ARS Pharmaceuticals Reviews Recent Clinical Updates and Commercial Opportunity at neffy® Investor Day

March 7, 2024

- Significant unmet need with 80-90% of patients with current epinephrine Rx not using as directed, and only ~15% of diagnosed severe Type I allergy population with a current epinephrine prescription
- Multiple favorable attributes and potential best-in-class profile of ***neffy*** highlighted at the event
- Potential for epinephrine market to significantly expand from today due to availability of ***neffy***

SAN DIEGO, March 07, 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 hosted an investor event highlighting ***neffy***® (epinephrine nasal spray), an investigational new drug, for the treatment of Type I allergic reactions. The event included presentations by members of the ARS Pharma management team and by two distinguished allergists, Dr. Jonathan Spergel, M.D., Ph.D. and Dr. Thomas B. Casale, M.D.

"During our ***neffy*** Investor Day, we highlighted the substantial unmet need faced by patients suffering from severe allergies, and how current epinephrine treatments, while effective, have limitations – largely stemming from needle-related risks and portability issues," said Richard Lowenthal, Co-Founder, President and CEO of ARS Pharma. "Dr. Spergel and Dr. Casale discussed the limitations of today's needle-based treatments and how a product with ***neffy***'s profile increases the likelihood that patients will easily carry and confidently administer epinephrine without anxiety or hesitation. We believe we have addressed the deficiencies identified in FDA's CRL for ***neffy***, and we expect to submit a response early in the second quarter of 2024 and, if approved, look forward to bringing this innovative treatment to patients."

Dr. Jonathan Spergel, M.D., Ph.D., Professor of Pediatrics and Chief of the Allergy Program at Children's Hospital of Philadelphia, commented, "Epinephrine has been used for more than 100 years and we know that it is an effective treatment to reverse the symptoms of anaphylaxis, yet approximately 40% of patients do not fill their epinephrine prescriptions. Of the patients that do fill their prescription, 80-90% either do not carry or use their treatment as indicated. Prompt administration of epinephrine is the most critical factor that translates to better efficacy, regardless of device. The availability of an additional epinephrine option will help with compliance, especially with respect to children who account for almost half of the population with active prescriptions today."

Multiple Favorable Attributes of *neffy's* potential Profile, if approved, Highlighted during Investor Day

Effectiveness and Reliability	**Safety**	**Ease of Use**
Rapid effects within minutes based on pharmacodynamic response observed even 1 minute after dosing, as well as oral food challenge anaphylaxis and treatment-refractory chronic spontaneous urticaria efficacy data	Well-tolerated – mild nasal discomfort (9.7%) and mild headache (6%) are the most frequent adverse events (>5%)	Ease of use with 100% of untrained adults and children in human factors studies able to successfully dose ***neffy***
99.999% reliable device with proven use in emergency settings – tens of millions of units sold each year across seven other FDA approved products	No needle eliminates risk of needle-related injuries and accidental blood vessel injections	Portable – two ***neffy***'s fit easily in your pocket
Consistent pharmacokinetic and pharmacodynamic profile within the range of approved injection products even for repeat dosing and under challenge conditions such as rhinitis	High bioavailability with low 2 mg dose that minimizes risk of overexposure and side effects that mimic anaphylaxis such as vomiting and GI symptoms	Ability to dose not interfered by frequently observed anaphylaxis symptoms[1] such as vomiting (~20%), angioedema of the face, lips, tongue or larynx (~45%) or difficulty breathing (~55%)
		No meaningful pain or irritation as assessed by formal scales (mean visual analogue scale, or VAS, scores of 5 to 8 out of 100) Positive palatability with no taste or smell

[1] Frequency of symptoms observed during anaphylaxis based on an analysis of 4,805 cases reported in peer-reviewed journal publications

In September 2023, ARS Pharma announced that the U.S. Food and Drug Administration ("FDA") issued a Complete Response Letter ("CRL") regarding its New Drug Application ("NDA") for ***neffy***. ARS Pharma believes it has successfully addressed the deficiencies identified in the CRL and expects to submit a response early in the second quarter of 2024. Following an expected up to six-month review period, ARS Pharma anticipates an FDA action date and potential launch of ***neffy*** in the second half of 2024. The marketing authorization application ("MAA") for ***neffy*** is also under review by the European Medicines Agency (EMA) with a decision expected in the second quarter of 2024. Additional submissions to other foreign regulatory authorities are planned for 2024.

