ARS Pharmaceuticals Announces Availability of Briefing Documents for FDA Advisory Committee Meeting on neffy® for the Treatment of Type I Allergic Reactions Including Anaphylaxis

May 9, 2023

SAN DIEGO, May 09, 2023 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (NASDAQ: SPRY), 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 the U.S. Food and Drug Administration (FDA) posted briefing documents for the Pulmonology, Allergy-Drugs Advisory Committee (PADAC) meeting to review the new drug application (NDA) for ***neffy***®. ***neffy*** has the potential to be the first, non-injectable epinephrine nasal spray medicine for the treatment of patients with allergic reactions (type 1), including anaphylaxis.

The advisory committee meeting is scheduled to begin at 9:00 AM ET on May 11, 2023. Briefing materials, including FDA's addendum to the documents, and webcast information for the meeting can be accessed at https://www.fda.gov/advisory-committees/advisory-committee-calendar/may-11-2023-pulmonary-allergy-drugs-advisory-committee-meeting-announcement-05112023#event-materials. The Company is not responsible for the content of, nor the statements made in, the briefing materials that were prepared by the FDA.

"We are confident in the robust data package with ***neffy*** and believe our submission contains the information FDA indicated would be appropriate to support a potential approval of the first-ever non-injectable epinephrine spray," said Richard Lowenthal, Co-Founder, President and Chief Executive Officer at ARS Pharma. "We look forward to discussing this information with the PADAC members and presenting the details of our clinical findings across multiple registrational studies later this week."

ARS's NDA submission was based on data from four primary registrational studies showing that 2.0 mg intranasal dose of ***neffy*** met all clinical endpoints recommended by FDA and that its pharmacokinetics were within the range of approved epinephrine injection products. These data included studies in adults, with self-administration and caregiver administration, as well as in children with Type I allergies ≥30 kg (66 lbs). In addition, ***neffy*** has been well-tolerated to date with more than 600 individuals in clinical trials receiving at least one dose, and many with repeat administration. Adverse events in ***neffy*** clinical trials were generally mild in nature without any meaningful nasal irritation or pain, and no serious adverse events were reported in any clinical study.

The Company's NDA submission for ***neffy*** was accepted for review by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date anticipated in mid-2023.

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***® (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 of ***neffy*** to be the first, non-injectable epinephrine nasal spray medicine for the treatment of patients with allergic reactions (type 1), including anaphylaxis; ARS's belief that its NDA submission for ***neffy*** will be sufficient to support a potential approval of ***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 PADAC or the FDA may not view the data used to support the NDA submission to be sufficient to recommend the approval of, or to approve, respectively, ***neffy***; and the PADAC meeting or the PDUFA target action date may be delayed due to various factors outside ARS's control. 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's Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission (SEC) and available at www.sec.gov. This and other documents ARS files with the SEC can also 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 press release 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.

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