ARS Pharmaceuticals Submits Response for neffy® (epinephrine nasal spray) Marketing Authorization Application to EMA's CHMP and Enters License Agreement with CSL Seqirus for Commercialization of neffy in Australia and New Zealand

April 30, 2024

*CHMP opinion on **neffy** Marketing Authorization Application anticipated in the second quarter of 2024*

*Response addresses all issues previously identified by CHMP, and includes results from a repeat dose PK/PD study of **neffy** under NAC conditions and updated testing concerning nitrosamine levels*

*Exclusive licensing deal for Australia and New Zealand with CSL Seqirus; CSL Seqirus will be responsible for applying for regulatory approval, reimbursement and commercialization of **neffy**. ARS Pharmaceuticals will be responsible for manufacturing and product supply.*

SAN DIEGO, April 30, 2024 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to development of products to protect patients from severe allergic reactions that could lead to anaphylaxis, announced today that it has submitted its Day 180 response to the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for its Marketing Authorization Application (MAA) for ***neffy***® (epinephrine nasal spray), an investigational new drug to be indicated for the treatment of Type I allergic reactions including anaphylaxis.

The submission follows receipt of Day 180 comments in the fourth quarter of 2023 that requested completion of a repeat dose study of ***neffy*** under nasal allergen challenge (NAC) conditions, and completion of updated nitrosamine testing.

In February 2024, ARS Pharma announced the completion of its clinical study assessing repeat doses of ***neffy*** in patients with seasonal allergic rhinitis under nasal allergen challenge conditions. ARS Pharma also completed its nitrosamine testing, per the FDA's draft guidance issued in August 2023, with no measurable levels of nitrosamines detected. Based on the timetable included in the Day 180 comments, ARS Pharma expects CHMP to issue its opinion on the ***neffy*** MAA in the second quarter of 2024.

In parallel, ARS Pharma executed an exclusive license and distribution agreement for Australia and New Zealand with CSL Seqirus, a subsidiary of CSL Limited (ASX: CSL). CSL Limited is the largest Australian pharmaceutical company by market capitalization. Under the terms of the agreement, CSL Seqirus will apply for regulatory and pricing and reimbursement approvals, and will be responsible for commercializing ***neffy*** across Australia and New Zealand.

"We're thrilled to be partnering with an innovative company in ARS Pharma to work towards making this innovative needle free adrenaline device for anaphylaxis treatment available for people in Australia and New Zealand who live with severe allergies," says Danielle Dowell, CSL Seqirus Executive Director of Commercial Operations Asia-Pacific.

"We are encouraged that CSL Seqirus recognizes the importance of making a needle-free epinephrine treatment available to severe allergy patients in Australia and New Zealand, as well as by the robust and compelling ***neffy*** product profile and registrational data as we pursue final approval globally," says Richard Lowenthal, Co-Founder, President and CEO of ARS Pharma. "CSL Seqirus is not only one of the leading fully integrated commercialization partners for vaccines and pharmaceuticals in Australia and New Zealand, but it has a proven track record of successfully commercializing multiple innovative medicines that it has in-licensed for its allergy portfolio over the years."

ARS Pharma will receive an upfront payment and be eligible for event-driven milestone payments. Following local regulatory approval of ***neffy***, ARS Pharma will be responsible for supplying finished product to CSL Seqirus in exchange for a transfer price.

About ARS Pharmaceuticals, Inc.
ARS Pharma is a biopharmaceutical company dedicated to development of medicinal products to protect at-risk patients from severe allergic reactions that could lead to anaphylaxis. The Company is developing ***neffy***® (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.

About CSL Seqirus
CSL Seqirus is part of CSL Limited (ASX: CSL). As one of the largest influenza vaccine providers in the world, CSL Seqirus is a major contributor to the prevention of influenza globally and a transcontinental partner in pandemic preparedness. With state-of-the-art production facilities in the U.S., the U.K. and Australia, and leading R&D capabilities, CSL Seqirus utilizes egg, cell and adjuvant technologies to offer a broad portfolio of differentiated influenza vaccines in more than 20 countries around the world.

In Australia, CSL Seqirus operates the only local manufacturing facility for seasonal and pandemic influenza vaccine and produces a range of unique medicines in the national interest including antivenoms and the world's only human vaccine for Q fever. CSL Seqirus's commitment to Australia's health also extends to providing access to paediatric and adult vaccines, and innovative pharmaceuticals for patients living with allergies, cardiovascular disease, severe pain, dry eye disease, iron deficiency, kidney diseases, rare diseases and neurological conditions.

About CSL
CSL (ASX: CSL; USOTC: CSLLY) is a leading global biotechnology company with a dynamic portfolio of lifesaving medicines, including those that treat haemophilia and immune deficiencies, as well as vaccines to prevent influenza. Since CSL's start in 1916, CSL has been driven by its promise to save lives using the latest technologies. Today, CSL – including our three businesses, CSL Behring, CSL Seqirus and CSL Vifor – provides lifesaving products to patients in more than 100 countries and employs 30,000 people. CSL's unique combination of commercial strength, R&D focus and operational excellence enables it to identify, develop and deliver innovations so its patients can live life to the fullest. For inspiring stories about the

promise of biotechnology, visit CSLBehring.com/Vita and follow us on Twitter.com/CSL. For more information about CSL, visit www.csl.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 belief that ARS Pharma’s response has addressed all issues previously identified by CHMP; the timing for an expected CHMP opinion on the ***neffy*** MAA; the potential approval of ***neffy*** in the European Union; statements regarding activities to be performed under the license agreement with CSL Seqirus; the timing and size of payments to be made under the license agreement with CSL Seqirus; 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 “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***; there is no guarantee that new issues will not be identified by CHMP, which could delay or prevent its opinion or result in an adverse opinion; whether CHMP 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 a positive opinion; 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 “Investors & Media” tab.

ARS Investor Contact

Justin Chakma

ARS Pharmaceuticals

justinc@ars-pharma.com

ARS Pharmaceuticals, Inc.