ARS Pharmaceuticals Announces EURneffy (adrenaline nasal spray) Recommended for Approval by CHMP for Emergency Treatment of Allergic Reactions (anaphylaxis)

June 28, 2024

EURneffy *positioned to be the first and only needle-free adrenaline option authorized for emergency treatment of allergic reactions (anaphylaxis) in Europe*

Positive CHMP opinion and recommendation for approval of a mixed application for marketing authorization based on comprehensive data package comparing ***EURneffy*** *to approved injectable products across a range of dosing scenarios as well as supportive historical data from injectable products*

Same data package under review by FDA with a PDUFA date of October 2, 2024

SAN DIEGO, June 28, 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 Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion on the application for marketing authorization for **EUR*neffy*®** (adrenaline nasal spray) and recommended related market authorization in the European Union (EU) for the emergency treatment of allergic reactions (anaphylaxis). The CHMP positive opinion will now be submitted to the European Commission (EC) for the formal marketing authorization process, which is expected to occur in Q3 2024.

"Today's announcement marks a major milestone in the treatment of severe allergies and moves us one step closer to bringing **EUR*neffy*** to patients in the EU as the first and only needle-free adrenaline option for the emergency treatment of allergic reactions, up to anaphylaxis," 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 outcome of allergic reactions."

The positive opinion and recommendation for approval of a mixed application for marketing authorization grounded on Article 8(3) of Directive 2001/83./EC from the CHMP is based on 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 basis of approval for **EUR*neffy*** in Europe was efficacy supported by surrogate pharmacodynamic endpoints. 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. The **EUR*neffy*** mixed application under Article 8(3) of Directive 2001/83./EC will benefit from an eight-year period of data protection whereby another applicant cannot rely on support from the **EUR*neffy*** application, and a ten-year period of marketing protection during which a generic, hybrid or biosimilar cannot be placed on the market. The issued composition of matter and method of treatment patents covering **EUR*neffy*** in Europe have an expiration date in 2039.

Following grant of marketing authorization by the EC expected in Q3 2024, ARS Pharma anticipates that **EUR*neffy*** will be made available to patients in Europe in Q4 2024 by a pharmaceutical company with an already established commercial footprint in Europe.

The same data package reviewed by CHMP that resulted in its positive opinion and approval recommendation was submitted to the U.S. Food and Drug Administration (FDA) on April 2, 2024. FDA acknowledged receipt of the submission and considered it a complete response to the September 19, 2023 action letter with no comments. The company's New Drug Application is under review by FDA, with a ***neffy*®** PDUFA action date assigned by the FDA of October 2, 2024.

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 Europe. 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 developing ***neffy***® (trade name **EUR*neffy*** in the EU) (previously 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 potential approval of ***neffy*** in the EU or U.S.; the expected timing for the EC decision; the PDUFA action date for ***neffy***; the needle-free profile of ***neffy*** increasing the likelihood that patients will both carry *and* administer adrenaline; 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

positive opinion from CHMP does not guarantee the EC will approve the related marketing authorization; the ability to obtain and maintain regulatory approval for ***neffy***; 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 March 31, 2024, filed with the Securities and Exchange Commission (SEC) on May 9, 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.

ARS Investor Contact:
Justin Chakma
ARS Pharmaceuticals
justinc@ars-pharma.com

ARS Media Contact:
Christy Curran
Sam Brown Inc.
christycurran@sambrown.com