FDA Issues Complete Response Letter for neffy® (epinephrine nasal spray) New Drug Application with Request for Additional Study

September 20, 2023

*Company aligned with FDA in August 2023 on both physician labeling and post-market requirements, which included a repeat-dose study of **neffy** under allergen-induced allergic rhinitis conditions*

*FDA Advisory Committee (PADAC), held in May 2023, recommended **neffy** approval based on current data set and without recommending additional trials*

*FDA now requests repeat-dose study be completed prior to **neffy** approval as opposed to previously agreed-upon post-marketing requirement*

*Well-capitalized with anticipated cash, cash equivalents and short-term investments on hand of approximately $195 million at the time of our anticipated **neffy** launch, if approved in 2H24, following our resubmission to the FDA in 1H24*

SAN DIEGO, Sept. 19, 2023 (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, today announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding its New Drug Application (NDA) for ***neffy***® (epinephrine nasal spray) in the treatment of Allergic Reactions (Type I), including anaphylaxis for adults and children ≥30 kg. ARS Pharma plans to submit a Formal Dispute Resolution Request (FDRR) to appeal the issuance of this CRL.

In the letter, the FDA requested completion of a pharmacokinetic/pharmacodynamic study assessing repeat doses of ***neffy*** compared to repeat doses of an epinephrine injection product under allergen-induced allergic rhinitis conditions to support approval. This request comes after the recommendation of the FDA Advisory Committee (PADAC) in May 2023 to approve ***neffy*** without the need for additional studies to demonstrate its efficacy or safety. Further, FDA and ARS Pharma previously aligned in August 2023 on final physician's labeling and a post-marketing requirement to conduct this study as informative for labeling.

The PADAC meeting was held on May 11, 2023, and concluded a favorable benefit-risk profile of ***neffy***, with a 16:6 vote in favor for adults and 17:5 vote in favor for children (≥30 kg) for the treatment of patients with allergic reactions (Type I), including anaphylaxis. In that session, no member of the Committee raised specific concerns about the result of the completed study in people with allergen-induced acute rhinitis with single-dose ***neffy***, which showed enhanced absorption during the time period when a clinical response would be expected.

"We are very surprised by this action and the late requirement at this time to change the repeat-dose study from a post-marketing requirement, which we had previously aligned on with FDA, to a pre-approval requirement, particularly given the positive Advisory Committee vote. In fact, multiple Committee members highlighted the favorable profile of ***neffy*** in our completed single-dose nasal allergy challenge study and that any decline in exposure 20 minutes after dosing, after the expected response period, is of no concern," said Richard Lowenthal, Co-founder, President and CEO of ARS Pharma. "We stand by the totality of the ***neffy*** data package generated in a comprehensive registration program that was aligned upon with FDA and believe strongly in the value ***neffy*** can provide for patients, families and caregivers living daily with severe allergic reactions."

Mr. Lowenthal continued, "If approved, ***neffy*** would represent the first-ever needle-free nasal spray epinephrine treatment for people with severe allergic reactions that has been shown to be more easily carried and administered, without anxiety or hesitation, which is critical to stopping disease progression. We have heard a tremendous outpouring of support from the patient, advocacy, and physician communities, who have a critical need for a needle-free epinephrine treatment. We are deeply disappointed that this action further delays the availability of ***neffy*** for the millions of people who are at risk of a potentially life-threatening severe allergic reaction. Patients and caregivers are waiting for ***neffy***, and we aim to complete the newly requested trial as quickly as possible to meet the needs of patients."

As ARS Pharma previously agreed with FDA to conduct a repeat-dose study under allergen-induced allergic rhinitis conditions as a post-marketing commitment, ARS Pharma anticipates a resubmission to the FDA in the first half of 2024, positioning ARS Pharma for an anticipated FDA action date in the second half of 2024.

ARS Pharma expects to have anticipated cash, cash equivalents and short-term investments on hand of approximately $195 million at the time of the anticipated launch of ***neffy***, if approved in the second half of 2024.

The CRL requested additional information on nitrosamine impurities to be tested for based on new draft guidance issued after the ***neffy*** NDA submission. ARS Pharma does not believe the additional testing would be a rate-limiting step for its resubmission to the FDA.

A marketing authorization application for ***neffy*** is also under review by the European Medicines Agency with a Committee for Medicinal Products for Human Use opinion expected by year end 2023. Submissions to other regulatory authorities in additional countries are planned for 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 due to food, venom or insect stings. 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 Pharma is a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect patients 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 ARS Pharma's ability to complete the newly required trial and provide the additional information requested by the FDA in the CRL on the timing anticipated, or at all; the potential approval of ***neffy***; the expected timing for the Committee for Medicinal Products for Human Use opinion with respect to the marketing authorization application for ***neffy*****;** the expected submissions of ***neffy*** to other regulatory authorities in additional countries and the timing thereof; ARS Pharma's cash, cash equivalents and short-term investments on hand upon any future 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 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***; the ability to successful complete the newly requested trial on the timeframe anticipated at all, as a result of challenges inherent to enrolling, conducting and completing clinical trials; the results of the new clinical trial may not support the approval of ***neffy***; results from clinical trials may not be indicative of results that may be observed in the future; 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; 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the Securities and Exchange Commission on August 10, 2023. This document can also be accessed on ARS Pharma'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 Pharma assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

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