ARS Pharmaceuticals Submits Response to FDA Complete Response Letter for neffy® (Epinephrine Nasal Spray)

April 3, 2024

- Response addresses all additional requests in FDA CRL, including positive data from a repeat dose PK/PD study of ***neffy*** under nasal allergen challenge (NAC) conditions, and updated testing that detected no measurable nitrosamine levels, conducted per August 2023 FDA Guidance
- Submission of CRL response triggers up to six-month review period by the FDA

SAN DIEGO, April 03, 2024 (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, announced today that it has submitted its response to the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for ***neffy***® (epinephrine nasal spray), for the treatment of Type I allergic reactions including anaphylaxis.

The submission follows receipt of a Complete Response Letter (CRL) from the FDA in September 2023, which identified two additional requests: completion of a repeat dose pharmacokinetic (PK) / pharmacodynamic (PD) study of ***neffy*** under nasal allergen challenge (NAC) conditions, and completion of updated nitrosamine testing per the FDA's draft guidance issued in August 2023.

In February 2024, ARS Pharma announced the successful completion of the repeat dosing study of ***neffy*** in seasonal allergic rhinitis under NAC conditions. ARS Pharma also completed the nitrosamine testing requested with no measurable levels of nitrosamines detected.

"After approximately six months of receiving the CRL for ***neffy***, we were able to pivot quickly to successfully complete the repeat dosing nasal allergen challenge study and updated nitrosamine testing with no measurable levels of nitrosamines detected, and submit our response to the CRL," said Richard Lowenthal, Co-Founder, President and CEO of ARS Pharma. "Based on multiple meetings with the FDA, we believe that we have responded fully and completely to the Agency's concerns and appreciate its insights along the way. Our focus on addressing any requests from the FDA to optimize our labeling remains critical in our mission to bring ***neffy*** to patients, providers, and caregivers who continue to show substantial enthusiasm for a needle-free, safe, effective, and easy to carry epinephrine solution. We look forward to working with the FDA in our efforts to make ***neffy*** available to allergy patients as soon as possible."

The original ***neffy*** NDA was submitted in August 2022. In May 2023, the FDA Advisory Committee (PADAC) determined a favorable benefit-risk profile for ***neffy*** (16:6 for adults and 17:5 for children). No PADAC member requested a repeat dose study during allergen-induced allergic rhinitis.

ARS Pharma anticipates an FDA review period of up to six months, and the PDUFA date is anticipated to be October 2, 2024, based on the submission receipt date of April 2, 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. Of those, only 3.2 million had an active epinephrine autoinjector prescription in 2023, 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.

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: the anticipated FDA review period; the anticipated FDA action date and launch of ***neffy***, if approved; the belief that ARS Pharma has fully and completely responded to the FDA's concerns; 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," "believes," "potential," "will," 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***; even though the FDA has stated that completion of the repeat-dose study under allergen-induced allergic rhinitis conditions for ***neffy*** will sufficiently address the agency's outstanding questions, there is no guarantee that new issues will not be identified which could delay or prevent the approval of ***neffy***; whether the FDA will view the results from ARS Pharma's repeat dose study under allergen induced allergic rhinitis conditions for ***neffy*** as successful and sufficient to support approval; the PDUFA target action date may be further delayed due to various factors outside ARS Pharma's control; 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; uncertainties related to capital requirements; 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 Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission (SEC) on March 21, 2024. This and other documents ARS Pharma files with the SEC can also be accessed on ARS Pharma's website at ir.ars-pharma.com by clicking on the link "Financials & Filings" under the

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