in inflammatory reactions in the body. The composition of deuruxolitinib also means it is specially designed to be long lasting in the body. By inhibiting the JAK pathway, deuruxolitinib reduces the immune system's attack on hair follicles. If licensed, deuruxolitinib will offer an additional treatment option for adults with alopecia areata.

Proposed Indication

The treatment of adults with alopecia areata.

Technology

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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Description

Deuruxolitinib (Leqselvi, CTP-543) is Janus kinase (JAK) inhibitor that attenuates the inflammatory response around hair follicles through selective targeting of JAK1 and JAK2.[1] In alopecia areata, the immune system mistakenly attacks hair follicles, causing inflammation.[2] The JAK signal transducer and activator of transcription pathway has been implicated in the pathophysiology of alopecia areata, as it regulates the expression of inflammatory mediators.[1]

Deuruxolitinib is in clinical development for the treatment of alopecia areata in adults. In the phase III trials (THRIVE-AA1; NCT04518995, THRIVE-AA2; NCT04797650), participants were randomised in 3:5:2 (THRIVE-AA1) and 1:2:1 (THRIVE-AA2) ratios to receive deuruxolitinib 12mg orally BID (twice daily); 8mg orally BID; or a matched placebo.[3,4] The long-term safety and efficacy of deuruxolitinib is now being monitored in the phase III clinical trials (NCT05041803; NCT03898479) with the participants of previous trials.[4-6] If licensed, deuruxolitinib will provide an additional treatment option for people with alopecia areata.

Key Innovation

Deuruxolitinib is a deuterated (replacement of hydrogen atoms with deuterium) form of ruxolitinib (Jakavi), a JAK inhibitor with a half-life of around 3 hours.[7-9] Deuteration allows the drug to circumvent extensive oxidative metabolism, which increases the duration of the pharmacological activity of deuruxolitinib; this extends the half-life to approximately 4 hours, whilst the only approved alopecia areata treatment has a half-life range of 1.3-2.3 hours.[7,10] A longer half-life means a person needs to take the treatment less frequently than the one with a shorter half-life. This can be helpful for promoting compliance for those who may have difficulties administering the treatment.[11]

Regulatory & Development Status

Deuruxolitinib does not currently have Marketing Authorisation in the EU/UK for any indication.

Deuruxolitinib has the following regulatory designations:[12,13]

- a Breakthrough Therapy by the US FDA for the treatment of alopecia areata in July 2020.
- a Fast Track designation by the US FDA for the treatment of alopecia areata in January 2018.

Deuruxolitinib is not currently in phase II or III trials for any other indication.

Patient Group

Disease Area and Clinical Need

Alopecia areata is a common autoimmune condition that causes non-scarring hair loss. Non-scarring hair loss means that the roots of the hairs have not been permanently lost; therefore, the hair potentially can grow back.[2] Alopecia areata usually causes small, coin-sized, round patches of baldness on the scalp, although hair on other parts of the body, such as the beard, eyebrows, eyelashes, body, can be affected. Those with more than half the hair lost at the beginning or with complete hair loss at any stage have only about a 1 in 10 chance of full recovery. The chances of regrowth are lower in young children, people with family history of alopecia areata or other autoimmune conditions, those with hair loss affecting the hairline at the back of the scalp and those with nail disease. Most people experience further episodes of alopecia areata. A UK based study has demonstrated that alopecia areata patients have higher rates of depression and anxiety than those without alopecia areata which can impact on their daily activities.[2] Alopecia areata

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can affect both males and females of any age. In about 50% of cases, it starts in childhood. A family history of alopecia areata and/or of other autoimmune conditions are present in 10–25% of patients. Alopecia areata is a polygenic condition, so there are several genes involved; however, it is still unknown what triggers the immune system to attack healthy hair follicles.[14]

Alopecia areata affects up to 2% of the global population.[15] In the UK it is estimated to affect approximately 15 in 10,000 people.[16] In England, 2023-2024, there were 146 finished consultant episodes (FCEs) and 146 hospital admissions for alopecia areata (ICD-10 code L63) which resulted in 35 FCE bed days and 139 day cases. Of these, there were 4 FCEs and 4 hospital admissions for alopecia (capitis) totalis (ICD-10 code L63.0) which resulted in 0 FCE bed days and 4 day cases, and there were 3 FCEs and 3 admissions for alopecia universalis (ICD-10 code L62.1) which resulted in 3 FCE bed days and 1 day case.[17]

