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Health Technology Briefing
August 2025

Remibrutinib for treating chronic spontaneous urticaria in adolescents

Company/Developer	Novartis Pharmaceuticals UK Ltd

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 36787	NICE ID: Not available	UKPS ID: Not available

Licensing and Market Availability Plans

Currently in phase III clinical trials.

Summary

Remibrutinib is currently in development for the treatment of chronic spontaneous urticaria inadequately controlled by H1-antihistamines (medicines used to relieve allergy symptoms) in adolescents aged 12 to less than 18 years. Urticaria, also called hives or nettle rash, is a swelling on the surface of the skin that results in a red, raised, itchy rash. Chronic urticaria is a type of urticaria that persists for 6 weeks or longer. Chronic spontaneous urticaria has no identifiable external cause or trigger, but may be aggravated by heat, stress, infections and certain drugs, such as non-steroidal anti-inflammatory drugs. The main symptom of urticaria is an itchy rash. H1-antihistamines are the main treatment for chronic spontaneous urticaria. However, more than half of people with chronic spontaneous urticaria do not get enough relief from the usual first treatment with antihistamines. Even after a second treatment, about one in three still have symptoms or do not fully recover. Hence, there is a need for a new treatment option.

Remibrutinib is a new oral medicine 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 licensed, remibrutinib may provide a new treatment option for chronic spontaneous urticaria inadequately controlled by H1-antihistamines in adolescents aged 12 to less than 18 years.

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 spontaneous urticaria (CSU) inadequately controlled by H1-antihistamines in adolescents aged 12 to less than 18 years.[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.[1-8]

Remibrutinib is currently in clinical development for the treatment of CSU inadequately controlled by H1-antihistamines in adolescents aged 12 to less than 18 years. In the phase III clinical trial (NCT05677451), participants received oral remibrutinib twice a day for up to 6 cycles of 24 weeks.[1]

Key Innovation

International treatment guidelines recommend the use of second-generation H1 antihistamines or updosing of H1 antihistamines if needed, as the first-line treatment for management of CSU.[9-11] However, more than half of the patients do not respond to standard H1 antihistamine treatment adequately.[10,12] Also, nearly one-third of patients remain symptomatic or do not achieve complete control of the signs and symptoms of CSU after a second-line immunotherapy.[9,10,13] Hence, there is a need for a new treatment option. As a highly selective BTK inhibitor, remibrutinib may offer a disease-modifying treatment that induces long-term CSU remission after drug withdrawal.[14] In the phase III clinical trial of remibrutinib in adults with CSU, it was reported that treatment with remibrutinib resulted in a significant improvement in a composite measure of itching and hives at week 12.[8] If licensed, remibrutinib may provide a new treatment option for CSU inadequately controlled by H1-antihistamines in adolescents aged 12 to less than 18 years.

Regulatory & Development Status

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

Remibrutinib is also in phase II/III clinical development for the treatment of the following indications:[15]

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

Patient Group

Disease Area and Clinical Need

Urticaria is a superficial swelling of the skin (epidermis and mucous membranes) that results in a red, raised, itchy rash.[16] Urticaria is classified as either acute (symptoms less than 6 weeks) or chronic (symptoms lasting 6 weeks or longer).[16] CSU, which was previously called chronic idiopathic urticaria is a common and distressing type of urticaria that causes red, raised, itchy and sometimes painful wheals often referred to as hives, bumps or nettle rash) on the skin. Often there is no obvious external trigger or aggravating factor that causes these symptoms. This is because CSU differs from other urticarial reactions in that there is

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often no known cause. CSU is linked with autoimmune disorders in 50% of individuals with the condition, so tests for thyroid function and autoimmune disorders may be performed.[17] CSU may be aggravated by heat, stress, infections and certain drugs, such as non-steroidal anti-inflammatory drugs.[16,17]

CSU is thought to affect 0.5-1% of the population in the UK, with women more than twice as likely than men to be diagnosed with it. CSU can affect children, it is more common in older children and adolescents than infants.[17] In the UK, approximately 15% of people experience urticaria at some time in their lives. For around 40–50% of people with urticaria, the cause of their condition is unknown.[18] In England (2023-24), there were 731 finished consultant episodes (FCEs) and 714 finished admission episodes for idiopathic urticaria (ICD-10 code L50.1), which resulted in 565 day cases and 161 FCE bed days.[19]

Recommended Treatment Options
The National Institute for Health and Care Excellence (NICE) recommends omalizumab as add-on therapy for treating severe CSU in adults and young people aged 12 years and over.[20]

Clinical Trial Information

Trial	NCT05677451, **EudraCT 2022-502159-78-00**; A Double-blind, Randomized, Placebo-controlled Trial to Evaluate the Efficacy, Pharmacokinetics and Safety of Remibrutinib (LOU064) for 24 Weeks in Adolescents From 12 to Less Than 18 Years of Age With Chronic Spontaneous Urticaria Inadequately Controlled by H1-antihistamines Followed by an Optional Open-label Extension for up to Another 3 Years and an Optional Safety Long-term Treatment-free Follow-up Period for up to an Additional 3 Years **Phase III** – Recruiting **Location(s):** Five EU countries, UK, USA, Canada, and other countries **Primary completion date:** April 2026
Trial Design	Randomised, parallel assignment, quadruple masking, placebo-controlled
Population	N=100 (estimated); subjects with a diagnosis of CSU duration of greater than or equal to 6 months before screening, and inadequately controlled by second-generation H1-antihistamines aged 12 to less than 18 years.
Intervention(s)	Remibrutinib administered orally
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome measure: • Change from baseline in Urticaria Activity Score 7 [Time frame: Baseline to week 12] • Change from baseline in Itch Severity Score 7 [Time frame: Baseline to week 12] • Change from baseline in Hives Severity Score 7 [Time frame: Baseline to week 12]
Results (efficacy)	-
Results (safety)	-

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Estimated Cost

The cost of remibrutinib is not yet known.

Relevant Guidance

NICE Guidance

- NICE technology appraisal in development. Dupilumab for treating chronic spontaneous urticaria in people 12 years and over (GID-TA11272). Expected date of issue to be confirmed.
- NICE technology appraisal. Omalizumab for previously treated chronic spontaneous urticaria (TA339). June 2015.
- NICE clinical guideline. Drug allergy: diagnosis and management (CG183). September 2014
- NICE quality standard. Drug allergy (QS97). July 2015.
- NICE Clinical Knowledge Summaries. Urticaria: Scenario - Managing urticaria. March 2024

NHS England (Policy/Commissioning) Guidance

- NHS England. 2013/14 NHS Standard Contract for Specialised Allergy Services (All Ages). B09/S/b

Other Guidance

- British Society for Allergy and Clinical Immunology (BSACI). BSACI guidelines for the management of chronic urticaria and angio-oedema. 2015.[21]

Additional Information

Novartis Pharmaceuticals UK Ltd did not enter information about this technology onto the UK PharmaScan database; the primary source of information for UK horizon scanning organisations on new medicines in development. As a result, the NIHR Innovation Observatory has had to obtain data from other sources. UK PharmaScan is an essential tool to support effective NHS forward planning; allowing more effective decision making and faster uptake of innovative new medicines for patients who could benefit. We urge pharmaceutical companies to use UK PharmaScan so that we can be assured of up-to-date, accurate and comprehensive information on new medicines.

References

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