ARS Pharmaceuticals Announces Exclusive Agreement with Global Allergy Leader ALK to Commercialize neffy® in Europe, Canada and Other Geographies Outside the United States

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Agreement leverages ALK's global footprint in developing and commercializing innovative allergy products

ARS Pharma to receive an upfront cash payment of $145 million, with total deal consideration of up to $465 million plus double-digit royalties on net sales

ARS Pharma retains all U.S. rights, and existing partnerships in Japan, China, Australia and New Zealand with Alfresa, Pediatrix and CSL, respectively

SAN DIEGO, Nov. 11, 2024 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis, today announced a licensing agreement with ALK-Abelló A/S ("ALK", Nasdaq: ALK B), that provides ALK exclusive rights to commercialize ***neffy***® (epinephrine nasal spray) (trade name **EUR*neffy***® in Europe), the first and only needle-free emergency treatment for Type I allergic reactions including anaphylaxis, in Europe, Canada and other geographies outside of the U.S. ARS Pharma retains all rights to ***neffy*** in the U.S., and there are no changes to its existing partnerships in Japan, China, Australia and New Zealand.

"ALK is a specialized pharmaceutical company and a global leader in the allergy field, serving millions of allergy patients across 46 countries. As a multi-billion-dollar, commercial leader with strong ties to regulators, healthcare practitioners and patients, ALK is the ideal partner to further accelerate and expand the global reach of ***neffy***," said Richard Lowenthal, Co-Founder, President, and CEO of ARS Pharma. "This collaboration enhances our strategic agreements to better ensure that individuals who need ***neffy*** can access this innovative, needle-free treatment for Type I allergic reactions, including anaphylaxis. Additionally, the capital from this agreement enables us to focus fully on our ongoing U.S. commercial launch of ***neffy***, with significant operational flexibility. We are excited about ***neffy's*** future and our ability to positively impact the lives of millions, empowering patients and their caregivers to manage allergic reactions with confidence."

Under the terms of the agreement, ARS Pharma will receive an upfront payment of $145 million and is eligible to receive up to an additional $320 million in regulatory and sales milestones, as well as tiered, double-digit royalties in the teens on net sales in licensed geographies. ARS Pharma will be responsible for manufacturing and supplying ***neffy*** to ALK.

"We are thrilled to partner with ARS Pharma, a company that shares our commitment to advancing transformative allergy solutions for patients. We have closely followed developments with ***neffy*** since ARS Pharma first demonstrated that safe, low-dose, injection-like delivery of epinephrine could be achieved through a nasal spray," said Peter Halling, President and CEO of ALK. "We believe that nasal delivery of epinephrine could become an important new standard of care in anaphylaxis management over the next decade, as nasal delivery addresses the hesitation often associated with needle-based options. ***neffy*** offers strong scientific and commercial ties to our existing product portfolio and sales channels, and this licensing agreement is an important step in our strategic efforts to establish leading positions in anaphylaxis, food allergy, and other adjacent disease areas to supplement our core offering in respiratory allergy. We look forward to making this much-needed treatment accessible to patients."

In August 2024, the U.S. Food and Drug Administration approved ***neffy*** in the U.S. That same month, the European Commission granted marketing authorization for **EUR*neffy*** in the EU. ARS Pharma plans to file for regulatory approval in Canada by the end of 2024.

ARS Pharma is also evaluating its intranasal epinephrine technology for the treatment of acute flares in patients with chronic urticaria, with plans to being a Phase 2b clinical trial in early 2025. The license agreement with ALK also provides them exclusive rights for any new indications in the licensed territories.

About *neffy*®
neffy is an intranasal epinephrine product for patients with Type I allergic reactions including food, medications, and insect bites that could lead to life-threatening anaphylaxis.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR ***neffy*** (epinephrine nasal spray)

INDICATION

neffy 2 mg is indicated for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater.

IMPORTANT SAFETY INFORMATION

It is recommended that patients are prescribed and have immediate access to two ***neffy*** nasal sprays at all times. In the absence of clinical improvement or if symptoms worsen after initial treatment, administer a second dose of ***neffy*** in the same nostril with a new nasal spray starting 5 minutes after the first dose.

neffy is for use in the nose only.

Advise patients when to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.

Absorption of ***neffy*** may be affected by underlying structural or anatomical nasal conditions.

Administer with caution to patients who have heart disease; epinephrine may aggravate angina pectoris or produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or taking cardiac glycosides, diuretics, or anti-arrhythmics.

The presence of a sulfite in ***neffy*** should not deter use.

neffy may alter nasal mucosa for up to 2 weeks after administration and increase systemic absorption of nasal products, including ***neffy***.

Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions.

Epinephrine can temporarily exacerbate the underlying condition or increase symptoms in patients with the following: hyperthyroidism, Parkinson's disease, diabetes, renal impairment. Epinephrine should be administered with caution in patients with these conditions, including elderly patients and pregnant women.

Adverse reactions to ***neffy*** may include throat irritation, intranasal paresthesia, headache, nasal discomfort, feeling jittery, paresthesia, fatigue, tremor, rhinorrhea, nasal pruritus, sneezing, abdominal pain, gingival pain, hypoesthesia oral, nasal congestion, dizziness, nausea, and vomiting.

These are not all of the possible side effects of ***neffy***. To report suspected adverse reactions, contact ARS Pharmaceuticals Operations, Inc. at 1-877-MY-NEFFY (877-696-3339) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For additional information on ***neffy***, please see Full Prescribing Information at www.***neffy***.com.

About Type I Allergic Reactions Including Anaphylaxis
Type I 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 allergic reactions. Of this group, over the last three years, approximately 20 million people have been diagnosed and treated for Type I allergic reactions that may lead to anaphylaxis, but (in 2023, for example) only 3.2 million filled their 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 their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis. The Company is commercializing ***neffy***® 2 mg (trade name **EUR*neffy***® in the EU) (previously referred to as ARS-1), an epinephrine nasal spray indicated in the US for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater, and in the EU for emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products, and other allergens as well as idiopathic or exercise induced anaphylaxis in adults and children who weigh 30 kg or greater. 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 belief that the license agreement with ALK-Abelló will accelerate and further expand the global reach of ***neffy***; ARS Pharma's plans regarding regulatory submissions in Canada, the United Kingdom, China, Japan and Australia; 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 "could," "enables," "ideal," "excited," "look forward," "plans," "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: ARS Pharma's reliance on ALK-Abelló for the commercialization of ***neffy*** outside the United States in previously unpartnered territories; the potential that ARS Pharma may not receive milestone payments or royalty payments under the ALK-Abelló license agreement in the amounts and at the times expected, if at all; 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. These documents can also be accessed on ARS Pharma's website at www.ars-pharma.com by clicking on the link "Financials & Filings" under the "Investors & Media" tab.

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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