ARS Pharmaceuticals to Present Positive Clinical Efficacy Data for neffy® (epinephrine nasal spray) at 2024 AAAAI Annual Meeting

February 5, 2024

- *Six posters and oral presentations to be presented, including efficacy data for **neffy** from two distinct clinical studies in oral food challenge induced anaphylaxis and chronic urticaria patients*
- *100% response rate with a single dose of **neffy** observed in pediatric subjects experiencing anaphylaxis symptoms following oral food challenge; efficacy data intended to support post-marketing promotion of **neffy**, if approved*
- *On track to report topline results in Q1 2024 from repeat dose study of **neffy** under nasal allergen conditions requested by FDA, with NDA re-submission expected in the middle of H1 2024*

SAN DIEGO, Feb. 05, 2024 (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 new clinical data, including efficacy outcomes supporting ***neffy*** (epinephrine nasal spray), will be presented during the 2024 American Academy of Allergy, Asthma and Immunology (AAAAI). The meeting will be held February 23-26, 2024, in Washington, DC.

One late-breaking presentation reports efficacy outcomes for the first time with ***neffy*** in pediatric patients who developed anaphylaxis symptoms following oral food challenge. The efficacy data demonstrated that 100% of patients responded to a single dose of ***neffy*** with a 16-minute median time to complete resolution of anaphylaxis symptoms.

"I believe the robust and rapid clinical responses observed with ***neffy*** during anaphylaxis due to oral food challenge demonstrate that ***neffy*** is at least as effective as injection," says **Motohiro Ebisawa, M.D., Ph.D.**, Director of Clinical Research Center for Allergy and Rheumatology at Sagamihara National Hospital, Past-President of the World Allergy Organization, and Principal Investigator of the study. "My allergy colleagues and I are eagerly awaiting regulatory approval of ***neffy***, so that we can prescribe this needle-free and easy-to-carry treatment option to our severe allergy patients – many of whom do not carry, do not administer or delay use of epinephrine autoinjectors."

A second presentation details the statistically significant and clinically meaningful reductions in urticaria symptoms achieved by ***neffy*** across all endpoints in its randomized, controlled proof-of-concept study.

"Epinephrine is the first-line treatment and only medication for anaphylaxis that reduces risk of hospitalization and death," says **Sarina Tanimoto, M.D., Ph.D.,** Chief Medical Officer and Co-Founder of ARS Pharma. "The data from these studies to be presented at AAAAI in anaphylaxis and urticaria patients demonstrated that ***neffy*** worked as well and as fast as delivering epinephrine by injection, but without the need for a needle and its accompanying limitations."

ARS Pharma will share data across six presentations, further demonstrating the company's commitment to advancing its scientific leadership position in the allergy community. Additional ***neffy*** data to be presented include pharmacokinetic/ pharmacodynamic (PK/PD) effects in pediatric subjects, improved temperature stability versus injection products, improvements in patient quality of life, and increased device carriage, use and time to use rates.

Design of *neffy* efficacy study in oral food challenge induced anaphylaxis

This study (jRCT2031230143) assessed the safety and efficacy of a single dose of ***neffy*** given to pediatric patients with anaphylaxis symptoms induced by an oral food challenge.

2 mg (30 kg+ body weight) or 1 mg (15-30 kg body weight) doses of ***neffy*** were administered when patients exhibited gastrointestinal, respiratory or circulatory symptoms that were grade two or higher on the three-grade scale in the Severity Classification of Organ Symptoms by the Japanese Society of Allergology Anaphylaxis Guidelines 2022.[1]

Results from *neffy* efficacy study in oral food challenge induced anaphylaxis

A total of 15 patients aged 6 to 17 were enrolled; 6 subjects (15-30 kg body weight) were dosed with 1 mg ***neffy***, and 9 subjects (30 kg+ body weight) were dosed with 2 mg ***neffy***.

Treatment guidelines indicate a second dose of epinephrine should be given if clinical response is not observed within the first 15 minutes.

- **100% of the patients responded to the single dose of *neffy***
- After dosing ***neffy***, the median time to complete resolution of anaphylaxis symptoms was 16 minutes.
- 1 of 15 patients (6.7%) experienced a biphasic reaction 2 hours and 45 minutes following complete resolution of symptoms with the single dose of ***neffy*** and required additional epinephrine treatment. For epinephrine injection products, biphasic reactions are reported to occur at a frequency of 12.8% in children with food-induced anaphylaxis (Gupta et al. JACI: In

Practice, 2021).

- For epinephrine injection products, two or more doses of epinephrine are required for 10.8% of oral food challenges treated with epinephrine (n = 2,436 events) (Patel et al. JACI, 2021).

