



ACARIZAX® (12 SQ-HDM SLIT) becomes first-in-class treatment approved by NICE for the treatment of allergic rhinitis disease caused by house dust mite allergy

- **12 SQ-HDM SLIT is the only licensed oral treatment and allergy immunotherapy (AIT) treatment in England and Wales that targets the cause of house dust mite allergic rhinitis disease, as opposed to symptomatic management.**^{1,2,3}
- **The underlying protection provided by 12 SQ-HDM SLIT leads to improved disease control and enhanced quality of life through symptom relief and reduced need for other medications, ultimately helping to alleviate a significant burden on the NHS.**^{3,4,5}

30 JANUARY 2025, READING, UNITED KINGDOM

ALK (*ALKB:DC / OMX: ALK B*) today announced that NICE has recommended ACARIZAX (12 SQ-HDM SLIT, also known as ‘sublingual immunotherapy’) for the treatment of moderate to severe house dust mite allergic rhinitis disease in people 12 to 65 years that is persistent despite symptom-relieving medicine.⁶ 12 SQ-HDM SLIT is the first treatment of its kind to be approved by NICE.⁶ This decision paves the way for patient access to this therapy through the NHS.

Allergic rhinitis disease is a prevalent condition in the UK, affecting approximately 26% of adults.⁷ Among these, house dust mite is the most common airborne allergy, affecting approximately half of those living with allergic rhinitis disease – upwards of 5 million people in the UK.⁸ Despite a range of symptomatic treatment options, approximately one million people still live with debilitating and uncontrolled symptoms.⁹

Symptoms of allergic rhinitis disease can include runny/blocked nose, sneezing, wheezing and breathlessness.¹⁰ These symptoms can take a toll on individuals physical health, mental wellbeing, and overall quality of life.¹⁰ Managing allergic rhinitis disease often requires lifestyle adjustments and financial investments, such as frequent deep-cleaning and purchasing specialised products like hypoallergenic bedding.¹¹ The ongoing cost of living crisis further compounds these challenges, disproportionately affecting those living with allergic rhinitis disease.^{11,12}

House dust mite allergy is also a significant strain on the NHS, due to frequent doctor visits, medication costs, and even hospital admissions.^{4,13,14} A modified Delphi Panel (a panel of experts) concluded that the estimated total cost to the NHS of managing people with uncontrolled Allergic Respiratory Disease – a condition where the body produces specific antibodies (called IgE) in response to airborne allergens, affecting the nose, throat, and/or lungs¹⁵ - is approximately £143 million each year.⁵

Prof Adam Fox, Professor of Paediatric Allergy, Guy’s and St Thomas’ Hospitals, “House dust mite allergic rhinitis disease is more than just a nuisance. This chronic condition presents a significant and poorly addressed challenge, impacting patients’ physical health, mental well-being, and overall quality of life,¹⁰ and places a substantial burden on the NHS.^{4,5} NICE’s recommendation of sublingual

immunotherapy is significant as it offers a potential long-term solution,³ offering relief to thousands of people with allergic rhinitis and alleviating strain on our healthcare system.”

12 SQ-HDM SLIT received its marketing authorisation in the UK in May 2021.³ A type of sublingual immunotherapy, these tablets contain a high concentration of dust mite allergens.³ By taking a daily dose, patients can gradually build tolerance in their immune system to the allergy trigger, reducing symptoms and offering a potential long-term solution for those struggling with allergy to house dust mites.³ Through targeting the cause of sufferers’ airborne allergies, sublingual immunotherapy tablets can improve patients’ quality of life, reducing absence from work or school and allowing for greater participation in their daily activities.¹⁶ The use of sublingual immunotherapy is also linked to a reduction in the need for long-term daily medications like steroids and antihistamines.^{2,3,13,14} According to international treatment guidelines, a treatment period of three years is required for allergy immunotherapy to achieve disease modification.¹⁷

12 SQ-HDM SLIT efficacy has been demonstrated in the world’s largest house dust mite sublingual immunotherapy tablet clinical development programme in allergic rhinitis disease and allergic asthma. The programme has involved upwards of 9,000 patients across three continents, and 25 countries, offering 15 years of robust clinical evidence and safety information.*

Amena Warner, Head of Clinical Services, Allergy UK, “When not well managed, house dust mite driven allergic rhinitis can severely impact quality of life for anyone affected. The inability to sleep, work or go to school, along with there being little respite from symptoms, can also bring a mental health burden. Allergy UK welcomes the decision from NICE which recommends an immunotherapy treatment that can offer the potential of a long-term solution for those who haven’t found meaningful relief through existing approaches, like antihistamines and steroids. This is good news for the UK’s airborne allergy community.”

