EURneffy® approved as the first needle-free anaphylaxis treatment of adults and children in the UK

July 18, 2025

Inside Information

ALK (*ALKB:DC / OMX: ALK B*) today announced that the Medicines and Healthcare Products Regulatory Agency (MHRA) has approved EUR*neffy*® 2 mg in the United Kingdom (UK) for anaphylaxis treatment of adults and children (≥30 kg). The market launch in the UK is expected within the coming months once market access negotiations are completed.

EUR*neffy*® (the trade name for *neffy*® in the EU and the UK) constitutes the first approved adrenaline nasal spray for timely emergency treatment of allergic reactions (anaphylaxis) and holds the potential to transform the lives of patients with severe allergies in the UK. As Europe's largest anaphylaxis market, UK represents an important market for ALK.

With an intuitive, needle-free design, EUR*neffy*® can help more people confidently use adrenaline when it matters most, supporting fast, reliable emergency treatment and ultimately helping improve the chances of successful outcomes and save lives. EUR*neffy*® offers a longer shelf life (30 months) and superior temperature stability compared to existing adrenaline auto-injectors (AAIs).

Executive Vice President of R&D, Henriette Mersebach (MD), said: *"The approval of EURneffy® 2 mg in the UK introduces an alternative and novel adrenaline treatment option for adult and adolescent patients with life-threatening allergies. EURneffy® could improve the lives of people with severe allergic reactions and may facilitate that patients and caregivers continually carry adrenaline wherever they go."*

The MHRA approval was based on the review of data from the EUR*neffy*® development programme involving over 700 participants. No serious adverse events were reported in clinical studies with EUR*neffy*®. The extensive clinical pharmacological data of EUR*neffy*® 2 mg was comparable to AAIs, with the pharmacodynamics and pharmacokinetics evaluated across a range of dosing conditions.

In Europe, anaphylaxis occurs in up to eight out of every 100,000 people each year, and one in 300 people experiences it at some point in their lives. In emergency situations, uncertainty and hesitation with larger auto-injectors are apparent among those at risk.

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.

The approval does not affect ALK's financial guidance for 2025.

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 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.

Attachment

- Company release_11_25UK_180725_neffy approval UK