neffy® (epinephrine nasal spray) Approved in China as the First and Only Community Use Epinephrine Product for the Treatment of Allergic Reactions (anaphylaxis)

December 29, 2025

__neffy__ is the first epinephrine product approved for use out of a hospital setting in China for adults and children (≥30 kg) living with severe allergic reactions

Pediatrix Therapeutics, which has a license from ARS Pharma to market __neffy__ in China under the trade name 优敏速®, expects availability in the spring of 2026

SAN DIEGO, Dec. 29, 2025 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a commercial-stage biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis, announced that the National Medical Products Administration (NMPA) in China has granted approval for ***neffy*** 2 mg (epinephrine nasal spray) for the emergency treatment of Type 1 allergic reactions (anaphylaxis) in adults and children who weigh 30 kg or more. In China, the trade name is 优敏速® meaning “Excellent Allergy (treatment) Fast”. 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.

There are currently no approved community use epinephrine products in China, including auto-injectors. Approximately 4.0% to 8.2% of the population of China (about 50 to 100 million people), is estimated to be affected by food allergies and at risk for severe allergic reactions.[1] Additionally, for chronic spontaneous urticaria (CSU), which is currently in Phase 2b development by ARS Pharma, 6.5 million people are estimated to be diagnosed and treated with antihistamines or biologics today in China.[2]

“The approval of ***neffy*** in China represents a significant advancement for the millions of patients and caregivers managing severe allergic reactions whose only option until now was to seek emergency medical help without the option to self-administer epinephrine in a community setting,” said Richard Lowenthal, Co-founder, President and CEO of ARS Pharma. “As the first community use epinephrine product available in the Chinese market, ***neffy*** has the potential to transform how severe allergies are treated, enabling earlier epinephrine use at the first signs of symptoms and reducing barriers that can delay care. We believe this innovation can meaningfully improve preparedness, confidence, and outcomes for patients and families across China and we look forward to working with the Pediatrix Therapeutics team to make ***neffy*** available promptly.”

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 temperature excursions up to 122^{o}F (50^{o}C), and, if accidentally frozen, can be used once thawed without damage to the device or product within.

ARS Pharma entered into an exclusive licensing agreement with Pediatrix Therapeutics in 2021, providing them with exclusive rights to commercialize ***neffy*** in China for severe allergic reactions (anaphylaxis) as well as certain other diseases such as chronic spontaneous urticaria. ARS Pharma will receive a final regulatory milestone of $4 million and is eligible to receive up to $80 million in sales milestones, as well as tiered royalties in the low double digits on annual net sales. ARS Pharma will be responsible for manufacturing and supplying ***neffy*** to Pediatrix Therapeutics in China at cost of goods and expects ***neffy*** to be available in the spring of 2026.

The regulatory clearance in China follows recent approval in Australia for ***neffy*** in partnership with CSL Seqirus, a subsidiary of CSL Limited (ASX: CSL). The Therapeutics Goods Administration (TGA), the Australian authority responsible for evaluating medicines and medical devices, granted approval for ***neffy*** (epinephrine nasal spray) for the emergency treatment of allergic reactions (anaphylaxis) in adults and children who weigh 15 kg or more. Both 1 mg and 2 mg doses were concurrently approved by the TGA. Approval in New Zealand is expected by the end of 2025.

neffy is commercially available in the U.S. for the emergency treatment of allergic reactions, including anaphylaxis, in adults and children aged 4 years and older who weigh at least 33 pounds (15 kg). Earlier this year, ARS Pharma’s European partner, ALK successfully launched **EUR*neffy*** in Europe and the U.K.

Pediatrix Therapeutics is a pediatrics-focused biotechnology company based in China bringing high quality, pediatric-friendly and affordable therapeutics and healthcare products to children and families. Pediatrix Therapeutics was jointly founded in 2021 by Eight Roads, F-Prime Capital, and Creacion Ventures with established offices in Shanghai and Beijing.

About *neffy*®

neffy is approved in the United States as both a 1 mg and 2 mg dose for emergency treatment of allergic reactions including anaphylaxis, in adults and children aged 4 years and older 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 aged 4 years and older 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 **EU*Rneffy***® 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 4 years of age and older 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 needle-free, compact, portable and easy to use design, and temperature stability; evaluations, judgments and expectations regarding ARS Pharma’s commercialization strategies; the potential market and demand for ***neffy*** in China; expected benefits from the licensing agreement with Pediatrix Therapeutics and the potential to achieve regulatory milestone or receive royalty payments; the anticipated timing of regulatory decisions for ***neffy*** in New Zealand; the expected timing of commercial launch in China; the anticipated timing of filing for approval of ***neffy*** 1 mg dose for children greater than 15 kg and less than 30 kg in China; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, filed with the SEC on November 10, 2025. 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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