EUR*neffy*® 1 mg approved across the EU as the first and only needle-free adrenaline treatment for young children (≥15 kg) at risk of anaphylaxis

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Today, ALK announced that children aged 4 and older living with severe allergies across the EU can now access the first and only needle-free adrenaline treatment for anaphylaxis, after the European Commission (EC) granted marketing authorisation for EUR*neffy*® 1 mg – extending a class of treatment previously available only by injection.

EUR*neffy*® 1 mg is now indicated for the emergency treatment of anaphylaxis due to insect stings or bites, foods, medicinal products and other allergens, as well as idiopathic or exercise-induced anaphylaxis in children aged 4 years and older with a bodyweight between 15 kg and 30 kg. This approval extends the existing marketing authorisation for EUR*neffy*® 2 mg, granted by the EC in August 2024 for the emergency treatment of anaphylaxis in adults and children weighing ≥30 kg.[1,2]

Anaphylaxis – the most severe, life-threatening form of allergic reaction requiring immediate intervention – affects an estimated 1 to 761 out of every 100,000 children in Europe each year, with food allergies responsible for more than two-thirds of cases.[3-5] This approval means more people with severe allergies including children aged 4 years and older (≥15 kg) will be eligible for treatment with EUR*neffy*®, the only needle-free adrenaline-based product currently approved across the EU.

Flora Beiche-Scholz, EVP Commercial Operations Europe, ALK says: *"This approval reflects our continued commitment to expanding treatment options for children with severe allergies. For decades, children at risk of anaphylaxis have been limited to injectable adrenaline – yet fear of needles, hesitancy to act and incorrect administration mean adrenaline is too often not carried or used in time. EURneffy® 1 mg aims to address these barriers, offering an efficacious, needle-free, user-friendly adrenaline solution with the potential to transform the lives of those living with, or caring for, children with severe allergies. This approval brings us closer to ensuring every family affected by severe allergies has a treatment they will actually carry and use."*

Clinical evidence and safety profile

- EUR*neffy*® provides rapid absorption of adrenaline within minutes of administration.[2]
- EUR*neffy*® has an established safety profile, based on clinical data from the EUR*neffy*® development programme involving over 700 participants.[2,6]

- The most common adverse reactions in subjects weighing 15 kg to less than 30 kg treated with EUR*neffy*® 1 mg included: nasal congestion (19.0%), upper respiratory tract congestion (14.3%), dry throat, nasal dryness, and paraesthesia (each 9.5%).[7]
- There were no clinically relevant differences in the safety between the paediatric and adult populations treated with EUR*neffy*®.[7]
- EUR*neffy*® 2 mg performed as well as traditional adrenaline auto-injectors or intramuscular adrenaline across a range of real-world scenarios examining the clinical pharmacological effect including single and repeat doses, self-administration, and situations with nasal congestion from allergies.[2,8]
- EUR*neffy*® 1 mg dose demonstrated a comparable absorption and pharmacodynamic effect in children (15-30 kg) as the 2 mg dose in children and adults above 30 kg.[6]

This approval applies to all 27 European Union (EU) member states, Iceland, Norway and Liechtenstein.

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About EURneffy®

EURneffy® is well absorbed through the nose and distributed quickly into body tissues, offering a portable, pocket-sized alternative to injectable forms of adrenaline for treating severe allergic reactions.[1,2,9] EUR*neffy® has a total shelf life of 30 months (2 mg) and 24 months (1 mg), no special storage requirements and freezing does not affect its shelf life.[2,10] Upon activation, the EURneffy® nasal spray delivers a full, single dose of adrenaline, without the need for priming.[2]*

In the United States (US), Japan and China, EURneffy® 2 mg is approved under the brand name neffy®. In 2025 the US Food and Drug Administration (FDA) approved neffy® 1 mg for the treatment of Type I Allergic Reactions, including anaphylaxis, in children who are aged 4 years and older and weigh 15–30 kg and Japan's Pharmaceuticals and Medical Devices Agency (PDMA) approved neffy® 1 mg and 2 mg doses for the emergency treatment of allergic reactions (anaphylaxis) in adults and children who weigh ≥15 kg.[10,11] EURneffy® / neffy® 2 mg has also been approved by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) and China's National Medical Products Administration (NMPA).[12,13]

About anaphylaxis

Anaphylaxis is the most severe form of an allergic reaction, characterised by the acute onset of symptoms involving different organ systems.[3] 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.[3] Adrenaline is the recommended first-line treatment for anaphylaxis and delays in treatment are associated with increased morbidity and mortality.[14-16] Adrenaline auto-injectors have been shown to be highly efficacious, however there are established limitations with their use.[17-19] Research shows that approximately half of those living with a severe allergy did not administer their auto-injector when needed in an emergency and half did not consistently carry their prescribed auto-injector.[19]

About ALK

ALK is a global specialty pharmaceutical company focused on allergy. ALK's activities cover the entire value chain of developing, sourcing, producing, and marketing a diversified portfolio of products for diagnosing and treating respiratory allergies and severe allergic reactions (anaphylaxis) in both children and adults. Headquartered in Denmark, ALK employs around 2,700 people worldwide and is listed on Nasdaq Copenhagen (Nasdaq: ALK B). Visit us 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.

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