ARS Pharmaceuticals Showcases Intranasal Epinephrine Data at 2024 American College of Allergy, Asthma & Immunology (ACAAI) Annual Scientific Meeting

October 24, 2024

SAN DIEGO, Oct. 24, 2024 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from severe allergic reactions that could lead to anaphylaxis, announced today that seven abstracts will be featured tomorrow, Friday, October 25 at the 2024 ACAAI Annual Scientific Meeting taking place in Boston, Massachusetts. The posters highlight a wide range of studies focused on intranasal epinephrine administration, including cardiovascular safety, human factor study of carrying two devices at all times, and real-world administration data in pediatric patients.

"The research being presented at the ACAAI Annual Scientific Meeting is part of the extensive body of knowledge that ARS has contributed on epinephrine administration through our comprehensive clinical research," said Richard Lowenthal, Co-Founder, President, and CEO of ARS Pharmaceuticals, the developer of ***neffy*®** (epinephrine nasal spray) the first and only needle-free treatment for Type I allergic reactions, including anaphylaxis, in adults and children who weigh ≥30 kg (66 lbs.). "Our studies have brought forward valuable new data that demonstrates nasal spray delivery of epinephrine is not only successfully administered in real-world situations, but it also provides valuable insights into the broader understanding of how epinephrine works in the body. Our research contributes to the allergy community's knowledge of both ***neffy***s performance and expands scientific findings and hypothesis, helping us advance treatment options for patients with severe allergies."

The complete list of ARS Pharmaceuticals' poster presentations is below. Full posters can be viewed online here.

Poster Presentation #1

Time:	3:15-3:30pm EDT
Title:	"Cardiovascular Safety of Intramuscular and Intranasal Epinephrine Administration"
Authors:	Jay A. Lieberman, Richard D Wainford, Carlos A. Camargo Jr, Thomas B Casale, Richard Lowenthal, Sarina Tanimoto
Abstract ID:	8064
ePoster ID:	R235

Poster Presentation #2

Time:	3:30-3:45pm EDT
Title:	"Blood Pressure And Pulse Rate Increases, Without Concomitant Epinephrine Increases, During Acute Allergic Reactions"
Authors:	Jonathan M. Spergel, Motohiro Ebisawa, Anne K. Ellis, Thomas B. Casale, John Oppenheimer, Carlos A. Camargo, Jr., Aikaterini Anagnostou, Richard Lowenthal, Sarina Tanimoto
Abstract ID:	8065
ePoster ID:	R236

Poster Presentation #3

Time:	3:45-4:00pm EDT
Title:	"Successful Administration of ARS-1 (Intranasal Epinephrine) when Provided with a Two-Dose Carrying Case-Human Factor Study"
Authors:	Vivian Hernandez-Trujillo, Joel Brooks, Raffi Tachdjian, Brian Dorsey, Richard Lowenthal, Sarina Tanimoto
Abstract ID:	8066
ePoster ID:	R237

Poster Presentation #4

Time:	4:00-4:15pm EDT
Title:	**"**Significant Differences in Pharmacokinetic Profiles Among Epinephrine Products-What is the Mechanism for Efficacy?"
Authors:	Matthew Greenhawt, Jay A Lieberman, Thomas B. Casale, Anna Nowak-Wegrzyn, Jonathan M. Spergel, Richard Lowenthal, Sarina Tanimoto
Abstract ID:	8067
ePoster ID:	R238

Poster Presentation #5

Time:	4:15-4:30pm EDT
Title:	**"**Pharmacokinetics And Pharmacodynamics Following Repeat Dosing of ARS-1 versus Intramuscular Injection During Allergic Rhinitis"
Authors:	John Oppenheimer, Thomas Casale, Jonathan Spergel, David Bernstein, Carlos A. Camargo, Jr., Anne Ellis, Richard Lowenthal, Sarina Tanimoto
Abstract ID:	8068
ePoster ID:	R239

Poster Presentation #6

Time:	4:30-4:45pm EDT
Title:	“ARS-1 Development, From Pharmacokinetics and Pharmacodynamics to Real-World Data in Pediatric Food Allergy Patients”
Authors:	Motohiro Ebisawa, David M. Fleischer, H Henry Li, Michael Kaliner, Richard Lockey, Neetu Talreja, Richard Lowenthal, Sarina Tanimoto
Abstract ID:	8069
ePoster ID:	R240

Poster Presentation #7

Time:	4:45-5:00pm EDT
Title:	“HCP Interest in ARS-1, a Self-Administered Intranasal Epinephrine Device”
Authors:	Nicole Chase, Autumn Burnette, Daniel Soteres, Justin Greiwe, Harris Kaplan, Ayman Kafal
Abstract ID:	8070
ePoster ID:	R241

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 due to food, venom or insect stings. Of those, only 3.3 million currently have an 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 *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 ARS Pharmaceuticals, Inc.
ARS Pharmaceuticals is a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from severe 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 US 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 significance of the results from ARS Pharmaceuticals' studies; the needle-free profile of ***neffy*** potentially increasing the likelihood that patients may both carry *and* administer epinephrine; the potential market and demand 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 "can," "could," "may," "potential," "will," 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: the ability to obtain and maintain regulatory approval for ***neffy***; potential safety and other complications from ***neffy***; 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 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 June 30, 2024, filed with the Securities and Exchange Commission (SEC) on August 6, 2024. This and other documents ARS Pharmaceuticals files with the SEC can also be accessed on ARS Pharmaceuticals' website at ir.ars-pharma.com by clicking on the link "Financials & Filings" under the "Investors & Media" tab.

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

Alex Straus
THRUST Strategic Communications
alex@thrustsc.com

ARS Media Contact:
Christy Curran
Sam Brown Inc.
615.414.8668
christycurran@sambrown.com

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