ARS Pharmaceuticals Announces Planned Launch of neffyinSchools Program to Provide Life-Saving Needle Free Epinephrine to Eligible K-12 Schools at No Cost

December 4, 2024

*Qualifying public and private K-12 Schools in the U.S. will be eligible to receive two free cartons (four single use doses) of **neffy**® (epinephrine nasal spray) 2mg for use in emergency treatment of allergic reactions including anaphylaxis*

*Interested schools are encouraged to review applicable state laws and regulations to ensure **neffy** for undesignated use meets all requirements*

SAN DIEGO, Dec. 04, 2024 (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 it will be launching the ***neffy*inSchools** Program in January 2025. The program will provide eligible public and private K-12 schools in the U.S. the opportunity to receive two cartons (four single use doses) of ***neffy***® *(epinephrine nasal spray)* 2mg for use in emergency situations at no cost to the school. ***neffy*** 2mg was recently approved for the treatment of Type I Allergic Reactions, including anaphylaxis, in adults and children who weigh ≥30 kg (66 lbs.) Participating schools will be eligible to receive replacement doses when the product is used or expires.

Type 1 allergic reactions can be life-threatening, can happen in minutes, and can be caused by stinging and biting insects, foods, medication, exercise, or other unknown causes. Studies show that up to 18% of children with food allergies have had a reaction from accidentally eating food allergens while at school.[1] In addition, 25% of severe and potentially life-threatening reactions (anaphylaxis) reported at schools happened in children with no previous diagnosis of food allergy.[1]

“The potential for severe allergic reactions to food, medication, exercise or insect bites can quickly result in an emergency if epinephrine is not available. Since many unexpected allergic reactions happen during the school day, readily available epinephrine is crucial,” says Richard Lowenthal, Co-Founder, President and CEO of ARS Pharmaceuticals. “Additionally, many people, including students, have a fear of needles which could impact, delay or prevent the use of an auto-injector. We are committed to making ***neffy,*** the only needle-free epinephrine treatment option, available free of charge to all eligible schools through our ***neffy*inSchools** program because we know ***neffy*** will save lives**.** We also understand that there are currently many challenges for schools that stock epinephrine. ***neffy*** is safer for school staff when administering epinephrine in allergy emergency situations, is easier to dispose as ***neffy*** doesn’t contain any sharps, and it has a long shelf life of 30 months.”

In advance of the ***neffy*inSchools** launch, schools are encouraged to review applicable state legislation to ensure ***neffy*** meets the requirements of local epinephrine stocking and indemnification laws for undesignated use. Currently, 49 states and Washington DC have legislation in place to allow schools to stock epinephrine. The details of each state’s legislation, and ability to stock ***neffy*** specifically, may vary. For states that do not yet allow for ***neffy*** because stocking protocols have not been updated to reflect this product and/or route of administration, school administrators may need to contact their state legislator to request modifications to state legislation to ensure school personnel are indemnified from liability for use of FDA approved epinephrine products. Many patient advocacy groups have information and resources on this topic that can be found here.

A webinar will be hosted on December 12 to provide information to school nurses and adminstrators about the ***neffy*inSchools** program, general information about ***neffy*** as well as training and other online resources. Following the program’s official launch in January 2025, ARS Pharma will provide application instructions to schools to receive ***neffy*** 2mg.

More information about this program can be found at www.ars-pharma.com and www.neffy.com under the Community Program tab. Additional updates will be provided on ARS LinkedIn and X pages. The ***neffy*inSchools** program is subject to the more detailed terms and conditions which will be available on the Company’s website prior to the official launch of the neffyinSchools program.

