neffy® (epinephrine nasal spray) Approved in Japan as the First and Only Needle-Free Emergency Treatment of Allergic Reactions (anaphylaxis)

September 19, 2025

__neffy__ 1 mg and 2 mg doses approved by Japanese regulators

__neffy__ offers a new delivery method for epinephrine in Japan for adults and children (≥15 kg) living with severe allergic reactions

Alfresa Holdings, which owns the rights to market __neffy__ in Japan, expects availability in Q4 2025

SAN DIEGO, Sept. 19, 2025 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect themselves from allergic reactions that could lead to anaphylaxis, announced today that the Pharmaceuticals and Medical Devices Agency (PMDA), the Japanese authority responsible for the scientific review of drugs and medical devices, has granted approval for ***neffy***® (epinephrine nasal spray) 1 mg and 2 mg doses, for the emergency treatment of allergic reactions (anaphylaxis) in adults and children who weigh greater than 15 kilograms.

“We are proud to receive this approval in partnership with Alfresa, which broadens access of ***neffy*** and offers the first needle-free epinephrine treatment available in Japan for both adults and children with severe allergies,” said Richard Lowenthal, Co-founder, President and CEO of ARS Pharma. “This represents a significant breakthrough as ***neffy*** meets a vital need for patients who may not carry, or hesitate to use, an injectable option for use during emergencies. With its compact design, and extended shelf life, compared to other forms of epinephrine, of 24 months, this advancement empowers patients and caregivers to consistently carry and administer epinephrine at the earliest signs of a severe reaction.”

Approximately 900,000 Japanese individuals are estimated to be affected by food allergies, with the prevalence in children doubling from 2010 to 2019.[1] In a 2025 survey of Japanese patients who had experienced anaphylaxis, only 14% reported they had an epinephrine auto-injector prescription, and only half used their epinephrine auto-injector at the time of their most recent anaphylactic episode. The remainder visited a hospital or clinic to receive treatment.[2]

In 2020, ARS Pharma entered into an exclusive licensing agreement with Japanese pharmaceutical company, Alfresa Holdings, granting them the rights to commercialize ***neffy*** (epinephrine nasal spray) in Japan. Under the terms of the agreement, following listing of ***neffy*** on the Japanese National Health Institute (NHI) Drug Price List, ARS Pharma is eligible to receive a final regulatory milestone of $2 million, and to sell ***neffy*** to Alfresa at a transfer price. Alfresa expects ***neffy*** to be available in the fourth quarter of 2025.

neffy is commercially available in the U.S. for the emergency treatment of allergic reactions, including anaphylaxis, in adults and children aged 4 years and older who weigh at least 33 pounds (15 kg). Earlier this year, ARS Pharma’s European partner, ALK successfully launched **EUR*neffy*** in Germany and received approval in the U.K. Regulatory approvals for ***neffy*** in Canada (with ALK), Australia and New Zealand (in partnership with CSL), are expected by the end of 2025, with commercial rollouts planned for early 2026. As well, regulatory approval for ***neffy*** in China (in partnership with Pediatrix) is expected in the first half of 2026.

About *neffy*®

neffy is a nasal spray used for emergency treatment of allergic reactions including anaphylaxis, in adults and children aged 4 years and older who weigh 33 lbs. or greater.

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

INDICATION

neffy is indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients aged 4 years and older who weigh 33 lbs. or greater.

IMPORTANT SAFETY INFORMATION

neffy contains epinephrine, a medicine used to treat allergic emergencies (anaphylaxis). Anaphylaxis can be life-threatening, can happen in minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or other unknown causes.

Always carry two ***neffy*** nasal sprays with you because you may not know when anaphylaxis may happen and because you may need a second dose of ***neffy*** if symptoms continue or come back. Each ***neffy*** contains a single dose of epinephrine. ***neffy*** is for use in the nose only.

Use ***neffy*** right away, as soon as you notice symptoms of an allergic reaction. If symptoms continue or get worse after the first dose of ***neffy***, a second dose is needed. If needed, administer a second dose using a new ***neffy*** in the same nostril starting 5 minutes after the first dose. Get emergency medical help for further treatment of the allergic emergency (anaphylaxis), if needed after using ***neffy***.

Tell your healthcare provider if you have underlying structural or anatomical nasal conditions, about all the medicines you take, and about all your medical conditions, especially if you have heart problems, kidney problems, low potassium in your blood, Parkinson's disease, thyroid problems, high blood pressure, diabetes, are pregnant or plan to become pregnant, or plan to breastfeed.

Tell your healthcare provider if you take or use other nasal sprays or water pills (diuretics) or if you take medicines to treat depression, abnormal heart beats, Parkinson's disease, heart disease, thyroid disease, medicines used in labor, and medicines to treat allergies. ***neffy*** and other medications may affect each other, causing side effects. ***neffy*** may affect the way other medicines work, and other medicines may affect how ***neffy*** works.

***neffy* may cause serious side effects. If you have certain medical conditions or take certain medicines, your condition may get worse, or you may have more or longer lasting side effects when you use *neffy*.**

Common side effects of ***neffy*** include: nasal discomfort, headache, throat irritation, chest and nasal congestion, feeling overly excited, nervous or anxious, nose bleed, nose pain, sneezing, runny nose, dry nose or throat, tingling sensation, including in the nose, feeling tired, dizziness, nausea, and vomiting.

Tell your healthcare provider if you have any side effects that bother you or that do not go away after using ***neffy***.

These are not all of the possible side effects of ***neffy***. Call your healthcare provider for medical advice about side effects. To report side effects, contact ARS Pharmaceuticals Operations, Inc. at **1-877-MY-NEFFY (877-696-3339)** or the FDA at **1-800-FDA-1088** or www.fda.gov/medwatch.

Please see the full Prescribing Information and Patient Information for *neffy*.

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 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 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 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 allergic reactions that could lead to anaphylaxis. The Company is commercializing ***neffy***® (trade name **EUR*neffy***® in the EU), an epinephrine nasal spray indicated in the U.S. for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult patients and pediatric patients 4 years of age and older who weigh 33 lbs. 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 patient benefits and effectiveness of ***neffy***, including its needle-free, compact, portable and easy to use design, temperature stability, and extended shelf life; the potential market and demand for ***neffy***; the anticipated timing of regulatory decisions for ***neffy*** in Canada, Australia and New Zealand, and China; and the expected timing of commercial launches in Japan, Canada, and Australia and New Zealand; 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,” “believe,” “can,” “could,” “expect,” “if,” “may,” “on track to/for,” “potential,” “plan,” “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***; the ability to obtain and maintain regulatory approval for ***neffy*** in its currently approved indications; the scope, progress and expansion of developing and commercializing ***neffy***; the scope, progress and expansion of developing our intranasal epinephrine technology; clinical trial results; the potential for governments and payors to delay, limit or deny coverage for ***neffy***; the size and growth of the market for ***neffy*** 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, regulations and policies. 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, 2025, filed with the SEC on August 13, 2025. This document can also be accessed on ARS Pharma’s 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 Pharma assumes no obligation and does not intend to update these forward-looking statements, except as required by law. For more information, visit www.ars-pharma.com, and follow us on LinkedIn and X.

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