ARS Pharmaceuticals Announces FDA Approval of neffy® 1 mg (epinephrine nasal spray) for Type I Allergic Reactions, Including Anaphylaxis, in Pediatric Patients Weighing 15 to < 30 Kilograms

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neffy 1 mg *is the first and only needle-free epinephrine treatment approved for younger children*

SAN DIEGO, March 05, 2025 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from allergic reactions that could lead to anaphylaxis, announced today that the U.S. Food and Drug Administration (FDA) has approved ***neffy*® 1 mg** (epinephrine nasal spray) for the treatment of Type I Allergic Reactions, including anaphylaxis, in children who are aged 4 years and older and weigh 15 to < 30 kilograms (33 to < 66 lb.). This approval represents the first significant innovation in the delivery of epinephrine for this patient population in more than 35 years.

In the general population, approximately one in 13 children have severe food allergies, and more than 40 percent have experienced severe reactions.[1] Despite the clear link between early epinephrine use and better outcomes, research shows that approximately 40 percent of patients delay treatment[2], and 56 percent of caregivers fear using needle-based auto-injectors on their child[3]. ***neffy*** eliminates needles, delivering a precise epinephrine dose via a simple nasal spray, almost instantly, with no nasal hold time required.

"Today's FDA approval of ***neffy* 1 mg** marks a major milestone towards our efforts to transform the management of severe allergic reactions," says Richard Lowenthal, Co-Founder, President, and CEO of ARS Pharma. "Many children and caregivers fear needle-based auto-injectors, which can delay lifesaving treatment. ***neffy's*** needle-free, easy-to-use design addresses this unmet need, offering families a long-awaited alternative. With nearly four out of 10 U.S. epinephrine prescriptions written for children under the age of 18—and nearly a third of those for children weighing 15 to 30 kilograms[4] —we believe ***neffy* 1 mg** will improve access to a needle-free option for the treatment of severe allergies and reduce hesitation in treating this vulnerable group. It will also eliminate risks like accidental needle injuries to children or caregivers."

The approval of ***neffy* 1 mg** is based on data from extensive clinical trials, including pharmacokinetic (PK) and pharmacodynamic (PD) responses in pediatric and adult subjects that were consistent with those of epinephrine injection products. Adverse events in pediatric trials were generally mild and transient. Human factor studies also show children as young as 10 can use ***neffy*** effectively by following instructions, and that even untrained individuals, such as babysitters or teachers, can effectively administer ***neffy***. The device has a shelf-life of 24 months at room temperature and tolerance to temperature exposures up to 122°F (50°C) based on testing for up to 3 months. If accidentally frozen, ***neffy*** can be thawed without impact on the product quality and reliability.

"The availability of a needle-free epinephrine option for children is a breakthrough in the treatment of severe allergic reactions," says Dr. David Fleischer, Section Head of Allergy & Immunology, and Professor of Pediatrics, at Children's Hospital Colorado. "Many people wait to administer epinephrine until symptoms progress or take antihistamines as a first line of defense because they are afraid of injection. ***neffy's*** small, user-friendly design addresses these challenges, empowering people to actually carry epinephrine and act quickly and confidently during an allergic emergency. This innovation will likely significantly improve health outcomes and enhance quality of life."

ARS Pharma is committed to access and affordability, and ***neffy* 1 mg** is expected to be available in the U.S. by the end of May 2025. The ***neffy***Connect program provides patients, caregivers, and healthcare professionals with information to guide their treatment journey, details about medication fulfillment services, financial support and navigating insurance requirements. Most commercially insured patients will pay no more than $25 for two single-use neffy devices through a co-pay savings program. The co-pay savings card can be accessed at neffy.com and downloaded to an Apple Wallet and provided to the pharmacy. If the product isn't covered by insurance, the cash price of $199 for two doses is available through BlinkRx and coupon can be downloaded from GoodRx for use at local retail pharmacies. 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.

Eligible schools participating in the ***neffy***inSchools program can receive ***neffy* 1 mg** upon availability. For more information, and to register for ***neffy***Connect, visit www.neffy.com.

The approval of ***neffy* 1 mg** follows FDA approval for ***neffy*** 2 mg on August 9, 2024 for children and adults weighing 30kg (66 lb.), and approval for **EUR*neffy*** in the EU by the European Commission on August 22, 2024.

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) (previously referred to as ARS-1), an epinephrine nasal spray indicated in the U.S. for emergency treatment of Type I allergic reactions, including anaphylaxis, 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 expectation that ***neffy*** will save lives; the effectiveness of ***neffy***; ***neffy****Connect*’s ability to help patients and HCPs access financial support and medication fulfillment services; ARS Pharmaceuticals’ commercial coverage goals and the timing thereof; the expected timing for product availability of ***neffy* 1 mg**; ***neffy’s*** ability to improved health outcomes and quality of life; ***neffy’s*** shelf life and its effectiveness after being subject to extreme temperatures; 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,” “expects,” “if,” “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: 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-Q for the quarter ended September 30, 2024, filed with the Securities and Exchange Commission (“SEC”) on November 13, 2024. These documents 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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