Recommended Treatment Options

The National Institute of Health and Care Excellence (NICE) currently recommends ritlecitinib as a treatment option for people aged 12 years and over with severe alopecia areata.[18]

There is no standard treatment for severe alopecia areata, and access to treatment varies widely. Some pharmacological treatment options are available in secondary and tertiary care. These include corticosteroids and contact immunotherapy, and for those with more severe hair loss, systemic corticosteroids or immunosuppressants.[19]

Clinical Trial Information

Trial	**THRIVE-AA1**; NCT04518995; 2020-002704-40. A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of CTP-543 in Adult Patients With Moderate to Severe Alopecia Areata **Phase III –** Completed **Location(s):** Three EU countries, USA, and Canada **Study completion date:** April 2022
Trial Design	Randomised, parallel assignment, quadruple-blind
Population	N=706 (actual); participants diagnosed with alopecia areata; aged 18 to 65 years
Intervention(s)	**Experimental Arm 1:** Deuruxolitinib 8mg orally BID for 24 weeks **Experimental Arm 2:** Deuruxolitinib 12mg orally BID for 24 weeks
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome measure: • Percentage of participants achieving an absolute SALT score of ≤20 at week 24 [Time frame: week 24] See trial record for full list of other outcomes.
Results (efficacy)	See trial record
Results (safety)	See trial record

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Trial	**THRIVE-AA2;** NCT04797650; 2021-000387-30. A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of CTP-543 in Adult Patients With Moderate to Severe Alopecia Areata **Phase III** – Completed **Location(s):** Five EU countries, USA, and Canada **Study completion date:** June 2022
Trial Design	Randomised, parallel assignment, quadruple-blind
Population	N=517 (actual); participants diagnosed with alopecia areata; aged 18 to 65 years
Intervention(s)	**Experimental Arm 1:** Deuruxolitinib 8mg orally BID for 24 weeks **Experimental Arm 2:** Deuruxolitinib 12mg orally BID for 24 weeks
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome measure: • Percentage of participants achieving an absolute SALT score of ≤20 at week 24 [Time frame: week 24] See trial record for full list of other outcomes.
Results (efficacy)	See trial record
Results (safety)	See trial record

Trial	NCT03898479. A Multicenter, Open-Label, Extension Study to Assess the Long-Term Safety and Efficacy of CTP-543 in Adult Patients With Moderate to Severe Alopecia Areata **Phase III** – Active, not recruiting **Location(s):** USA and Canada **Primary completion date:** May 2025
Trial Design	Single group assignment, open-label
Population	N=1000 (estimated); participants who have completed 24 weeks of treatment in a deuruxolitinib clinical trial; aged 18 to 65 years
Intervention(s)	Deuruxolitinib BID
Comparator(s)	-
Outcome(s)	Primary outcomes measures: • Number of participants with adverse events as a measure of safety [Time Frame: up to 332 weeks] • Effect of deuruxolitinib on treating hair loss as measured by the SALT [Time Frame: up to 332 weeks] See trial record for full list of other outcomes.

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Results (efficacy)	-
Results (safety)	-

Trial	NCT05041803; 2021-002365-18. A Multicenter, Open-Label, Extension Study to Assess the Long-Term Safety and Efficacy of CTP-543 in Adult Patients with Moderate to Severe Alopecia Areata **Phase III** – Completed **Location(s):** Five EU countries **Study completion date:** July 2024
Trial Design	Single group assignment, open-label
Population	N=407 (actual); participants who have completed 24 weeks of treatment in a deuruxolitinib clinical trial; aged 18 to 65 years
Intervention(s)	Deuruxolitinib BID
Comparator(s)	-
Outcome(s)	Primary outcomes measures: • Number of participants with adverse events as a measure of safety [Time Frame: 108 weeks] • Effect of deuruxolitinib on treating hair loss as measured by the SALT [Time Frame: 108 weeks] See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	NCT03137381. A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of CTP-543 in Adult Patients With Moderate to Severe Alopecia Areata **Phase II** – Completed **Location:** USA **Study completion date:** July 2019
Trial Design	Randomised, sequential assignment, quadruple-blind
Population	N=149 (actual); participants diagnosed with alopecia areata; aged 18 to 65 years
Intervention(s)	Deuruxolitinib 4mg or 8mg or 12mg orally BID
Comparator(s)	Matched placebo
Outcome(s)	Primary outcomes measures: • Percentage of participants achieving at least a 50% relative reduction in SALT score from baseline [Time frame: 24 weeks]

