FDA Advisory Committee Votes in Support of Favorable Benefit-Risk Profile for neffy® (Intranasal (IN) Epinephrine) for the Treatment of Allergic Reactions (Type 1), Including Anaphylaxis

May 11, 2023

- *FDA Advisory Committee Votes: **neffy** Data Support a Favorable Benefit-Risk Assessment in Adults (16:6 in Favor) and in Children <18 years of age and ≥30 kg (17:5 in Favor)*
    - *If Approved, **neffy** Will Become the First Needle-Free Epinephrine Product for the Treatment of Severe Allergic Reactions*
    - *FDA Approval Decision Anticipated Mid-2023*

SAN DIEGO, May 11, 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's (FDA) Pulmonary-Allergy Drug Advisory Committee (PADAC) voted 16:6 in favor for adults, and 17:5 in favor for children (<18 years of age and ≥30 kg), that available data support a favorable benefit-risk assessment for ***neffy*** in the treatment of severe allergic reaction (Type 1), including anaphylaxis,for adults and children who weigh more than 30kg.

"We'd like to thank PADAC members for their robust scientific discussions and clinical perspectives. The committee's thoughtful review of the data, and support of the potential for ***neffy*** to address significant unmet needs of the severe allergy community, if approved, is highly encouraging," said Richard Lowenthal, Co-founder, President and Chief Executive Officer, ARS Pharmaceuticals. "We believe our clinical data from more than 600 individuals demonstrate ***neffy***'s absorption-enhancing nasal spray technology is comparable to injectable products in delivering potentially lifesaving epinephrine, but with unique advantages of being small, needle-free and conveniently sized. We are committed to making it easier for patients and caregivers to carry and administer epinephrine without the anxiety and hesitation associated with using a needle-based device. We were moved by the outpouring of support for ***neffy*** ahead of and throughout this meeting, and we are especially grateful to those individuals who shared their personal experiences, illustrating the positive impact ***neffy*** may create for millions of individuals and families in the future."

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 PADAC decision was based on a review of comprehensive data from clinical studies developed in agreement with the FDA, which support a positive risk-benefit profile for intranasal (IN) epinephrine safety and effectiveness, compared to epinephrine injection. The studies demonstrated and the Committee's discussion supported that ***neffy*** shows:

- Comparable pharmacokinetic (PK) data (epinephrine levels in the blood) vs. intramuscular injection including the first 10 to 20 minutes when clinical response is observed
- Comparable or greater pharmacodynamic (PD)response (systolic blood pressure and heart rate) vs. intramuscular injection that is observed even at 1 minute after dosing of ***neffy***
- Effective IN delivery of systemic epinephrine and PD response even with nasal congestion or runny nose (e.g., during allergic rhinitis or upper respiratory tract infection)
- Comparable safety to injection that is generally mild in nature without any meaningful nasal irritation or pain, without needle-related risks

Additionally, ***neffy's*** sprayer device has been approved by FDA for drug delivery for six other products in the United States, many of which are intended for emergency use.

"Patients need options – with different administration methods – to facilitate actual epinephrine use in an emergency event," said Carlos Camargo, MD, DrPH, Professor of Emergency Medicine, Harvard Medical School. "The data presented today show robust evidence of comparable pharmacokinetic (PK) and pharmacodynamic (PD) responses for ***neffy*** compared to injection, even in patients with rhinitis or nasal congestion. The effects of epinephrine on blood pressure and heart rate are surrogates for efficacy and are important in determining if someone is responding to treatment. With ***neffy***, blood pressure and heart rate are comparable to EpiPen with a single dose – and with a second dose of ***neffy***, increases in systolic blood pressure were statistically higher, even better than revealed in the available data from EpiPen, which is crucial for patients requiring a second dose for a severe allergic reaction."

While PADAC recommendations are non-binding, the FDA will consider this outcome in its review of the pending New Drug Application (NDA) for ***neffy***. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date anticipated mid-2023. If approved, ***neffy*** would be the first non-injectable treatment available to patients with allergic reactions (Type 1) including anaphylaxis.

"Millions of people have been waiting decades for a new delivery method of epinephrine, and we are grateful to the community for sharing their personal experiences and illustrating the potential ***neffy*** has in changing lives. We continue discussions with private payers, pharmacy benefit managers, and retail pharmacies to ensure that if ***neffy*** receives FDA approval, we are ready to make this important new treatment modality widely available for those who need it," Mr. Lowenthal added.

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 PADAC decision; ARS being ready to make ***neffy***, if approved, widely available for those who need it; 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," "may" 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 PADAC decision should not be relied on as an indication that ***neffy*** will ultimately be approved; the FDA is not bound by the PADAC decision or any of its recommendations and there are a number of instances where the FDA has voted against the recommendations of advisory committees; the PDUFA target action date may be delayed due to various factors outside ARS's control; the FDA's prior approval of ***neffy's*** sprayer device for drug delivery for six other products should not be relied on as an indication that FDA will approve the sprayer device for the administration of ***neffy***; the labelling for ***neffy***, if approved; the scope, progress and expansion of developing and commercializing ***neffy***, if approved, including the ability to enter into distribution arrangements and obtain favorable reimbursement; 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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