EURneffy (adrenaline nasal spray) Approved in the EU as the First and Only Needle-Free Emergency Treatment of Allergic Reactions (anaphylaxis)

August 26, 2024

***EURneffy** offers adults and children (≥30 kg) in Europe living with severe allergic reactions the first new delivery method for adrenaline in more than 30 years in the EU*

European Commission decision follows FDA approval in the United States on August 9, 2024

SAN DIEGO, Aug. 26, 2024 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to the development of products to better protect patients from severe allergic reactions that could lead to anaphylaxis, announced today that the European Commission has approved **EUR*neffy*®** (adrenaline nasal spray) for the emergency treatment of allergic reactions (anaphylaxis) on August 22, 2024.

"Adrenaline is the only first-line treatment for allergic reactions including anaphylaxis, yet there is significant underutilization of adrenaline due to the limitations of current available therapy," said Antonella Muraro, MD PhD, Professor of Food Allergy at the University of Padua, and lead author of the European Academy of Allergology and Clinical Immunology (EAACI) treatment guidelines for anaphylaxis. "The approval of EUR *neffy* provides the first needle-free treatment option available in the EU for adults and children (≥30 kg) with severe allergies, many of whom may not carry, or delay use of an injectable adrenaline product."

"Today's approval marks an important moment for the severe allergy community in the EU, and the first novel adrenaline delivery method in more than three decades," said Richard Lowenthal, Co-Founder, President and CEO of ARS Pharma. "**EUR*neffy***s needle-free, smaller form and longer and less temperature-sensitive shelf-life may increase the likelihood that patients will both carry *and* administer adrenaline, which improves the outcome of allergic reactions."

The approval of the mixed application for marketing authorization grounded on Article 8(3) of Directive 2001/83/EC by the European Commission was granted following the review of data from one of the most extensive nasal spray development programs in history involving more than 700 study participants and over 1,200 administrations, as well as studies and peer-reviewed literature substituting or supporting certain tests and studies. The pharmacodynamics and pharmacokinetics of 2 mg **EUR*neffy*** were evaluated across a range of dosing conditions, including single and repeat dosing, self-administration by patients, dosing in pediatrics, and during multiple nasal conditions that can cause congestion and rhinorrhea such as nasal allergen challenge or infectious rhinitis caused by a cold/flu.

EUR*neffy* benefits from an eight-year period of data protection whereby another applicant cannot rely the data submitted as part of the EUR*neffy* marketing authorization application, and a ten-year period of marketing protection during which a generic, hybrid or biosimilar cannot be placed on the market in the EU. The issued composition of matter and method of treatment patents covering *EURneffy* in Europe expire in 2039.

ARS Pharma anticipates that EUR*neffy* will be made available to patients in certain European Union Member States in Q4 2024 by a pharmaceutical company with an already established commercial footprint in Europe.

EUR*neffy* is the trade name for ***neffy***® (epinephrine nasal spray) in the European Union.

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 approved medication for these reactions in the European Union. While adrenaline 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. 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 the development of products to better protect patients from severe allergic reactions that could lead to anaphylaxis. The Company is commercializing ***neffy***® (trade name **EUR*neffy*** in the EU),, 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 potential market and demand for **EUR*neffy***; the needle-free profile of ***neffy*** potentially increasing the likelihood that patients may both carry *and* administer adrenaline; the expected intellectual property protection; the timelines for commercialization of **EUR*neffy*** in the European Union; ARS Pharma's marketing and commercialization strategies, including potential partnerships in foreign jurisdictions; 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," "expects," "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***; potential safety and other complications from ***neffy***; the labelling for ***neffy*** in any future indication or patient population, if approved; the scope, progress and expansion of developing and commercializing ***neffy***; the potential for payors to delay, limit or deny coverage for ***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, 2024, filed with the Securities and Exchange Commission (SEC) on August 6, 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 “Investors & Media” tab.

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Source: ARS Pharmaceuticals, Inc.