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	• Number of participants experiencing at least one treatment-emergent adverse event See trial record for full list of other outcomes.
Results (efficacy)	See trial record
Results (safety)	See trial record

Trial	NCT03941548. A Randomized Parallel-Group Study to Evaluate the Efficacy and Tolerability of Two Dosing Regimens of CTP-543 in Adult Patients With Moderate to Severe Alopecia Areata **Phase II** – Completed **Location(s):** USA and Canada **Study completion date:** April 2020
Trial Design	Randomised, parallel assignment, triple-blind
Population	N=66 (actual); participants diagnosed with alopecia areata; aged 18 to 65 years
Intervention(s)	**Experimental Arm 1:** Deuruxolitinib 12mg orally daily + matched placebo BID for 24 weeks **Experimental Arm 2:** Deuruxolitinib 24mg orally daily + matched placebo once daily for 24 weeks
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome measure: • Relative change from baseline in SALT score [Time Frame: week 24] See trial record for full list of other outcomes.
Results (efficacy)	See trial record
Results (safety)	See trial record

Trial	NCT03811912. A Randomized Parallel-Group Study to Evaluate the Efficacy and Tolerability of Two Dosing Regimens of CTP-543 in Adult Patients With Moderate to Severe Alopecia Areata **Phase II** – Completed **Location:** USA **Study completion date:** November 2019
Trial Design	Randomised, parallel assignment, triple-blind
Population	N=57 (actual); participants diagnosed with alopecia areata; aged 18 to 65 years
Intervention(s)	**Experimental Arm 1:** Deuruxolitinib 8mg orally daily + matched placebo BID for 24 weeks **Experimental Arm 2:**

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	Deuruxolitinib 16mg orally daily + matched placebo once daily for 24 weeks
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome measure: • Relative change from baseline in SALT score [Time Frame: week 24] See trial record for full list of other outcomes.
Results (efficacy)	See trial record
Results (safety)	See trial record

Trial	NCT04784533. A Study to Evaluate Maintenance of Hair Regrowth Following Dose Reduction of CTP-543 in Adult Patients With Moderate to Severe Alopecia Areata **Phase II** – Completed **Location:** USA **Study completion date:** April 2023
Trial Design	Randomised, parallel assignment, quadruple-blind
Population	N=317 (actual); participants diagnosed with alopecia areata; aged 18 to 65 years
Intervention(s)	See trial record
Comparator(s)	Matched placebo (Part A: Period 2)
Outcome(s)	Primary outcome measures: • Part A, Period 2: Percentage of participants achieving LOM criteria defined by SALT score > 20 following dose reduction [Time Frame: From week 24 to week 58] • Part A, Period 2: Percentage of participants achieving LOM criteria defined by SALT score > 20 following drug discontinuation [Time Frame: From week 24 to week 48] • Part B: Percentage of participants by dose group who achieved restoration of regrowth at week 24 [Time Frame: Week 24 of re-treatment] See trial record for full list of other outcomes.
Results (efficacy)	See trial record
Results (safety)	See trial record

Estimated Cost

The cost of deuruxolitinib is not yet known.

Relevant Guidance

NICE Guidance

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NHS England (Policy/Commissioning) Guidance

- NHS England. Specialised Dermatology Services (Adult and Children). A12 S/a – 240501S. August 2024.

Other Guidance

- Lintzeri DA, Constantinou A, Hillmann K, Ghoreschi K, Vogt A, Blume- Peytavi U. Alopecia areata – Current understanding and management. 2022.[20]
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