

neffy® approved as the first needle-free anaphylaxis treatment of adults and children in Canada

ALK (ALKB:DC / Nasdaq Copenhagen: ALK B) today announced that Health Canada has approved *neffy*® 2 mg 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 adult and paediatric patients (≥30 kg).

The approval addresses a critical need for Canadians affected by severe allergies that put them at risk of anaphylaxis. *neffy*® constitutes the first approved nasal adrenaline spray for timely emergency treatment.

neffy® is designed to fit into a pocket for portability. It also has a 30-month shelf life from time of manufacture and can withstand temperature excursions up to 50°C, key differentiators from adrenaline autoinjectors (AAIs).

Executive Vice President, Commercial Operations North America, Edward Jordan said: *“We welcome the approval which marks an important milestone for people in Canada living with the risk of severe allergic reactions. neffy® 2 mg brings a portable, needle-free treatment option designed to help patients and caregivers act quickly and confidently when every minute matters.”*

The regulatory approval was based on the review of data from the *neffy*® development programme involving over 700 participants. No serious side effects were reported in clinical studies with *neffy*®. Moreover, the clinical development programme has generated important clinical evidence across a range of real-world clinical scenarios.

It is estimated that up to 2.5 million people in Canada are affected by severe allergies. Canada will expectedly become ALK’s largest market outside of Europe. The market launch of *neffy*® 2 mg in Canada is expected within the coming months. Submission for regulatory review in Canada of *neffy*® 1 mg for children weighing 15-30 kg is expected later in 2026.

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*® 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 2026.

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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.