ALK receives positive recommendation for EURneffy® 1 mg: A needle-free anaphylaxis treatment for children

January 29, 2026

Inside Information

ALK (ALKB:DC / OMX: ALK B) today announced that the Committee for Medicinal Products for Human Use ('CHMP') of the European Medicines Agency has adopted a positive opinion recommending the granting of the marketing authorisation for EUR*neffy*® (the trade name for *neffy*® in the EU) to include a 1 mg nasal adrenaline spray 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 children aged 4 years and older with a bodyweight between 15 kg and 30 kg.

The positive CHMP opinion supports an extension to the existing marketing authorisation for EUR*neffy*® 2 mg granted by the European Commission ('EC') in August 2024 for the emergency treatment of anaphylaxis in adults and children who weigh ≥30 kg.

Executive Vice President of R&D, Henriette Mersebach (MD) said: *"We are delighted with the European health authorities' recommendation to grant the EURneffy® 1 mg marketing authorisation which, if approved, will reinforce our paediatric focus by complementing the tablet approvals already obtained for treatment of children with respiratory allergy. EURneffy® 1 mg has the potential to transform the lives of those living with or caring for children with severe allergic reactions, offering a needle-free, ready-to-use adrenaline solution."*

The CHMP opinion will now be reviewed by the EC. If granted, the marketing authorisation, which is expected within the coming months, will be valid in all EU member states, as well as Iceland, Liechtenstein and Norway.

Anaphylaxis is the most severe form of allergic reaction and can be life-threatening with required immediate medical intervention. In Europe, the anaphylaxis incidence rate is approximately 1 to 761 out of every 100,000 children each year. Foods are now the most common trigger of anaphylaxis in children, accounting for more than two-thirds of cases, and hospitalisations because of food allergies in children are increasing.

neffy® is developed by US-based ARS Pharmaceuticals, Inc. ("ARS Pharma"). In November 2024, ALK entered into a strategic license agreement with ARS Pharma granting ALK exclusive global rights to commercialise *neffy*® (including EUR*neffy*® in the EU) with exception of the USA, Australia, New Zealand, Japan, and China. In May 2025, the partnership was extended to include a co-promotion agreement in the USA.

ALK-Abelló A/S

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This announcement contains inside information. This is information that ALK-Abelló A/S is obliged to make public pursuant to the EU Market Abuse Regulation.

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.

Attachment

- Company release_01_26UK_290126_neffy 1mg EU recommendation_UK