ARS Pharmaceuticals Announces Preliminary Fourth Quarter 2024 Financial Results and 2025 Objectives for neffy® (epinephrine nasal spray)

January 13, 2025

*Preliminary fourth quarter **neffy**® net product revenue of approximately $6.5 million*

Preliminary cash, cash equivalents and short-term investments of $314.0 million at year-end 2024 to support an operating runway of at least three years

Company to present at 43rd Annual J.P. Morgan Healthcare Conference on Wednesday, January 15, 2025 at 7:30am PT

SAN DIEGO, Jan. 13, 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, today announced preliminary, unaudited ***neffy***® (epinephrine nasal spray) net product revenue for the fourth quarter and full year 2024 and outlined its 2025 commercial and clinical objectives.

"For ARS Pharma, 2024 marked a pivotal year, securing regulatory approvals for ***neffy*** as the first and only intranasal epinephrine treatment, laying a solid foundation for our commercial success in the United States and expansion worldwide through partnerships. While early in the launch of ***neffy***, the first three months of sales have exceeded expectations with very positive demand indicators," said Richard Lowenthal, President and CEO of ARS Pharma. "Looking ahead to 2025, we are poised to accelerate the growth of ***neffy*** through targeted commercial initiatives, including advancing education and awareness among our key prescribers, achieving over 80 percent commercial insurance coverage and launching impactful direct-to-consumer marketing campaigns for the ***neffy*** brand. ***neffy*** is transforming the lives of patients by offering a simple, effective, and life-saving treatment option, and we are very pleased to be making such a meaningful difference in the lives of patients, families and caregivers."

Preliminary Fourth Quarter 2024 Financial Results

- **Product revenue:** Preliminary ***neffy*** net product revenue for the fourth quarter of 2024 was approximately $6.5 million, with total net product sales for 2024 of approximately $7.1 million since ***neffy*** became available to wholesalers and pharmacies on September 23, 2024. More than 14,500 ***neffy*** two-pack units were delivered in the fourth quarter of 2024, including more than 1,500 units in the last week of 2024.
- **Cash position:** Cash, cash equivalents and short-term investments were approximately $314.0 million as of December 31, 2024. ARS Pharma reiterates its guidance that the company expects its cash, cash equivalents and short-term investments to be sufficient to fund its current operating plan for at least three years.

2025 Key Strategic Priorities for Accelerating *neffy* U.S. Sales and Recent Highlights

- **Increase demand and traction among target prescribers**, with continued sales force and medical science liaison engagement, expansion of the company's ***neffy*** Experience Program, and rollout of additional continuing medical education (CME) programs
  - More than 3,000 healthcare providers have prescribed ***neffy*** to date, of which 80 percent are in the highest decile categories for prescribing epinephrine
  - More than 1,750 healthcare providers have participated in the ***neffy*** Experience Program
- **Expand commercial access of *neffy***
  - Express Scripts, the second largest pharmacy benefits manager in the U.S., added ***neffy*** to its commercial national formularies in November 2024
  - On track for more than 60 percent commercial coverage by the end of the first quarter of 2025, and more than 80 percent commercial coverage by the end of the third quarter of 2025
  - Contracting consistent with target long-term total gross-to-net revenue of 50 percent
- **Increase consumer awareness of *neffy* and availability of a needle-free option**
  - Preparations are underway to launch a branded ***neffy*** direct-to-consumer marketing campaign beginning in May 2025
  - Designed to build momentum ahead of the 'back-to-school' season, the campaign will extend throughout the summer, driving brand recognition and encouraging patients to request ***neffy*** by name
  - In parallel, to amplify public awareness of the needle-free epinephrine option, Food Allergy Research and Education (FARE) is set to launch a public service announcement campaign featuring a celebrity ambassador with ARS Pharma support later this year
- **Obtain approval of *neffy* 1 mg for children** who weigh 15 to 30 kg
  - The sNDA filed with the U.S. FDA for ***neffy*** for children 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 in the second

quarter of 2025

Presentation at the 43rd Annual J.P. Morgan Healthcare Conference
On Wednesday, January 15, 2025, at 7:30am PT, Richard Lowenthal, President and CEO of ARS Pharma, will present a company overview at the 43rd Annual J.P. Morgan Healthcare Conference. A live webcast of the presentation and Q&A session can be accessed here or by visiting the investors section of the company's website at www.ir.ars-pharma.com.

About Preliminary Financial Results

The preliminary results set forth above are unaudited, are based on management's initial review of the company's results for the quarter ended December 31, 2024, and are subject to revision based upon the company's year-end closing procedures and the completion and external audit of the company's year-end financial statements. Actual results may differ materially from these preliminary unaudited results following the completion of year-end closing procedures, final adjustments or other developments arising between now and the time that the company's financial results are finalized. In addition, these preliminary unaudited results are not a comprehensive statement of the company's financial results for the quarter and year ended December 31, 2024, should not be viewed as a substitute for full, audited financial statements prepared in accordance with generally accepted accounting principles, and are not necessarily indicative of the company's results for any future period.

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***; ARS Pharmaceuticals' preliminary financial results for the quarter ended December 31, 2024; ARS Pharmaceuticals' projected operating runway; the belief that ARS Pharmaceuticals is poised to accelerate the growth of ***neffy*** and how it expects to do so; ARS Pharmaceuticals' commercial coverage goals and the timing thereof; 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: risks related to preliminary financial results, as described above; 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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