ARS Pharmaceuticals Announces Scheduling of a Type A Meeting with the U.S. FDA for neffy® (epinephrine nasal spray)

October 6, 2023

SAN DIEGO, Oct. 06, 2023 (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 the United States (U.S.) Food and Drug Administration (FDA) has scheduled a Type A meeting to discuss the contents of a Complete Response Letter (CRL) previously issued regarding its new drug application (NDA) for ***neffy***® (epinephrine nasal spray) for the treatment of allergic reactions (Type I), including anaphylaxis.

The Type A meeting with FDA will be held by the end of October.

"Patients and caregivers are waiting for ***neffy*** to be approved and have expressed to us disappointment with the delay in the FDA approval. We intend to work with FDA to meet the critical need for a needle-free epinephrine treatment as quickly as possible. Millions of people are at risk of a potentially life-threatening severe allergic reaction, and in practice, many are without any treatment option today, due to their inability to carry, or hesitancy or refusal to inject epinephrine in a timely manner. We are committed to meeting this urgent unmet medical need," said Richard Lowenthal, Co-founder, President, and CEO of ARS Pharma. "We were surprised by the late decision of FDA to request an additional study, based on prior discussions with FDA that this study could be conducted post approval, as informative for labeling. We are moving rapidly to conduct the study and look forward to the Type A meeting, which will provide an opportunity to discuss the CRL and pathway forward with FDA."

In May 2023, an FDA Advisory Committee (the Pulmonary-Allergy Drugs Advisory Committee (PADAC)) concluded a favorable benefit-risk profile and recommended approval of ***neffy***. Multiple PADAC members highlighted the favorable profile of ***neffy*** in our completed single-dose nasal allergen challenge study, which showed enhanced absorption during the time period when a clinical response would be expected. No member of the Committee requested a repeat dose study with ***neffy*** during allergen-induced allergic rhinitis, and ARS Pharma aligned with FDA in May 2023 and re-confirmed in August 2023 that such a study could be completed as a post-marketing requirement and had also aligned on final physician labeling.

Lowenthal added, "It is important to remember that there are less than 5% of food allergy cases where some degree of rhinitis is present and the unmet medical need and urgent benefit of ***neffy*** in the community are for those that are unwilling to accept a prescription for an injection device or who don't carry or use their epinephrine autoinjector when they experience an allergic reaction."

An estimated 45% of severe allergy patients do not fill their epinephrine prescriptions, and among the 3.3 million people who do obtain an injection device, more than 50% do not carry their autoinjector devices with them and 25% to 50% do not use it when presented with a serious allergic event.

Clinical data from a rigorous registration program of more than 600 subjects demonstrated that ***neffy*** achieved both a pharmacokinetic (PK) and pharmacodynamic (PD) profile that is comparable to approved injection products as well as a safety profile that is well-tolerated, but without needle-related risks. The company plans to complete a repeat dose study with ***neffy*** in allergen-induced allergic rhinitis and file its NDA resubmission to the FDA in the first half of 2024, with an anticipated launch of ***neffy***, if approved, in the second half of 2024.

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 due to food, venom, or insect stings. 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 patients 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 anticipated timing for the Type A meeting; ARS Pharma's plan to complete the repeat dose study with ***neffy*** in allergen-induced allergic rhinitis and file its NDA resubmission to the FDA in the first half of 2024, with an anticipated launch of ***neffy***, if approved, in the second half of 2024; 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," "intend," "plan," "expect," "will," "potential" 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***; the ability to successful complete the newly requested trial on the timeframe anticipated at all, as a result of challenges inherent to enrolling, conducting and completing clinical

trials; the results of the new clinical trial may not support the approval of ***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 Pharma'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" in ARS Pharma's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the Securities and Exchange Commission on August 10, 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.

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