ARS Pharmaceuticals Submits sNDA to FDA for neffy® 1 mg Dose for Pediatric Patients with Type I Allergic Reactions Who Weigh 15 to 30 kg (33-66 lbs.)

September 9, 2024

*If approved, **neffy 1 mg** will be the first and only needle-free epinephrine treatment available for younger school-aged children*

*The submission of **neffy 1 mg** sNDA follows FDA approval on August 9, 2024, of **neffy** (2 mg) for the treatment of Type I Allergic Reactions, including anaphylaxis, in adults and children who weigh 30 kg (66 lbs.) or greater*

SAN DIEGO, Sept. 09, 2024 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from severe allergic reactions that could lead to anaphylaxis, announced today the submission of a supplemental New Drug Application (sNDA) for ***neffy*® 1 mg** for the treatment of Type I Allergic Reactions, including anaphylaxis, in children who weigh 15 to 30 kg (33-66 lbs.). Pharmacokinetic (PK) data for ***neffy* 1mg** were slightly higher than that of adults who receive the same dose and pharmacodynamic (PD) response was similar.

Food allergies affect approximately six million children in the U.S., of which more than 40 percent have experienced a severe allergic reaction such as anaphylaxis. Additionally, studies show that two out of three children are afraid of needles and more than half of parents express fear about using their child's epinephrine auto-injector – a potentially lifesaving treatment.

"Fear of needles is a common reason children refuse treatment with auto-injectors. If approved, ***neffy* 1mg** will be the first needle-free epinephrine option for younger children, in addition to being the first new delivery method for this population in more than 35 years," says Richard Lowenthal, Co-Founder, President and CEO of ARS Pharmaceuticals. "Nearly half of all current epinephrine auto-injector prescriptions are for children, and more than half of those are for children weighing 15 to 30 kg (33-66 lbs.). We believe there is a clear need for innovative treatments like ***neffy* 1mg**."

Highlights from the data submitted to the FDA underscore several key attributes:

- No risk of needle-related adverse events including accidental injection into the hand or fingers of a child or caregiver. This occurs approximately 3,500 times each year in the U.S. with epinephrine injection devices and disproportionately affects 15 to 30 kg (33-66 lb.) pediatric patients.
- Simple insert and press mechanism delivers epinephrine almost instantly without any hold time required in the nose.
- Human factor studies showed that adults without knowledge of the disease or device (e.g. a babysitter or a teacher), were able to successfully use the device by simply reading the instructions. These studies also showed that untrained children as young as 10 years of age can easily use ***neffy*** with self-administration.
- ***neffy*** allows for temperature exposure up to 122°F (50°C). If accidentally frozen, it can be thawed and administered.

"There is no doubt that this innovation is going to save lives. Patients need options, and ***neffy*** is helping to solve that issue," said Eleanor Garrow-Holding, President and CEO of the Food Allergy & Anaphylaxis Connection Team (FAACT), a national patient advocacy group raising awareness for all individuals affected by food allergies and life-threatening anaphylaxis. "There has been little advancement in emergency treatments for this community, especially to address concerns about children carrying and using an epinephrine auto-injector. For the safety of our children with food allergies, making ***neffy* 1mg** available as soon as possible must be a high priority."

About Type I Allergic Reactions including Anaphylaxis
Type I severe 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 severe allergic reactions due to food, venom or insect stings. Of those, only 3.3 million currently have an 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 severe allergic reactions that could lead to anaphylaxis. The Company is commercializing ***neffy*® 2mg** (trade name **EUR*neffy*** in the EU) (previously referred to as ARS-1), an epinephrine nasal spray for patients 30 kg or greater with Type I allergic reactions including food, medications and insect bites that could lead to life-threatening anaphylaxis. 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 needle-free profile of ***neffy*** potentially increasing the likelihood that patients and caregivers may carry and administer epinephrine; ***neffy***'s potential benefits to patients and caregivers; 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 "can," "could," "potential," "will," and similar

expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS Pharma's 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: the ability to obtain and maintain regulatory approval for ***neffy***; potential safety and other complications from ***neffy***; the labelling for ***neffy*** in any future indication or patient population, if approved; 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 Pharma's 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 Pharma's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the Securities and Exchange Commission (SEC) on August 6, 2024. This and other documents ARS Pharma files with the SEC can also be accessed on ARS Pharma's website at ir.ars-pharma.com by clicking on the link "Financials & Filings" under the "Investors & Media" tab.

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