ARS Pharmaceuticals Files for Approval of neffy® in Canada and the United Kingdom on Behalf of Licensing Partner ALK-Abelló A/S

January 6, 2025

*Canada and United Kingdom represent two of the largest markets within the ALK portfolio with plans to expand filings of **neffy** (epinephrine nasal spray) 2 mg in other key global regions*

SAN DIEGO, Jan. 06, 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 ARS Pharma has filed for approval of ***neffy***® (epinephrine nasal spray) 2 mg in Canada and the United Kingdom (U.K.), where it will be marketed as **EUR*neffy***®, on behalf of its licensing partner, ALK- Abelló A/S (ALK). ***neffy*** was recently approved in the U.S. for the treatment of Type I Allergic Reactions, including anaphylaxis, in adults and children who weigh ≥30 kg (66 lbs.). In November 2024, ARS Pharma announced a licensing agreement providing ALK with exclusive rights to commercialize ***neffy*** in Europe, Canada, United Kingdom and certain other geographies outside of the U.S.

“Building upon the approval of ***neffy*** in the U.S. and Europe for the emergency treatment of severe allergic reactions, we are committed to helping facilitate access to this life-saving treatment worldwide,” says Richard Lowenthal, Co-Founder, President and CEO of ARS Pharma. “With submission in Canada and the U.K., ARS Pharma now has approval or has filed for approval in jurisdictions comprising more than 98 percent of the current world market for epinephrine. We look forward to hearing from the regulatory agencies following their review of the applications.”

Under the terms of the licensing agreement, ARS Pharma received an upfront payment of $145 million and is eligible to receive up to an additional $320 million in regulatory and sales milestones, as well as tiered, double-digit royalties in the teens on net sales in licensed geographies. ARS Pharma will be responsible for manufacturing and supplying ***neffy*** to ALK.

ARS Pharma retains all U.S. rights for ***neffy*** and has existing licensing partnerships in China, Japan, Australia and New Zealand with Pediatrix Therapeutics, Alfresa Pharma, and CSL Seqirus, respectively.

ARS Pharma is also evaluating its intranasal epinephrine technology for the treatment of acute flares in patients with chronic urticaria, with plans to begin a Phase 2b clinical trial in early 2025. The license agreement with ALK also provides them exclusive rights for any new indications in the licensed territories.

About *neffy*®

neffy is an intranasal epinephrine product for patients with Type I allergic reactions due to insect stings or bites, foods, medicinal products, other allergens, as well as idiopathic or exercise induced anaphylaxis 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, 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***; the expected timing for receiving regulatory approval in the U.K. and Canada; the plans and expected timing for initiating a Phase 2b clinical trial to evaluate ***neffy*** for the treatment of chronic urticaria; 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’ reliance on its licensing partners; the ability to obtain and maintain regulatory approval for ***neffy*** in any indication in the U.K. and Canada; whether the completed studies conducted will be sufficient to obtain regulatory approval for ***neffy*** in the U.K. and Canada; ARS Pharmaceuticals’ ability to achieve the milestones needed to receive milestone payments under the ALK license agreement; 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 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.

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