# ARS Pharmaceuticals Reacquires European Marketing Rights to neffy® (ARS-1) for the Treatment of Type I Allergic Reactions Including Anaphylaxis

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SAN DIEGO, Feb. 22, 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 company reached agreement to reacquire commercial rights to ***neffy***, known as ARS-1 in the European region, from Recordati S.p.A. The agreement followed a portfolio review conducted by Recordati aimed at focusing commercial efforts on core strategic therapeutic areas. In 2020, the original license and supply agreement between ARS and Recordati provided ARS with non-dilutive funding for the early clinical development of ***neffy***, while providing Recordati marketing rights to ***neffy*** in the European Union, Iceland, Liechtenstein, Norway, Switzerland, United Kingdom, Russia/CIS, Turkey, Middle East and French-speaking African countries. Today, ARS is in a strong position, with approximately $275 million in cash as of year-end 2022, and an anticipated 2023 US launch of ***neffy***, if approved. ARS' cash is projected to be at least three years of operating runway based on the company's current operating plan.

"We are grateful to Recordati for their support to date and, by reacquiring European rights with an anticipated EU regulatory decision later this year, we increase our optionality in pursuing potential strategic transactions or partnerships," said Richard Lowenthal, president and chief executive officer of ARS Pharmaceuticals. "Our MAA for ***neffy*** is currently under review by the EMA, and if approved in the EU, we see tremendous potential for commercial success. If approved, this product can be an important treatment option for patients around the world who fear using needle bearing injection devices."

"We believe **ARS-1** will be a differentiated product that will fill an unmet need for patients with Type I allergic reactions," said Alberto Martinez, Recordati Executive VP Specialty & Primary Care. "This agreement with ARS to re-acquire our rights was made as part of a portfolio review process. We are proud to have contributed to advancing the development of **ARS-1** for patients in Europe and wish ARS success as it moves **ARS-1** toward approval."

In connection with the agreement for ARS to reacquire commercial rights to ***neffy***, ARS is obligated to pay Recordati an upfront amount, milestones upon EU approval and commercial launch, and payments (subject to a specified cap) based on commercial sales in the EU, United Kingdom, and certain countries in the Middle East, Africa and Eurasia.

A new drug application (NDA) for ***neffy*** 2 mg is currently under review with the U.S. Food and Drug Administration (FDA), as well as a marketing authorization application (MAA) with the European Medicines Agency (EMA). In four primary registration studies of the 2 mg intranasal dose of ***neffy,*** all clinical endpoints recommended by regulators were met, and pharmacokinetics were within the range of approved epinephrine injection products. These data included studies in adults, with self-administration and caregiver administration, as well as in children with Type I allergies ≥30 kg (66 lbs). In addition, ***neffy*** has been well-tolerated to date with more than 600 individuals receiving at least one dose, and many with repeat administration. The majority of adverse events in clinical trials were mild in nature without any meaningful nasal irritation or pain. A supplemental application for regulatory approval for a ***neffy*** 1 mg product for children 15 kg to <30 kg is planned to be filed immediately after approval in the United States and/or Europe.

**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, ARS's projected cash runway; the anticipated timing for regulatory review decisions on ***neffy*** and the potential approval of ***neffy***; the anticipated US launch of ***neffy***, if approved, and the timing thereof; ARS's strategy of pursuing potential strategic transactions or partnerships for ***neffy*** in Europe, if approved; the estimated addressable patient population for ***neffy***; ARS's plan to file a supplemental regulatory application for a ***neffy*** 1 mg product for children 15 kg to <30 kg immediately after the approval of ***neffy*** 2 mg in the United States and/or Europe; 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'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***; 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'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—Risks Related to ARS Pharma" in the company's definitive merger proxy statement filed with the Securities and Exchange Commission on October 6, 2022. This document 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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