Health Technology Briefing
December 2025

Remibrutinib for treating chronic inducible urticaria

Company/Developer	Novartis Pharmaceuticals UK Ltd

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 37727	NICE ID: Not available	UKPS ID: 675280

Licensing and Market Availability Plans

Currently in phase III clinical trial.

Summary

Remibrutinib is currently in development for the treatment of chronic inducible urticaria inadequately controlled by H1-antihistamines in adults. Urticaria, also called hives, is a swelling of the skin surface that results in a red, raised, itchy rash. Chronic urticaria is a type of urticaria that persists for 6 weeks or longer. Chronic inducible urticaria is a type of chronic urticaria that has an identifiable external cause or trigger. The causes of chronic inducible urticaria include exposure to cold, heat, water, delayed pressure, vibration or light. Many patients with chronic inducible urticaria do not respond well to antihistamine treatment. Therefore, a significant unmet medical need exists for a new effective treatment option.

Remibrutinib is an oral drug that specifically targets and blocks a protein called Bruton's tyrosine kinase. By doing this, it stops certain immune cells from releasing substances that cause itching, hives, swelling, or a mix of these symptoms. If approved, remibrutinib may provide a new treatment option for chronic inducible urticaria inadequately controlled by H1-antihistamines in adults.

Proposed Indication

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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Treatment of chronic inducible urticaria (CIndU) inadequately controlled by H1-antihistamines in adults.[1]

Technology

Description

Remibrutinib (LOU064) is an oral, highly selective Bruton's tyrosine kinase (BTK) inhibitor that blocks BTK-mediated degranulation of mast cells and basophils downstream of FcεRI (a high-affinity immunoglobulin E receptor), which prevents the release of histamine and other proinflammatory mediators that lead to itch, hives, angioedema, or a combination of these symptoms.[1,2]

Remibrutinib is currently in development for the treatment of CIndU inadequately controlled by H1-antihistamines in adults. In the phase III clinical trial (NCT05976243), participants received oral remibrutinib twice daily.[1]

Key Innovation

Daily intake of second-generation antihistamines at the licensed dose is the first-line therapy advised for all CIndUs. Beyond second-generation antihistamines, there are currently no licensed drugs indicated for CIndU. However, many patients with CIndU do not respond adequately to antihistamine treatment.[3] Therefore, a significant unmet medical need exists for a new effective treatment option with a favourable safety profile. In the phase III clinical trial of remibrutinib in adults with chronic spontaneous urticaria, it was reported that treatment with remibrutinib resulted in a significant improvement in a composite measure of itching and hives at week 12.[2] Pathogenic mechanisms that are involved in chronic spontaneous urticaria appear to also play an important role in CIndU.[3,4] If licensed, remibrutinib may provide a new treatment option for CIndU inadequately controlled by H1-antihistamines in adults.

Regulatory & Development Status

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

Remibrutinib does not currently have any drug designations or awards for CIndU.

Remibrutinib is also in phase II/III clinical development for the treatment of the following indications:[5]

- Relapsing multiple sclerosis
- Generalised myasthenia gravis
- Hidradenitis suppurativa
- Chronic spontaneous urticaria
- Peanut allergy

Patient Group

Disease Area and Clinical Need

Urticaria is also called hives or nettle rash.[6] It is a superficial swelling of the skin (epidermis and mucous membranes) that results in a red, raised, itchy rash. Urticaria can be classified into two groups according to its duration as: (1) Acute urticaria with symptoms lasting for less than 6 weeks, and (2) Chronic urticaria with symptoms persisting for 6 weeks or longer, on a nearly daily basis.[7] CIndU is a subgroup of chronic urticaria characterised by the appearance of recurrent itchy wheals, angioedema, or both as a response to specific, definite, and reproducible triggers.[3] CIndU can be caused by several factors, including exposure to cold, heat, water, delayed pressure, vibration or light.[8,9] The main symptom of urticaria is an itchy rash.[6]

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The lifetime prevalence of chronic urticaria is estimated to be 4.4%, with the point prevalence of CIndU estimated to be 0.05%-1.5%.[10] In the UK, approximately 15% of people experience urticaria at some time in their lives, and the lifetime prevalence of chronic urticaria is 0.5–1%.[11] In England (2023-24), there were 8,209 finished consultant episodes (FCEs) and 7,778 finished admission episodes for urticaria (ICD-10 code L50), which resulted in 4,770 day cases and 2,338 FCE bed days.[12]

Recommended Treatment Options
There is no treatment option recommended by NICE for CIndU.

Clinical Trial Information

Trial	NCT05976243, EUCT 2023-505739-12-00; A 52-week Multi-center, Randomized, Double-blind, Placebo Controlled, Basket Study With an Open-label Extension to Investigate the Efficacy, Safety, and Tolerability of Remibrutinib (LOU064) in Chronic Inducible Urticaria (CIndU) in Adults Inadequately Controlled by H1-antihistamines. **Phase III** – Recruiting **Location(s):** Ten EU countries, Australia, Canada, UK, USA, and other countries **Primary completion date:** March 2026
Trial Design	Randomised, parallel assignment, triple-blinded, placebo-controlled
Population	N=348; participants aged 18 to 100 years with a confirmed CIndU diagnosis for symptomatic dermographism, cold urticaria or cholinergic urticaria for ≥ 4 months and inadequate control with H1-antihistamines
Intervention(s)	Oral administration of remibrutinib twice daily
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome measure: • Proportion of participants with complete response in Total Fric Score; symptomatic dermographism [Time frame: Week 12] • Proportion of participants with complete response in critical temperature threshold; cold urticaria [Time frame: Week 12] • Proportion of participants with itch numerical rating scale =0; cholinergic urticaria [Time frame: Week 12] See the trial record for a full list of other outcomes
Results (efficacy)	-
Results (safety)	-

Estimated Cost

The cost of remibrutinib is not yet known.

Relevant Guidance

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NICE Guidance
• NICE quality standard. Drug allergy (QS97). July 2015. • NICE clinical guideline. Drug allergy: diagnosis and management (CG183). September 2014.
NHS England (Policy/Commissioning) Guidance
NHS England. 2013/14 NHS Standard Contract for Specialised Allergy Services (All Ages). B09/S/b.
Other Guidance
NICE evidence summary. Chronic urticaria: off-label doses of cetirizine (ESUOM31). 2014.[13]

Additional Information

References

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NB: This briefing presents independent research funded by the National Institute for Health and Care Research (NIHR). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.

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