About *neffy*inSchools

ARS is committed to working with our communities to provide essential epinephrine in schools. Eligible public and private K-12 schools in the U.S. (excluding territories) will be able to receive two cartons (four single use doses) of ***neffy*** 2mg for adults and children who weigh ≥30 kg (66 lbs.), in emergency situations. The ***neffy*inSchools** program is only for undesignated use, and children with prescriptions for epinephrine from their healthcare provider must continue to supply medication to their school in accordance with school guidelines. Schools must review applicable state legislation to ensure ***neffy*** meets the requirements of local epinephrine stocking and administration laws for undesignated use. The supplemental NDA for ***neffy*** 1mg dose was granted priority review by the FDA and has a PDUFA date set for March 6, 2025. If approved, ***neffy*** 1mg will be available to schools for students who weigh between 33 and 66 lbs. The neffyinSchools program is subject to the more detailed terms and conditions which will be available on the Company’s website prior to the official launch of the neffyinSchools program

About *neffy*®

neffy is an intranasal epinephrine product for patients with Type I allergic reactions including food, medications, and insect bites that could lead to life-threatening anaphylaxis.

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

INDICATION

neffy 2 mg is indicated for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater.

IMPORTANT SAFETY INFORMATION

It is recommended that patients are prescribed and have immediate access to two ***neffy*** nasal sprays at all times. In the absence of clinical improvement or if symptoms worsen after initial treatment, administer a second dose of ***neffy*** in the same nostril with a new nasal spray starting 5 minutes after the first dose.

neffy is for use in the nose only.

Advise patients when to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.

Absorption of ***neffy*** may be affected by underlying structural or anatomical nasal conditions.

Administer with caution to patients who have heart disease; epinephrine may aggravate angina pectoris or produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or taking cardiac glycosides, diuretics, or anti-arrhythmics.

The presence of a sulfite in ***neffy*** should not deter use.

neffy may alter nasal mucosa for up to 2 weeks after administration and increase systemic absorption of nasal products, including ***neffy***.

Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions.

Epinephrine can temporarily exacerbate the underlying condition or increase symptoms in patients with the following: hyperthyroidism, Parkinson's disease, diabetes, renal impairment. Epinephrine should be administered with caution in patients with these conditions, including elderly patients and pregnant women.

Adverse reactions to ***neffy*** may include throat irritation, intranasal paresthesia, headache, nasal discomfort, feeling jittery, paresthesia, fatigue, tremor, rhinorrhea, nasal pruritus, sneezing, abdominal pain, gingival pain, hypoesthesia oral, nasal congestion, dizziness, nausea, and vomiting.

These are not all of the possible side effects of ***neffy***. To report suspected adverse reactions, contact ARS Pharmaceuticals Operations, Inc. at 1-877-MY-NEFFY (877-696-3339) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For additional information on ***neffy***, please see Full Prescribing Information at www.***neffy***.com.

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 autoinjectors 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 autoinjector prescription, and of those, only half consistently carry their prescribed autoinjector. Even if patients or caregivers carry an autoinjector, 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***® 2 mg (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, in adult and pediatric patients who weigh 30 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 expected timing and launch of ***neffy*****inSchools**; the needle-free profile of ***neffy*** and making ***neffy*** available at no cost to eligible public and private K-12 schools increasing the likelihood that such schools will both carry and administer adrenaline to students experiencing an allergic reaction; the expectation that ***neffy*** will save lives; the potential for stocking ***neffy*** to qualify under indemnification laws for undesignated use; 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***; ARS Pharmaceuticals may not receive the anticipated benefits from the ***neffy*****inSchools** program; public and private schools may be participate in the ***neffy*****inSchools** program to the degree or on the timelines expected by ARS Pharmaceuticals the scope, progress and expansion of developing and commercializing ***neffy***; the potential for 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; the impact of government laws and regulations; and the PDUFA target action date may be delayed due to various factors outside ARS Pharmaceuticals' control. 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.

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[1] Centers for Disease Control and Prevention. *Voluntary Guidelines for Managing Food Allergies in Schools and Early Care and Education Programs*. Washington, DC: US Department of Health and Human Services; 2013.