ARS Pharmaceuticals Launches neffyinSchools Program Providing Free Life-Saving Needle-Free Epinephrine For Emergency Use to Eligible K-12 Schools

January 21, 2025

*School administrators and nurses are encouraged to review applicable state laws and regulations to ensure **neffy**® (epinephrine nasal spray) 2 mg for undesignated use meets applicable state law requirements*

*Interested schools can visit **neffy.com**/community-programs to apply*

SAN DIEGO, Jan. 21, 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 the launch of the ***neffy*inSchools** program. ***neffy*inSchools** provides eligible public and private K-12 schools in the U.S. with the opportunity to receive two cartons (four single use doses) of ***neffy***® *(epinephrine nasal spray)* 2 mg for use in emergency situations at no cost to the school via the School Health Corp. SHConnect platform. ***neffy*** 2 mg is 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.

“School nurses play a pivotal role in the health and wellbeing of students. Unexpected allergic reactions can happen at any time – including during the school day – so it is crucial to have epinephrine readily available to administer by nurses and other trained school officials. The ***neffy*inSchools** program will help schools to obtain epinephrine free of cost. This positions schools to be ready to provide emergency treatment for severe allergic reactions,” said Kenneth Mendez, President and CEO of the Asthma and Allergy Foundation of America.

Life-threatening, Type 1 allergic reactions can happen quickly and be caused by foods, insects, medication, exercise, or other unknown causes. It is estimated that one-quarter of anaphylactic reactions in schools are among students with previously undiagnosed allergies.[1] Studies also show that food allergy affects approximately 1 in 20 school-aged children.[2]

"We are deeply committed to ensuring ***neffy*** is freely available to all eligible K-12 schools, providing life-saving epinephrine for emergency situations without fear or hesitation,” said Richard Lowenthal, Co-Founder, President, and CEO of ARS Pharma. “ ***neffy*** is a groundbreaking device with a simple, needle-free design that we believe will make schools safer and better prepared to address anaphylaxis. While anaphylaxis can progress rapidly and occur at any time, many states must update their legislation to include nasal delivery in local epinephrine stocking and indemnification laws, for undesignated use, before it can be provided to schools."

ARS Pharma will host a webinar for school nurses and administrators about ***neffy*** and the ***neffy*inSchools** program on January 22, 2025. Participants are encouraged to register here.

For more information, including details about patient advocacy groups and resources for schools, visit www.neffy.com/community-programs. For specific inquiries, please email CommunityPrograms@ars-pharma.com. Ongoing updates will be provided on ARS LinkedIn and X pages.

About *neffy*inSchools
ARS Pharma 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*** 2 mg 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*** 1 mg dose was granted priority review by the FDA and has a PDUFA date set for March 6, 2025. If approved, ***neffy*** 1 mg will be available to schools for students who weigh between 33 and 66 lbs.

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 epinephrine to students experiencing an allergic reaction; the expectation that ***neffy*** will save lives; the potential for ***neffy*** to qualify under local and state stocking and indemnification laws for undesignated use; the expected timing for obtaining regulatory approval for ***neffy*** 1 mg and the availability thereof; 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 not 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; and ARS Pharmaceuticals' ability to protect its intellectual property position; 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.

ARS Investor Contact:
Justin Chakma
ARS Pharmaceuticals
justinc@ars-pharma.com

ARS Media Contact:
Christy Curran
Sam Brown Inc.

615.414.8668
christycurran@sambrown.com

References:

1. Hogue SL, Muniz R, Herrem C, Silvia S, White MV. Barriers to the Administration of Epinephrine in Schools. J Sch Health. 2018 May;88(5):396-404. doi: 10.1111/josh.12620. PMID: 29609214.

2. Kao, L. M., Wang, J., Kagan, O., Russell, A., Mustafa, S. S., Houdek, D., Smith, B., & Gupta, R. (2018). School nurse perspectives on school policies for food allergy and anaphylaxis. *Annals of Allergy, Asthma and Immunology*, *120*(3), 304-309. https://doi.org/10.1016/j.anai.2017.12.019