ARS Pharmaceuticals Announces Presentation of Data Supporting neffy (epinephrine nasal spray) and Real-World Burden of Needle Injectors

February 23, 2023

Data to be Presented in Five Poster Presentations at the 2023 American Academy of Allergy, Asthma and Immunology Annual Meeting

*Data Support New Drug Application for **neffy**®, Currently Under Review with the FDA*

SAN DIEGO, Feb. 23, 2023 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect themselves from severe allergic reactions that could lead to anaphylaxis, today announced that positive data supporting ***neffy***® (previously referred to as ARS-1), the potential first non-injectable medicine for treatment of allergic reactions (Type I), including anaphylaxis, will be presented during the 2023 American Academy of Allergy, Asthma and Immunology (AAAAI) meeting. The meeting is being held February 24-27, 2023, in San Antonio, Texas.

Presentations will highlight findings from self-administration and pediatric clinical trials of ***neffy*** as well as an integrated analysis of more than 600 subjects, that were included in the company's New Drug Application (NDA) for ***neffy*** as an emergency treatment of allergic reactions (Type I), including anaphylaxis in adults and children ≥30 kg (66 lbs).

Data from the clinical trials demonstrated that ***neffy*** delivered consistent epinephrine levels to attain a pharmacokinetic (PK) and pharmacodynamic (PD) profile within the range of approved intramuscular (IM) injection products with a dose proportional exposure between once and twice dosing.

ARS will also present findings from surveys of 300 patients identifying that the needle is the principal reason why patients do not fill their epinephrine prescription today, and why they delay epinephrine use and use OTC products first despite treatment guidelines recommending immediate use of epinephrine.

"We are excited to share these data from two of our primary clinical trials and the integrated analysis demonstrating the performance of ***neffy***. The research demonstrates that ***neffy*** delivers consistent epinephrine levels across a range of administration conditions, including during self-administration and in children," said Richard Lowenthal, M.Sc., MSEL, co-founder and chief executive officer of ARS. "Severe allergic reactions can quickly progress and be life-threatening, and our real-world surveys of standard of care identify that people's fear of injecting epinephrine due to needle-phobia is the principal reason for failure to administer epinephrine or delayed treatment in an emergency situation. The totality of the data generated continues to support that ***neffy*** achieves a PK/PD profile comparable to injectable epinephrine products, while potentially offering patients an easy to use and rapidly administered, needle-free option to currently approved epinephrine autoinjectors."

Details of the presentations are as follows:

Title: Pharmacokinetics of Self-Administration of ARS-1 (*neffy*® Nasal Spray) 2.0 mg Versus Manual Intramuscular (IM) Epinephrine 0.3 mg by Health Care Provider (HCP)
Date & Time: [2/24/2023, 3:15 pm - 4:15 pm]
Data Summary: Pharmacokinetic profile following patient self-administration of ***neffy*** 2.0 mg is comparable to or better than manual injection. ***neffy's*** pharmacodynamic profile is also comparable to or better than manual injection.

Title: A Single-Period, Single-Dose Study of the Pharmacokinetics of Epinephrine after Administration of Intranasal ARS-1 (*neffy*® Nasal Spray) to Pediatric Subjects with a History of Systemic Allergic Reactions
Date & Time: [2/24/2023, 3:15 pm - 4:15 pm]
Data Summary: Pharmacokinetic profile in children ≥30 kg following administration of ***neffy*** 2.0 mg is comparable to adults, and dose-proportional with the 1.0 mg dose in development for children 15-30 kg. ***neffy's*** pharmacodynamic profile in children ≥30 kg is comparable to adults.

Title: ARS-1 (*neffy*® Nasal Spray) 2.0 mg Versus Epinephrine Injection Products: An Integrated Pharmacokinetic Analysis
Date & Time: [2/24/2023, 3:15 pm - 4:15 pm]
Data Summary: Integrated analysis of five clinical studies demonstrate the pharmacokinetic and pharmacodynamic profile of ***neffy*** 2.0 mg is within the range of currently approved injection products. ***neffy*** 2.0 mg appears dose-proportional between once and twice dosing.

Title: Epinephrine Autoinjectors Prescriptions Are Not Filled Due to Dislike of Needles: Results of a Patient Survey
Date & Time: [2/24/2023, 3:15 pm - 4:15 pm]
Data Summary: The most common reason for never filling or not refilling an epinephrine prescription included dislike of needles, portability issues, device size and complicated use instruction. Patients indicated they would be more likely to fill a prescription for a needle-free device versus an epinephrine autoinjector.

Title: Use of Over-the-Counter Products to Treat Severe Allergic Reactions Before an Epinephrine Auto Injection Device: Results of a Patient/Caregiver Survey
Date & Time: [2/24/2023, 3:15 pm - 4:15 pm]
Data Summary: Almost all patients reported using an OTC product alone or prior to their injectable device despite their ineffectiveness in stopping a severe allergic reaction. A majority of patients indicated they would use a needle-free device instead of or before an OTC product.

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 25 to 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 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.

Cautionary Note Regarding 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 data to be presented at the AAAAI and its ability to support the NDA for ***neffy***®; the design and potential benefits of ***neffy***®; the potential regulatory approval and commercialization of ***neffy***®; the potential market opportunity for ***neffy***®; 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'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***®; 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 labeling for ***neffy***®, if approved; the scope, progress and expansion of developing and commercializing ***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'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—Risks Related to ARS Pharma" heading of the company's definitive proxy statement filed with the Securities and Exchange Commission on October 6, 2022, available at www.sec.gov. This document can be also be accessed on ARS'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 assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

ARS Investor Contacts:
Justin Chakma
ARS Pharmaceuticals
justinc@ars-pharma.com

ARS Pharmaceuticals, Inc.