



neffy® (epinephrine nasal spray) Approved in Canada as the First and Only Needle-Free Emergency Treatment of Allergic Reactions (anaphylaxis)

April 15, 2026

neffy offers a new delivery method for epinephrine in Canada for adults and children (≥30 kg) living with severe allergic reactions

ALK- Abelló A/S, which licenses the rights to market neffy in Canada, expects availability in the summer of 2026

SAN DIEGO, April 15, 2026 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect against allergic reactions that could lead to anaphylaxis, announced today that Health Canada has granted approval for **neffy** 2 mg (epinephrine nasal spray) for the emergency treatment of allergic reactions (anaphylaxis) in adults and children who weigh 30 kg or more.

"The approval of **neffy** by Health Canada marks a meaningful advancement for the more than 2.5 million people living with allergic reactions that could lead to anaphylaxis¹ in Canada, delivering the first needle-free epinephrine for use at the first signs of an allergic reaction," said Richard Lowenthal, Co-founder, President and CEO of ARS Pharma. "**neffy**'s needle-free design reduces barriers to timely treatment while fitting more naturally into everyday life. It is easy to carry, simple to use, has a 30-month shelf life, temperature excursions up to 122°F (50°C), and, if accidentally frozen, can be used once thawed. In partnership with ALK Canada, we are focused on moving quickly to make **neffy** accessible across the country and helping people feel prepared in an allergic emergency."

ARS Pharma entered into an exclusive licensing agreement with ALK- Abelló A/S (ALK) in November 2024, providing ALK with exclusive rights to commercialize **neffy** in Europe, Canada, United Kingdom and certain other geographies outside of the U.S. Under the terms of the agreement, ARS Pharma has received upfront and milestone payments of \$155 million to date and is eligible to receive up to an additional \$310 million in regulatory and sales milestones, as well as tiered, double-digit royalties in the teens on net sales in licensed geographies. ARS Pharma will be responsible for manufacturing and supplying **neffy** to ALK in Canada and expects **neffy** to be available in the summer of 2026. ARS Pharma anticipates filing for approval of **neffy** 1 mg dose for children greater than 15 kg and less than 30 kg with Health Canada by this summer.

The regulatory clearance in Canada follows the latest granted approval in China for **neffy** in partnership with Pediatrix Therapeutics. The National Medical Products Administration (NMPA) in China is responsible for evaluating medicines and medical devices, previously granted approval for **neffy** 2 mg (epinephrine nasal spray) for the emergency treatment of allergic reactions (anaphylaxis) in adults and children who weigh 30 kg or more in December 2025. ARS Pharma and Pediatrix Therapeutics anticipate filing for approval of **neffy** 1 mg dose for children greater than 15 kg and less than 30 kg in the coming months.

neffy is commercially available in the U.S. for the emergency treatment of allergic reactions, including anaphylaxis, in adults and children who weigh at least 33 pounds (15 kg).

About neffy®

neffy is a nasal spray used for emergency treatment of allergic reactions including anaphylaxis, in adults and children who weigh 33 lbs. or greater.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR **neffy** (epinephrine nasal spray)

INDICATION

neffy is indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 33 lbs. or greater.

IMPORTANT SAFETY INFORMATION

neffy contains epinephrine, a medicine used to treat allergic emergencies (anaphylaxis). Anaphylaxis can be life-threatening, can happen in minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or other unknown causes.

Always carry two **neffy** nasal sprays with you because you may not know when anaphylaxis may happen and because you may need a second dose of **neffy** if symptoms continue or come back. Each **neffy** contains a single dose of epinephrine. **neffy** is for use in the nose only.

Use **neffy** right away, as soon as you notice symptoms of an allergic reaction. If symptoms continue or get worse after the first dose of **neffy**, a second dose is needed. If needed, administer a second dose using a new **neffy** in the same nostril starting 5 minutes after the first dose. Get emergency medical help for further treatment of the allergic emergency (anaphylaxis), if needed after using **neffy**.

Tell your healthcare provider if you have underlying structural or anatomical nasal conditions, about all the medicines you take, and about all your medical conditions, especially if you have heart problems, kidney problems, low potassium in your blood, Parkinson's disease, thyroid problems, high blood pressure, diabetes, are pregnant or plan to become pregnant, or plan to breastfeed.