- Clinical data in this ***neffy*** trial is therefore in line with historical clinical response data for injection products.

The trial demonstrated safety results similar to the previously reported safety profile of ***neffy*** and approved epinephrine products with adverse events reported in 7 subjects dosed with ***neffy***, all of which were mild or moderate and most of which resolved quickly.

ARS Pharma remains on track to announce topline results from its repeat dose study of ***neffy*** under nasal allergen challenge conditions in the first quarter of 2024 and re-submit its NDA mid-first half of 2024 with an expected PDUFA action date and US launch, if approved, in the mid-second half of 2024.

The ***neffy*** presentations at AAAAI are listed below:

neffy **clinical efficacy studies**

Title: neffy, epinephrine nasal spray, Demonstrates a Positive Efficacy and Safety Profile for the Treatment of Allergic Reactions in Pediatric Patients at-Risk of Anaphylaxis: Phase 3 Study Results
Date & Time: Saturday, February 24, 2024, 9:45 to 10:45 a.m. ET
Session: Late-Breaking Poster Session II
Location: Convention Center, Level 2, Hall D

Title: ARS-2, Low-Dose Intranasal Epinephrine, Improves Urticaria Scores in Patients with Frequent Urticaria Flares: Phase 2 Study Results
Date & Time: Monday, February 26, 2024 12:45 to 2:00 p.m. ET
Poster Number: 788
Session: Novel Insights into Urticaria/Angioedema/Atopic Dermatitis

neffy **PK/PD and product formulation studies**

Title: Pediatric Doses of neffy (Intranasal Nasal Spray) Demonstrate Pharmacokinetic Profiles That Are Equivalent to Epinephrine Injections Products
Date & Time: Friday, February 23, 2024, 3:15 to 4:15 p.m. ET
Poster Number: 033
Location: Convention Center, Level 2, Hall D

Title: Comparative Stability of Three Epinephrine Products Under Extreme Temperature Conditions
Date & Time: Saturday, February 24, 2024, 9:45 to 10:45 a.m. ET
Poster Number: L32
Location: Convention Center, Level 2, Hall D

neffy **real-world patient burden studies**

Title: Effect of Needle-Free Epinephrine on Food Allergy Patient and Caregiver Quality of Life
Date & Time: Saturday, February 24, 2024, 9:45 to 10:45 a.m. ET
Poster Number: 240
Location: Convention Center, Level 2, Hall D

Title: A Survey of Allergists, Pediatricians, and Primary Care Physicians About the Utilization of Epinephrine
Date & Time: Saturday, February 24, 2024, 9:45 to 10:45 a.m. ET
Poster Number: 299
Location: Convention Center, Level 2, Hall D

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 import of study/trial results, including whether a regulatory agency will ultimately determine that ***neffy*** is safe and effective; ARS Pharma’s plan to announce topline results from its repeat-dose study under nasal allergen challenge conditions and file its NDA re-submission to the FDA; the expected PDUFA action date for ***neffy***; the potential regulatory approval of ***neffy*** and the anticipated US launch of ***neffy***, if approved, and the timing thereof; whether allergy physicians will prescribe ***neffy***, if approved,

instead of injectable epinephrine; 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 “await,” “believe,” “demonstrate,” “plan,” “expect,” “will,” “potential,” “on track to,” 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 successfully complete the repeat-dose study under nasal allergen challenge conditions within the anticipated timeframe, as a result of challenges inherent to enrolling, conducting and completing clinical trials; study limitations, including relatively small sample size and the absence of a comparator arm; 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; it is possible that the FDA may refuse to accept our planned NDA for ***neffy*** or may conclude after review of our data that our NDA application is insufficient to obtain regulatory approval for ***neffy***; the ability to obtain and maintain regulatory approval for ***neffy***; potential safety and other complications from ***neffy***; the labelling for ***neffy***, if approved; ARS Pharma’s ability to protect its intellectual property position; the scope, progress and expansion of developing and commercializing ***neffy***; the size and growth of the market for ***neffy*** and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; 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 September 30, 2023, filed with the Securities and Exchange Commission on November 9, 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.

ARS Pharma Media Contacts:
Laura O’Neill
Laura.oneill@finnpartners.com

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

---

[1] Anaphylaxis symptoms that triggered dosing of *neffy* had to be at least moderate in severity per the guidelines and could include: generalized urticaria/exanthema/wheal pruritus, swollen face, throat pain, moderate abdominal pain, recurrent emesis/diarrhea, repetitive cough, chest tightness/wheezing detectable via auscultation, pale face/mild hypotension/tachycardia (>15 beats/min), light-headedness/feeling of “pending doom”/somnolence/headache.