EURneffy® adrenaline nasal spray data demonstrating a pharmacological response comparable to intramuscular adrenaline injection in patients with allergic rhinitis presented at EAACI 2025

June 13, 2025

EUR*neffy*® adrenaline (epinephrine) nasal spray data highlighting a comparable clinical pharmacological response to intramuscular adrenaline injection, despite congestion associated with allergic rhinitis, is presented at the European Academy of Allergy & Clinical Immunology Congress, 13-16 June 2025, Glasgow, United Kingdom (UK).[1]

Dr Anne Ellis, Professor and Chair of the Division of Allergy & Immunology, Department of Medicine, Queen's University, Kingston, Canada, and lead study investigator commented:

"For people living with severe allergies, anaphylaxis is a serious, potentially life-threatening reaction that requires immediate treatment with adrenaline. Injectable adrenaline has been the cornerstone of treatment for many years, significantly reducing morbidity and mortality, but people not carrying or delaying the use of their adrenaline can greatly impact outcomes. An adrenaline nasal spray offers an alternative method of adrenaline delivery that may be easier for patients to manage and administer, leading to timely treatment and potentially better results. Nasal spray delivery has been proven to provide a comparable pharmacological response to injected adrenaline across many dosing considerations, including in this study regardless of nasal congestion associated with allergic rhinitis."

The results of the randomized, crossover, pharmacokinetic (PK) and pharmacodynamic (PD) study demonstrated that in the presence of allergic rhinitis symptoms, two doses of EUR*neffy*® 2 mg nasal adrenaline spray resulted in similar or higher PK/PD responses compared to two doses of 0.3 mg intramuscular adrenaline injection administered manually, suggesting that nasal congestion does not interfere with the pharmacological response of EUR*neffy*® in patients requiring a second dose of adrenaline.[1]

The European Commission granted EUR*neffy*® 2 mg market authorisation in the EU in August 2024 for the emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens, as well as idiopathic or exercise-induced anaphylaxis in adults and children who weigh ≥30 kg.[2] Efforts to secure market access (pricing and reimbursement) for EUR*neffy*® in the individual countries across Europe is progressing. ALK expects to start launching the product from Q3 2025 onwards. EUR*neffy*® is approved and available for use in the United States under the brand name *neffy*® following approval from the US Food and Drug Administration in 2024.[3]

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About EURneffy®

EURneffy® is a compact nasal spray, designed to provide rapid absorption of adrenaline (epinephrine).[2] EURneffy® is well absorbed through the nose and distributed quickly into body tissues, offering a useful alternative to injectable forms of adrenaline for treating severe allergic reactions.[4,5] The solution is simple-to-use[6], non-invasive and more convenient for patients to carry and use; it offers a longer shelf life (30 months) and superior temperature stability compared with existing adrenaline auto-injectors (AAIs), with no special storage requirements.[2] Upon activation, the EURneffy® nasal spray delivers a full, single dose of adrenaline, eliminating the need for priming or complex instructions.[2]

About the EURneffy® development programme

The clinical evaluation of EURneffy® was based on data from the development programme involving over 700 participants.[7] No serious adverse events were reported in clinical studies with EURneffy®.[2] The extensive clinical pharmacological data of EURneffy® 2 mg was comparable to AAIs, with the pharmacodynamics and pharmacokinetics evaluated across a range of dosing conditions, including single and repeat dosing, self-administration by patients, dosing in paediatrics, and during multiple nasal conditions that can cause congestion and rhinorrhoea, such as nasal allergen challenge, and demonstrated to be comparable to AAIs.[2,8]

About anaphylaxis

Anaphylaxis is the most severe form of an allergic reaction, characterised by the acute onset of symptoms involving different organ systems.[9] It is a serious and potentially life-threatening event that can occur within minutes of exposure to an allergen and, regardless of the allergen involved, requires immediate medical intervention.[9] Adrenaline is the recommended first-line treatment for anaphylaxis in the European Union and UK, with AAIs available to patients in the community.[9,10] Prompt treatment with adrenaline significantly reduces morbidity and mortality associated with severe allergic reactions,[10,11] and AAIs have been shown to be highly effective, however there are established limitations with their use.[12-14]

About ALK

ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. ALK manufactures and markets allergy immunotherapy ('AIT') treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,800 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

Forward-looking statements

This announcement contains forward-looking statements, including forecasts of future revenue and operating profit as well as expected business-related events. Such statements are naturally subject to risks and uncertainties as various factors, some of which are beyond the control of ALK, may

cause actual results and performance to differ materially from the forecasts made in this announcement. Such factors include but are not limited to general economic and business-related conditions, including legal issues, uncertainty relating to demand, pricing, reimbursement rules, regulatory approvals, partners' plans and forecasts, fluctuations in exchange rates, competitive factors, and reliance on suppliers. Additional factors include the risks associated with the sourcing and manufacturing of ALK's products. ALK undertakes no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

References

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