Emil Stage Olsen, General Manager UK and Republic of Ireland, ALK, “NICE’s recommendation of 12 SQ-HDM SLIT marks a revolution in airborne allergy management for UK patients suffering with uncontrolled and debilitating symptoms from house dust mite allergic rhinitis disease. ALK is proud to have been the first allergy company successful in making sublingual immunotherapy for house dust mite allergy available on the NHS, and we look forward to continuing to work with NICE to ensure it can be accessed by eligible patients later this year.”

-ENDS-

Contact information

Media: Simon Bishop, Associate Director Marketing UK & ROI, simon.bishop@alk.net, +44 7385324960

Media: Lottie Williams, Curious Health, lottie@curioushealth.io, +44 7972 151 7972

*Trials: MT-01: 2005-002151-41; MT-02: 2006-001795-20 / NCT00389363; MT-03: 2007-000402-67; MT-04: 2010-018621-19 / NCT01433523; MT-06: 2011-002277-38 / NCT01454544; TO203-1: JapicCTI-111624(en); TO203-3-1: JapicCTI-121847(en); TO203-3-2: JapicCTI-121848(en); TO203-3-3: JapicCTI-152953(en); MK-8237-001: NCT01700192; MK-8237-003: 2012-001855-38 / NCT01644617; MK-8237-009: 2012-005621-70 / NCT01852825; MITI3001: ID:1000603874; MT-09: regID 2006L10180

Investor Relations: Per Plotnikof, Vice President, Corporate Communications, Investor Relations and Strategic Planning, per.plotnikof@alk.net, +45 4574 7527, mobile +45 2261 252

About ALK

ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. It markets allergy immunotherapy ('AIT') treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,900 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

References

-
- ¹ Demoly et al. Clin Transl Allergy 2022;12(3),e12129
 - ² Nolte et al., J Allergy Clin Immunol. 2016 Dec;138(6):1631-1638
 - ³ ACARIZAX® [SmPC](#), (Last accessed: January 2025)
 - ⁴ Modified Delphi advisory panel 2023, data on file
 - ⁵ ALK Value Narrative Calculations 2024, data on file
 - ⁶ National Institute for Health and Care Excellence, Technology Appraisal Guidance, Final Draft Guidance, 12 SQ-HDM SLIT for treating allergic rhinitis and allergic asthma caused by house dust mites (review of TA834). Available at <https://www.nice.org.uk/guidance/indevelopment/gid-ta11355/documents> (Accessed: January 2025)
 - ⁷ Scadding GK et al. Clin Exp Allergy 2017;47(7):856-889
 - ⁸ Demoly, P. et al. 2016; 137(2). doi:10.1016/j.jaci.2015.06.036.
 - ⁹ ALK data on file
 - ¹⁰ Bousquet et al., Allergy 2008; 63 (Suppl. 86): 8–160
 - ¹¹ Allergy UK. [Spotlight on House Dust Mite Allergy](#). March 2023 (Last accessed: January 2025)
 - ¹² Baldacci S. et al (2015) Respiratory Medicine, 109 (1089-1104)
 - ¹³ All Party Parliamentary Group for Allergy and the National Allergy Strategy Group, 2021
 - ¹⁴ Fritzsching. B et al., Lancet Reg Health Eur. REACT study. 2022 Feb; 13
 - ¹⁵ Navarro AM et al., Clin Transl Allergy 2017; 7,16
 - ¹⁶ Roger A. et al., Allergy Asthma Clin Immunol 2016, 12:40
 - ¹⁷ Roberts G et al. Allergy 2018;73(4):765–98