



ARS Pharmaceuticals Announces OptumRx, Cigna Healthcare and Navitus Health Systems Add **neffy®** (Epinephrine Nasal Spray) to National Formularies, Further Expanding Coverage for Patients

February 21, 2025

*Approximately five months after launch, the inclusion of **neffy** on these three additional formularies has expanded access to half of all patients and caregivers managing Type 1 allergic reactions, bringing the total number of formulary platforms covering **neffy** to 30*

SAN DIEGO, Feb. 20, 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 Cigna Healthcare, Navitus Health Systems and OptumRx, through their Group Purchasing Organization (GPO) Emisar, have added **neffy®** (epinephrine nasal spray) to their National Formularies.

"Millions of patients nationwide now have improved access to **neffy** through their commercial insurance, thanks to coverage from leading pharmaceutical benefit managers and health plans. **neffy** will also be available at the lowest branded copay for patients insured by OptumRx, Cigna Healthcare, and Navitus Health Systems - without the need for prior authorizations or restrictive step therapies," said Richard Lowenthal, Co-Founder, President, and CEO of ARS Pharma. "As a result, more patients will qualify for the low copay price of \$25 for **neffy**, when they apply the ARS Pharma copay assistance, and healthcare providers can prescribe it without the need for additional paperwork."

"This announcement also underscores the critical demand for a nasal spray epinephrine option within the severe allergy community and we remain committed to ensuring continued access for as many patients and caregivers as possible. While Emisar represents both OptumRx and UnitedHealthcare as their GPO at this time only OptumRx has agreed to the Emisar terms. ARS Pharma is working closely with UnitedHealthcare, as one of the country's largest healthcare providers, to add **neffy** to their formulary as soon as possible," said Lowenthal.

The addition of **neffy** to these formularies improves coverage for the approximately 20 million people who have been diagnosed and treated for the more severe Type I allergic reactions that may lead to anaphylaxis and need epinephrine therapy to protect themselves in their daily lives. To assist patients in navigating coverage and affordability challenges, ARS Pharma offers a number of programs for patients and caregivers. For more information, visit www.neffy.com/savings.

neffy 2 mg is for the treatment of Type I Allergic Reactions, including anaphylaxis, in adults and children who weigh ≥ 30 kg (66 lbs.). It is the first and only FDA-approved epinephrine nasal spray that provides a needle-free alternative to traditional injectable epinephrine. It's simple and intuitive design enables rapid administration, helping patients and caregivers act quickly and confidently, and the small size is easy to carry. Additionally, **neffy** has a shelf-life of 30 months and temperature exclusions up to 122 degrees Fahrenheit.

The supplemental NDA for **neffy** 1 mg, for children over four years of age who weigh 15 to 30 kg, has a Prescription Drug User Fee Act (PDUFA) target action date of March 6, 2025. Based on review timelines and subject to approval, product availability of **neffy** 1 mg is expected by the end of May 2025. ARS Pharma anticipates that by the epinephrine prescription renewal period, which occurs over the summer for many children in the United States, that school age children who meet the weight and age criteria will have access to **neffy**.

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 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 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 **EURneffy**® 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 impact from the inclusion of **neffy** on OptumRx, Cigna Healthcare and Navitus Health Systems' National Formularies; ARS Pharmaceuticals' expectation that other payors, such as UnitedHealthcare, will agree to terms to provide access to **neffy** and the timing by which they will provide such access, the critical demand for a nasal spray epinephrine option, the expectation that **neffy** will save lives; the effectiveness of **neffy**; the expected timing for product availability of **neffy 1 mg**; 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 maintain regulatory approval for **neffy** in its currently approved indication and to obtain and maintain regulatory approval for **neffy** for additional indications; 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 governments and 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. For more information, visit www.ars-pharma.com, and follow us on [LinkedIn](#) and [X](#).

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