ARS Pharmaceuticals' neffy® (epinephrine nasal spray) 1 mg is Now Available in the United States for Type I Allergic Reactions, including Anaphylaxis, in Pediatric Patients Weighing 15 to < 30 Kilograms

May 7, 2025

*The availability of **neffy** 1 mg extends protection to younger, school-aged children—who make up nearly 23% of people needing epinephrine*

Visit neffy.com for savings and support programs and pay as little as $25 (if eligible) in preparation for summer travel and back-to-school

SAN DIEGO, May 07, 2025 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis, announced ***neffy***® (epinephrine nasal spray) 1 mg is now available to patients and caregivers by prescription across the U.S. In March 2025, the U.S. Food and Drug Administration approved ***neffy*** for the treatment of Type I allergic reactions, including anaphylaxis, in children who are aged four years and older and weigh 15 to < 30 kilograms (33 to < 66 lb.).

"Many children fear needles, which can lead parents to delay administering needle-based epinephrine treatments. This delay may result in serious consequences," Eric Karas, Chief Commercial Officer of ARS Pharma, states. "The availability of the 1 mg dose before summer travel, camps, and back-to-school season will help communities better prepare for allergic emergencies. The needle-free design of ***neffy*** also eliminates the risk of adverse events, such as accidental injections into the hands or fingers of a child or caregiver, which happens about 3,500 times each year. Now is a great time for parents to reach out to their healthcare providers to ask for ***neffy*** as a treatment for their young children."

neffy is small and designed to be easy-to-use, making it convenient to carry in a backpack or lunchbox. Human factor studies show one hundred percent of users dosed ***neffy*** successfully by following instructions, compared with up to 35% error rates with injection devices. The device has a shelf life of 24 months and tolerance to temperature exposures up to 122°F (50°C) based on testing for up to three months. If accidentally frozen, ***neffy*** can be thawed without impact on the product quality and reliability.

ARS Pharma is committed to access and affordability, and provides comprehensive support programs to patients, caregivers, and healthcare professionals with information to guide their treatment journey, details about medication fulfillment services, financial assistance, and navigating insurance requirements. Eligible commercially insured patients will pay no more than $25 for two single-use ***neffy*** devices through a co-pay savings program and some insurers may also provide multiple packs so ***neffy*** can be kept handy at school, home, and other caregiving locations. The co-pay savings card will be automatically loaded at many retail pharmacies but can also be accessed at neffy.com, downloaded to an Apple Wallet, and provided to the pharmacy. The cash price for ***neffy*** is $199 for two doses on the GoodRx website. For certain uninsured or underinsured U.S. residents meeting eligibility criteria and exhausted all other options, the ARS Pharma Patient Assistance Program (PAP) will provide ***neffy*** at no cost.

"We've been focused on working with leading, national insurance companies to ensure that ***neffy*** is readily available to patients," says Richard Lowenthal, Co-Founder, President, and CEO of ARS Pharma. "We are making great progress with United Healthcare, Express Scripts, OptumRx and others, recognizing the value of ***neffy*** and we anticipate expanding commercial coverage over the summer so people can get ***neffy*** without restrictions or additional paperwork from physicians. We believe this will give young patients and caregivers greater peace of mind as they head into the new school year."

"The expanded availability of ***neffy*** represents real progress for our community, especially for young children who may be more likely to speak up about symptoms of a serious allergic reaction when they know epinephrine can be given without a needle," said Sung Poblete, PhD, RN, CEO of FARE (Food Allergy Research & Education), the leading nonprofit organization dedicated to food allergy. "This news means more families will have options that help them be ready to act and administer 'Epi first, Epi fast' when a reaction occurs—in those moments when every second counts. We commend ARS Pharma for its commitment to innovation, access, and the prioritization of the needs of patients with severe food allergy."

Eligible schools participating in the ***neffy***inSchools program can receive ***neffy*** 1 mg upon availability. For more information visit www.neffy.com. Additional details about ***neffy*** insurance coverage can be found here.

About *neffy*®
neffy is a nasal spray used 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 Pharmaceuticals 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 **EUR*neffy***® in the EU), an epinephrine nasal spray indicated in the U.S. for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult and pediatric patients 4 years of age and older who weigh 15 kg 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 potential market and demand for ***neffy***; the belief that the current availability of ***neffy*** 1 mg will help communities prepare ahead of the summer months and back-to-school season; the platforms through which ***neffy*** will be accessible, including GoodRx, the ARS Pharma Patient Assistance Program, and ***neffy***inSchools; expectations about the costs of ***neffy*** for patients; the belief that ARS Pharma is making progress with insurers and pharmacies and will expand commercial coverage and availability this summer; the needle-free profile of ***neffy*** potentially increasing the likelihood that patients may both carry and administer epinephrine; 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,” “if,” “likely,” “may,” “potential,” “on track to,” “plans,” “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: reliance on third parties to promote and sell ***neffy***; the potential safety and other complications from ***neffy***; the ability to maintain regulatory approval for ***neffy*** in its currently approved indications; the scope, progress and expansion of developing and commercializing ***neffy***; the potential for governments and payors to delay, limit or deny coverage for ***neffy***; the size and growth of the market therefor and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; ARS Pharmaceuticals’ ability to protect its intellectual property position; and the impact of government laws and regulations. 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 Pharmaceuticals’ Quarterly Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission (“SEC”) on March 20, 2025. This document can also be accessed on ARS Pharmaceuticals’ 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 Pharmaceuticals 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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