ARS Pharmaceuticals Announces PDUFA Date Extension for neffy® (Intranasal (IN) Epinephrine) for the Treatment of Allergic Reactions (Type 1), Including Anaphylaxis

June 20, 2023

Additional Time Needed for Labeling and Post-Marketing Requirements Discussions; PDUFA Date Set for September 19, 2023

SAN DIEGO, June 20, 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) extended the Prescription Drug User Fee Act (PDUFA) target action date by three months for the New Drug Application (NDA) for ***neffy*** (Intranasal (IN) Epinephrine) for the treatment of allergic reactions (Type 1), including anaphylaxis, for adults and children ≥30 kg. The updated PDUFA target action date is September 19, 2023.

Following a favorable benefit-risk assessment by the FDA Pulmonary-Allergy Drug Advisory Committee (PADAC) meeting on May 11, 2023, the Agency informed ARS that it requires additional time to complete its review; however, no additional pre-marketing studies have been requested and ARS has addressed all other information requests from the Agency to date. The additional time is needed for labeling and post-marketing commitment discussions regarding ***neffy***, and ARS has submitted proposals for post-marketing commitments based on input from the PADAC meeting in May.

"FDA is working on labeling and post-marketing commitments as the final steps in the review process," said Richard Lowenthal, Co-Founder, President and Chief Executive Officer, ARS Pharmaceuticals. "Following the strong endorsement of our clinical data for ***neffy*** at the May PADAC meeting, there was limited time to address any final questions and complete labeling. While the Agency extended the PDUFA timeline, we are hopeful that labeling discussions will be completed as soon as possible given the significant unmet need in the allergy community for a needle-free option that is easily carried and administered without anxiety or hesitation."

In addition, a marketing authorization application for ***neffy*** is under review by the European Medicines Agency with a decision expected in early 2024.

For more information, visit: https://ars-pharma.com/

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***; discussions regarding labeling and post-marketing commitments with FDA being the final steps in the review process and labeling discussions being concluded shortly; potentially bringing to market the first needle-free treatment option for severe allergic reactions; 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," "intends," "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 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 further delayed due to various factors outside ARS's control; even though ARS believes its discussions with the FDA regarding final labeling and post-marketing commitments are the final steps in the review process, there is no guarantee that those steps will be concluded in a manner favorable to ARS and likewise those steps should not be relied on as an indication that the FDA will ultimately approve ***neffy***, as the FDA may identify new issues that could delay or prevent the approval of ***neffy***; potential safety and other complications from ***neffy***; 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'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's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the Securities and Exchange Commission ("SEC") on May 15, 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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