ARS Pharmaceuticals Announces Filings for Approval of neffy® in China, Japan and Australia

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Licensing partners in key Asia Pacific countries have filed for approval of neffy (epinephrine nasal spray) 2 mg with regulatory agencies

SAN DIEGO, Dec. 12, 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 its licensing partners in China, Japan and Australia have filed for approval of ***neffy*®** (epinephrine nasal spray) 2 mg in their respective countries. ***neffy*** 2 mg 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).

“Given the life-saving potential of ***neffy*** for the emergency treatment of severe allergic reactions, our focus is on making it available as quickly and as broadly as possible worldwide,” says Richard Lowenthal, Co-Founder, President and CEO of ARS Pharmaceuticals. “People in the Asia Pacific region could soon be saying hello to ***neffy*** where the unique attributes of the product, such as being needle-free, easy to dispose, a smaller size with temperature excursions up to 122°F (50°C), and a 30 month shelf life are particularly important. We are thankful to our licensing partners in these countries for filing with their respective regulatory agencies.”

Among the numerous clinical trials conducted by ARS Pharma and our licensing partners in support of filings in Japan and China, the Company also conducted a Phase 3 study in Japanese pediatric patients aged 6-17 (n=15) who developed anaphylactic symptoms after an oral food challenge (OFC). ***neffy*** was dosed when patients demonstrated respiratory, gastrointestinal, or circulatory symptoms that were grade 2 or higher, per the Severity Classification of Organ Symptoms by the Japanese Society of Allergology Anaphylaxis Guidelines 2022. The results of this study found that 100% of the patients who developed symptoms responded to a single dose of ***neffy***. The median time to complete resolution of anaphylaxis symptoms was 16 minutes.

Pediatrix, the ARS partner in China, also conducted an 81 person PK/PD study in Chinese persons that replicated the U.S. primary studies conducted by the Company with single and repeat dose by caregivers, self-administration and nasal allergen challenge. The results obtained from these PK/PD studies in China gave very similar results to those obtained in the U.S. clinical trials with ***neffy***.

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 also has an exclusive agreement with ALK-Abelló to commercialize ***neffy*** in Europe (marketed as **EUR*neffy*** in the European Union and obtained EU approval in August, 2024), Canada and other geographies outside the United States.

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 expectation that ***neffy*** will save lives; the effectiveness of ***neffy***; the expected timing for receiving regulatory approval in the Asia Pacific region 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 China, Japan and Australia; whether the completed studies conducted will be sufficient to obtain regulatory approval for ***neffy*** in China, Japan and Australia; 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.

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