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

November 10, 2022

*Data from Pivotal Clinical Trials to be Presented in Five Poster Presentations at the 2022 American College of Allergy, Asthma and Immunology Annual Scientific Meeting*

*Data Support New Drug Application for **neffy**®, Currently Under Review with U.S. FDA*

SAN DIEGO, Nov. 10, 2022 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (NASDAQ: SPRY) (ARS or the Company), 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 clinical 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 2022 American College of Allergy Asthma and Immunology Annual Scientific Meeting (ACAAI). The meeting is being held November 10-14, 2022, in Louisville, Kentucky.

Presentations will highlight findings from multiple clinical trials of ***neffy*** (EPI-15 and EPI-16) 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). The U.S. Food and Drug Administration (FDA) has accepted the NDA for ***neffy*** for review with a Prescription Drug User Fee Act (PDUFA) target action date anticipated in mid-2023.

Data from the EPI-15 and EPI-16 clinical trials demonstrated that ***neffy*** delivered consistent epinephrine levels to attain pharmacokinetic (PK) profile in range of approved intra-muscular (IM) injection products' PK under normal and rhinitis conditions. Additionally, ***neffy's*** Pharmacodynamic (PD) profile, the surrogate measure for assessing clinical effectiveness in anaphylaxis (for example, increased blood pressure, heart rate), demonstrated comparable or greater PD response compared with currently approved IM injectable products. These data also provide important insights into the mechanism of action of intranasal epinephrine. ARS will also present findings from a physician/caregiver survey, which suggests that patients and caregivers have a preference for a needle-free epinephrine alternative and would dose ***neffy*** sooner in the course of an allergic reaction without the hesitation caused by fear of the needle and pain.

"We are pleased to share these data from two of our primary clinical trials for ***neffy***, both of which provide critical insights into ***neffy's*** potential as the first intranasal medicine for treating severe allergic reactions," said Richard Lowenthal, M.Sc., MSEL, co-founder and chief executive officer of ARS. "Severe allergic reactions can be life-threatening, and today's standard of care is needle-bearing injectable devices associated with numerous administration challenges. The totality of the data generated supports that ***neffy*** achieves a PK/PD profile comparable to injectable products, while potentially offering patients a safe, effective and easy to administer, no-needle, no-wait option to approved epinephrine injection devices. With our NDA currently under review by FDA, we are committed to partnering with the Agency and Advocacy groups to ensure we can bring ***neffy*** to patients with Type I allergic reactions and their caregivers."

Details of the presentations are as follows:

**Title:** Pharmacokinetics/Pharmacodynamics After Single and Repeat Administration of ARS-1, Epinephrine Auto-Injector, and Manual Intramuscular Injection (EPI-15)
**Date & Time:** Friday, Nov 11 at 5:30 PM ET
**Session**: Other anaphylaxis
**Data Summary:** Pharmacokinetic profile following ***neffy*** 2.0 mg is within the range of currently approved injection products. ***neffy's*** pharmacodynamic profile is comparable to or better than EpiPen or manual injection, suggesting that ***neffy*** may be at least as efficacious as these approved products.

**Title:** Pharmacokinetics and Pharmacodynamics of ARS-1 and Manual Intramuscular Injection in Subjects With/Without Allergic Rhinitis (EPI-16)
**Date & Time:** Friday, Nov 11 at 5:00 PM ET
**Session:** Other anaphylaxis
**Data Summary:** Epinephrine absorption via ***neffy*** 2.0 mg under rhinitis resulted in more rapid absorption due to nasal symptoms including mucosal oedema. ***neffy's*** pharmacodynamic profile under rhinitis is comparable to manual injection, suggesting that ***neffy*** may be at least as efficacious as this approved product.

**Title:** Epinephrine Nasal Spray (ARS-1) and Intramuscular Injection: Pharmacokinetic/Pharmacodynamic Differences and Differential Affinities for Adrenergic Receptors
**Date & Time:** Friday, Nov 11 at 5:15 PM ET
**Session :** Other anaphylaxis
**Data Summary:** ***neffy*** 1.0 mg increases systolic blood pressure and heart rate more efficiently than injections, eliciting a comparable pharmacodynamic response at a lower epinephrine concentration that may be attributed to its bypassing of the beta 2-receptors into skeletal muscle in the thigh.

**Title:** Time Before Use of Epinephrine Injectable Devices and Triggers Driving Use: A Patient/Caregiver Survey
**Date & Time:** Friday, Nov 11 at 4:15 PM ET
**Session :** Adverse Drug Reactions, Insect Reactions, Anaphylaxis
**Data Summary:** The reasons for the delay in use of an epinephrine injectable device had a significant relationship with needle, requirement to go to

ER, uncertainty about the symptom being warranted for injection, potential side effects, fear to use, pain, and size of device.
The results suggest that a device that addresses the reasons for delay and hesitation may help patients and caregivers to use the device without hesitation.

**Title:** Epinephrine Via Needle-Free Device Would Be Administered Faster After Symptoms: Results of a Patient/Caregiver Survey
**Date & Time:** Friday, Nov 11 at 4:45 PM ET
**Session:** Adverse Drug Reactions, Insect Reactions, Anaphylaxis
**Data Summary:** A needle-free option for administering epinephrine would be used sooner after symptoms developed and is perceived as being easier to use versus an injectable device. This underscores the need to develop epinephrine modalities utilizing a non-needle-based delivery system.

**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.

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 ACAAI, and the dates and times of such presentations; the design and potential benefits of ***neffy***®; the anticipated PDUFA target action date; 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 labelling 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” and elsewhere in ARS’s most recent filings with the U.S. Securities and Exchange Commission (SEC), including its definitive proxy statement on October 6, 2022, its Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 and any subsequent reports on Form 10-K, Form 10-Q or Form 8-K filed with the SEC from time to time and available at www.sec.gov. These documents can 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 presentation 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 Media Contacts:**
Caroline Cunningham
Porter Novelli
Caroline.Cunningham@porternovelli.com

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