Dr. Thomas B. Casale, M.D., Professor of Medicine and Pediatrics and Chief of the Allergy & Immunology Division at University of South Florida, added, "To consider recommending a novel epinephrine delivery product to the allergy patients in our clinics, I need to know that the product works, that it is safe and that patients will actually use it during an episode. ***neffy***, if approved, would not only offer a rapid and reliable response in reversing anaphylaxis symptoms, but its benign side effect profile combined with a portable, easy to use design make this an attractive option for the severe

allergy community that is eagerly awaiting a needle-free epinephrine treatment option. I am confident that patients will have a higher likelihood of filling their ***neffy*** prescription, and that they will more frequently carry their device and be less hesitant to use ***neffy*** shortly after symptom onset."

Eric Karas, ARS Pharma's Chief Commercial Officer, noted, "Roughly 20 million patients in the U.S. have been formally diagnosed with severe Type 1 allergies. There is a substantial opportunity to penetrate and significantly expand the epinephrine treatment market, starting with the more than six million patients today that either do not fill their epinephrine prescription, do not use their current device at all, or use their device incorrectly. During the Investor Day, we outlined in detail how we expect ***neffy***'s favorable attributes, combined with promotion and population growth, may potentially expand today's epinephrine market from the approximately five million two-pack autoinjector units sold annually in the U.S. today, to over 14 million two-pack units by 2034. Having a device that is needle-free, easy to carry and easy to use, we expect patients will be more likely to have ***neffy*** with them when an allergic reaction occurs and be less hesitant to use the device at symptom onset."

In addition to severe Type I allergic reactions including anaphylaxis, ARS Pharma is actively developing ***neffy*** for the treatment of urticaria. In late-February, the Company announced positive clinical data from a Phase 2 trial evaluating ***neffy*** in adults with chronic spontaneous urticaria. ARS Pharma plans to initiate an outpatient urticaria study in patients treated with antihistamines who experience frequent acute flares later in 2024, potentially followed by initiation of a single pivotal efficacy study.

The webcast replay and accompanying slides from today's investor event may be accessed through the Events & Presentations page in the Investors & Media section of the Company's website. A replay of the webcast will be archived on the Company's website for 90 days.

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 Urticaria
Urticaria is a skin disorder that causes itchy hives and/or angioedema. Approximately 50% of chronic urticaria cases are non-responsive to first-line antihistamine therapy. These non-responsive patients on stable therapy regimens can experience exacerbations or flares several times a year among acute cases, and even several times a week, including up to three or four emergency room visits, among chronic urticaria cases.

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***® (also 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 market, demand and expansion opportunities for ***neffy***; potential benefits and favorable attributes of ***neffy***, if approved, including the likelihood that allergy patients, especially children, as well as caregivers, will choose to carry and dose ***neffy*** compared to needle-bearing options; ARS Pharma's plan to file its NDA early in the second quarter of 2024, with an anticipated Prescription Drug User Fee Act ("PDUFA") action date and launch of ***neffy***, if approved, in the second half of 2024; the timing of the EMA's decision of ARS Pharma's MAA; the timing of additional submissions to other foreign regulatory authorities; ARS pharma's plans to initiate an outpatient urticaria study later in 2024, potentially followed by initiation of a single pivotal efficacy study; 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," "expects," "plans," "potential," "will," 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***; even though the FDA has stated that completion of the repeat-dose study under allergen-induced allergic rhinitis conditions for ***neffy*** will sufficiently address the agency's outstanding questions, there is no guarantee that new issues will not be identified which could delay or prevent the approval of ***neffy***; whether the FDA will view the results from ARS Pharma's repeat-dose study under allergen-induced allergic rhinitis conditions for ***neffy*** as successful and sufficient to support approval; the PDUFA target action date may be further delayed due to various factors outside ARS Pharma's control; 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***; potential for payers 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 Pharma's ability to protect its intellectual property position; uncertainties related to capital requirements; 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 ("SEC") on November 9, 2023. This and other documents ARS Pharma files with the SEC can also be accessed on ARS Pharma's website at ir.ars-pharma.com by clicking on the link "Financials & Filings" under the "Investors & Media" tab.

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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