ARS Pharmaceuticals Announces FDA Advisory Committee for neffy® for the Treatment of Allergic Reactions (Type 1), Including Anaphylaxis

March 28, 2023

SAN DIEGO, March 28, 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) has scheduled a Division of Pulmonology, Allergy and Critical Care Advisory Committee meeting on May 11, 2023 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 FDA stated the following regarding an Advisory Committee in its official pre-NDA meeting minutes received by ARS:

1. *An Advisory Committee is an important aspect of the review given the new route of administration for an emergency use product that has clinical efficacy trial feasibility issues.*

2. *Additional experts with knowledge in systemic allergic reactions and anaphylaxis will be invited to participate in the Advisory Committee.*

3. *The FDA would not be planning to bring ARS's application to an Advisory Committee if they did not feel the PK/PD provided by ARS had the potential for approval.*

"The majority of patients with type I allergic reactions including anaphylaxis have limited or unsatisfactory treatment options in real-world community settings because of reluctance to administer or carry their injectable epinephrine devices," said Richard Lowenthal, president and chief executive officer of ARS Pharmaceuticals. "The announcement to hold an Advisory Committee is in-line with our historical interactions with the FDA over the years, and we believe a positive step towards the potential approval of ***neffy***. We are excited to have the opportunity to discuss ***neffy*** with the FDA and the Advisory Committee."

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 anticipated timing for regulatory review decisions on ***neffy*** and the potential approval of ***neffy***; the implications of the FDA scheduling an Advisory Committee meeting, including ARS's belief that it reflects a positive step towards the potential approval of ***neffy***; the timing of the Advisory Committee Meeting; the estimated addressable patient population 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 "anticipate," "believe," "plan," "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 ability to obtain and maintain regulatory approval for ***neffy***; the FDA's scheduling of an Advisory Committee meeting should not be relied on as an indication that ***neffy*** will ultimately be approved, and there are multiple examples of the FDA scheduling advisory committee meetings for product candidates that were not ultimately approved; the outcome of the Advisory Committee is uncertain and it is possible that the Advisory Committee will have an adverse or split recommendation with respect to ***neffy***; even if the Advisory Committee recommends the approval of ***neffy***, the FDA is not bound by the Advisory Committee's recommendation; the PDUFA target action date may be delayed due to various factors outside ARS's control; the labelling for ***neffy***, if approved; the scope, progress and expansion of developing and commercializing ***neffy***, if approved; the size and growth of the market therefor and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; ARS's ability to protect its intellectual property position; the impact of government laws and regulations; and ARS's ability to execute its plans and strategies. 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 the company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission ("SEC") on March 23, 2023. 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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ARS Pharmaceuticals, Inc.