ARS Pharmaceuticals Announces Presentation of Clinical Data Supporting neffy® (epinephrine nasal spray) for the Treatment of Allergic Reactions (Type I) including Anaphylaxis

November 9, 2023

Data to be Presented in Four Oral Presentations and Posters at the 2023 American College of Allergy, Asthma and Immunology Annual Scientific Meeting

*Supports **neffy's** potential to be a safe and effective option across patient sub-populations based on data including the relationship between BMI/body weight and epinephrine exposure, congestion/rhinitis during upper respiratory tract infection, and pediatrics*

SAN DIEGO, Nov. 09, 2023 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (NASDAQ: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect patients from severe allergic reactions that could lead to anaphylaxis, today announced that clinical data supporting ***neffy*** (epinephrine nasal spray) will be presented during the 2023 American College of Allergy Asthma and Immunology (ACAAI) Annual Scientific Meeting. The meeting is being held November 9-13, 2023, in Anaheim, California.

Presentations will highlight clinical data from a rigorous registration program for ***neffy*** 2.0 mg of more than 600 subjects, including analyses of patients with upper respiratory tract infections, pediatric patients ≥30 kg with a history of type I allergic reaction, patients with allergen-induced allergic rhinitis and the relationship between body weight/BMI and epinephrine exposure.

Notably, data demonstrate that the pharmacokinetics of ***neffy*** are independent of BMI or body weight. Unlike injection products where exposures decreased with varying BMI or body weight, ***neffy*** could be a potentially effective epinephrine product in these patients. These results will be presented as a Distinguished Industry Oral Abstract on Saturday, November 11 at 4:30 PM PT (Session A).

"At ARS Pharma, we are committed to advancing much-needed science in allergic diseases to make a positive impact on the people and communities we serve. To that end, we are pleased to share these clinical data that provide critical insights into ***neffy's*** potential as the first intranasal medicine for treating severe allergic reactions," said Sarina Tanimoto, M.D., Ph.D., Chief Medical Officer and Co-Founder of ARS Pharma. "Severe allergic reactions can be life-threatening, and today's standard of care is needle-bearing injectable devices associated with numerous administration challenges. The data generated supports that ***neffy*** achieves a PK/PD profile comparable to injectable products across various patient subgroups while potentially allowing patients to easily carry and confidently administer epinephrine without hesitation or anxiety."

Details of the presentations are as follows:

Title: Acute Allergic Rhinitis Increases Endogenous Epinephrine Resulting in Increased Heart Rate
Date & Time: Friday, November 10 at 4:30 PM PT
Session: Adverse Drug Reactions, Insect Reactions, Anaphylaxis
Data Summary: Acute allergic rhinitis induces increases in circulating endogenous epinephrine and heart rate, possibly in response to changes in the distribution of blood flow.

Title: A Single-Period, Single-Dose Study of the Pharmacokinetics of Epinephrine After Administration ARS-1 to Pediatric Subjects
Date & Time: Friday, November 10 at 5:45 PM PT
Session: Adverse Drug Reactions, Insect Reactions, Anaphylaxis
Data Summary: The pharmacokinetic profile of ***neffy*** 2.0 mg in pediatric allergy subjects is comparable to what has been observed in adults and is expected to be a safe and effective option for the treatment of type I allergic reactions (including anaphylaxis) in pediatric subjects.

Title: Integrated Pharmacokinetic-Pharmacodynamic Analysis: Effect of Weight and BMI on Epinephrine Concentration
Date & Time: Saturday, November 11 at 4:30 PM PT
Session: Distinguished Industry Oral Abstracts – Session A
Data Summary: Based on the rigorous registration program of ***neffy***, the presentation will address the question about what is the effect of body weight and BMI on epinephrine absorption. Intramuscular and subcutaneous injections have a negative relationship with epinephrine exposures while ***neffy*** does not. This suggests ***neffy*** could be a potentially more effective epinephrine alternative to injection products in patients with elevated body weight or BMI.

Title: Effect of Upper Respiratory Tract Infection on the Pharmacokinetics of Intranasal Epinephrine
Date & Time: Adverse Drug Reactions, Insect Reactions, Anaphylaxis
Session: Sunday, November 12 at 11:35 AM PT
Data Summary: Epinephrine absorption via ***neffy*** 2.0 mg under viral upper respiratory tract infection did not significantly impact the pharmacokinetics and pharmacodynamics. ***neffy*** 2.0 mg is expected to be a safe and effective option for the treatment of type I allergic reactions (including anaphylaxis) in patients experiencing upper respiratory tract infections.

About Type I Allergic Reactions including Anaphylaxis
Type I severe 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 severe allergic reactions. Of those, only 3.3 million currently have an 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 Pharma is a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions that could lead to anaphylaxis. The Company is developing ***neffy***® (previously referred to as ARS-1), an intranasal epinephrine product in clinical development for patients and their caregivers with Type I allergic reactions including food, medications and insect bites that could lead to life-threatening anaphylaxis. 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 potential for ***neffy*** to be a safe and effective option across patient sub-populations, including pediatric patients and patients experiencing upper respiratory tract infections; the potential for ***neffy*** to be a more effective epinephrine alternative to injection products in patients with elevated body weight of BMI; 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," "plans," "expects," "will," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS Pharma's 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, the ability to obtain and maintain regulatory approval for ***neffy***; the ability to successful complete the repeat-dose study under allergen-induced allergic rhinitis conditions on the timeframe anticipated, as a result of challenges inherent to enrolling, conducting and completing clinical trials; the results of the repeat-dose study under allergen-induced allergic rhinitis conditions may not support the approval of ***neffy***; results from clinical trials may not be indicative of results that may be observed in the future; potential safety and other complications from ***neffy***; the labelling for ***neffy***, if approved; ARS Pharma's 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 Pharma's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the Securities and Exchange Commission on August 10, 2023. This document can also be accessed on ARS Pharma's web page at ir.ars-pharma.com by clicking on the link "Financials & Filings."

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.

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