Tell your healthcare provider if you take or use other nasal sprays or water pills (diuretics) or if you take medicines to treat depression, abnormal heart beats, Parkinson's disease, heart disease, thyroid disease, medicines used in labor, and medicines to treat allergies. **neffy** and other medications may affect each other, causing side effects. **neffy** may affect the way other medicines work, and other medicines may affect how **neffy** works.

neffy may cause serious side effects. If you have certain medical conditions or take certain medicines, your condition may get worse, or you may have more or longer lasting side effects when you use neffy.

Common side effects of **neffy** include: nasal discomfort, headache, throat irritation, chest and nasal congestion, feeling overly excited, nervous or anxious, nose bleed, nose pain, sneezing, runny nose, dry nose or throat, tingling sensation, including in the nose, feeling tired, dizziness, nausea, and vomiting.

Tell your healthcare provider if you have any side effects that bother you or that do not go away after using **neffy**.

These are not all of the possible side effects of **neffy**. Call your healthcare provider for medical advice about side effects. To report side effects, contact ARS Pharmaceuticals Operations, Inc. at **1-877-MY-NEFFY (877-696-3339)** or the FDA at **1-800-FDA-1088** or www.fda.gov/medwatch.

Please see the full [Prescribing Information](#) and [Patient Information](#) for **neffy**.

About Type I Allergic Reactions Including Anaphylaxis

Type I allergic reactions are serious and potentially life-threatening events that can occur within minutes of exposure to an allergen and require immediate treatment with epinephrine, the only FDA-approved medication for these reactions. While epinephrine auto-injectors have been shown to be highly effective, there are well published limitations that result in many patients and caregivers delaying or not administering treatment in an emergency situation. These limitations include fear of the needle, lack of portability, needle-related safety concerns, lack of reliability, and complexity of the devices. There are approximately 40 million people in the United States who experience Type I allergic reactions. Of this group, over the last three years, approximately 20 million people have been diagnosed and treated for severe Type I allergic reactions that may lead to anaphylaxis, but (in 2023, for example) only 3.2 million filled their active epinephrine auto-injector prescription, and of those, only half consistently carry their prescribed auto-injector. Even if patients or caregivers carry an auto-injector, more than half either delay or do not administer the device when needed in an emergency.

About ARS Pharmaceuticals, Inc.

ARS Pharma is a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis. The Company is commercializing **neffy**[®] (trade name **EURneffy**[®] in the EU and 优敏速[®] in China), an epinephrine nasal spray indicated in the U.S. for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult patients and pediatric patients who weigh 33 lbs. or greater, and in the EU for 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 or greater. For more information, visit www.ars-pharma.com.

Forward Looking Statements

Statements in this press release that are not purely historical in nature are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to: the patient benefits and effectiveness of **neffy**, including its extended shelf life, needle-free, compact, portable and easy to use design, temperature stability and temperature-handling flexibility; evaluations regarding **neffy** commercialization strategies in Canada; expected benefits from the licensing agreement with ALK and the potential to achieve regulatory milestone and royalty payments; the expected timing of commercial launch in Canada; the anticipated timing of filing for approval of **neffy** 1 mg in China and Canada; and other statements that are not historical fact. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “anticipate,” “believe,” “can,” “could,” “expect,” “if,” “may,” “on track to/for,” “potential,” “plan,” “will,” “would,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS Pharmaceuticals’ current expectations and involve assumptions that may never materialize or may prove to be incorrect.

Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation: potential safety and other complications from **neffy**; the ability to obtain and maintain regulatory approval for **neffy** in its currently approved indications; the scope, progress and expansion of developing and commercializing **neffy**; the scope, progress and expansion of developing our intranasal epinephrine technology; clinical trial results; the potential for governments and payors to delay, limit or deny coverage for **neffy**; the size and growth of the market for **neffy** and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; ARS Pharma’s ability to protect its intellectual property position; and the impact of government laws, regulations and policies. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption “Risk Factors” in ARS Pharma’s Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 9, 2026. This document can also be accessed on ARS Pharma’s website at www.ars-pharma.com by clicking on the link “Financials & Filings” under the “Investors & Media” tab.

The forward-looking statements included in this press release are made only as of the date hereof. ARS Pharma assumes no obligation and does not intend to update these forward-looking statements, except as required by law. For more information, visit www.ars-pharma.com, and follow us on [LinkedIn](#) and [X](#).

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