ARS Pharmaceuticals announces *neffy*® meets primary endpoints and shows rapid symptom control in Phase 2 urticaria clinical study

- ***neffy*** *demonstrated statistically significant and clinically meaningful improvement in pruritus, hives, body surface area and erythema in treatment-resistant chronic spontaneous urticaria patients, a skin disorder that causes itchy hives and/or angioedema*

- *Data supports continued development of* ***neffy*** *in urticaria with planned outpatient study in acute flares to initiate during 2024, with pivotal study to potentially initiate in 2025*

SAN DIEGO, Feb. 20, 2024 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (NASDAQ: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and caregivers to better protect patients from severe allergic reactions that could lead to anaphylaxis, today announced positive efficacy results in its phase 2 inpatient chronic spontaneous urticaria study with ***neffy***® (epinephrine nasal spray), an investigational new drug. The trial met its primary endpoints with both 1 mg and 2 mg ***neffy*** demonstrating statistically significant and clinically meaningful changes from baseline in itch, hives, urticaria and erythema scores as early as 5 minutes after dosing. Urticaria is a skin disorder that causes itchy hives and/or angioedema; 50% of chronic urticaria cases[1] are non-responsive to first-line antihistamine therapy.

These data for ***neffy*** are being presented in an oral presentation today, February 26, at 1:10 pm ET at the 2024 American Academy of Allergy, Asthma and Immunology (AAAAI) in Washington, D.C. in Room 207B (Level 2) of the Convention Center.

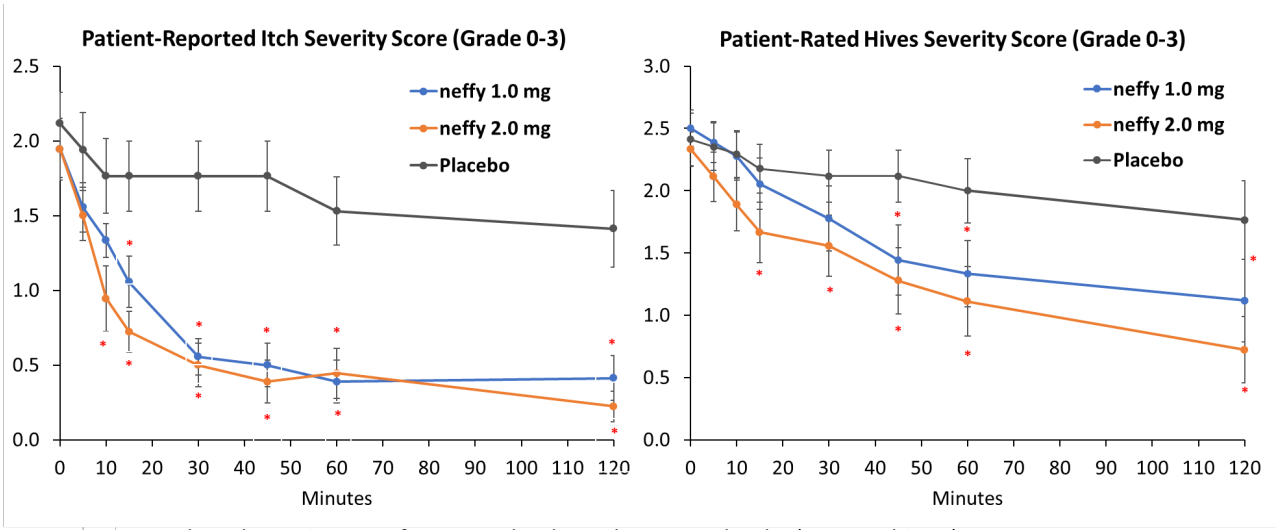
“The Phase 2 results in this highly refractory patient population are impressive and encouraging as they indicate ***neffy*** could be a game-changing therapeutic advance in the treatment of urticaria,” says **David Bernstein, M.D.**, Emeritus Professor of Pediatrics at the Cincinnati Children’s Hospital Medical Center, a former member of the Joint Task Force on Practice Parameters (urticaria guidelines) and Principal Investigator of the Study, “Urticaria symptoms clear within minutes after dosing, and ***neffy*** could offer patients a novel treatment option to address existing gaps in the efficacy of currently available antihistamines or biologics.”

Design of *neffy* efficacy study in urticaria

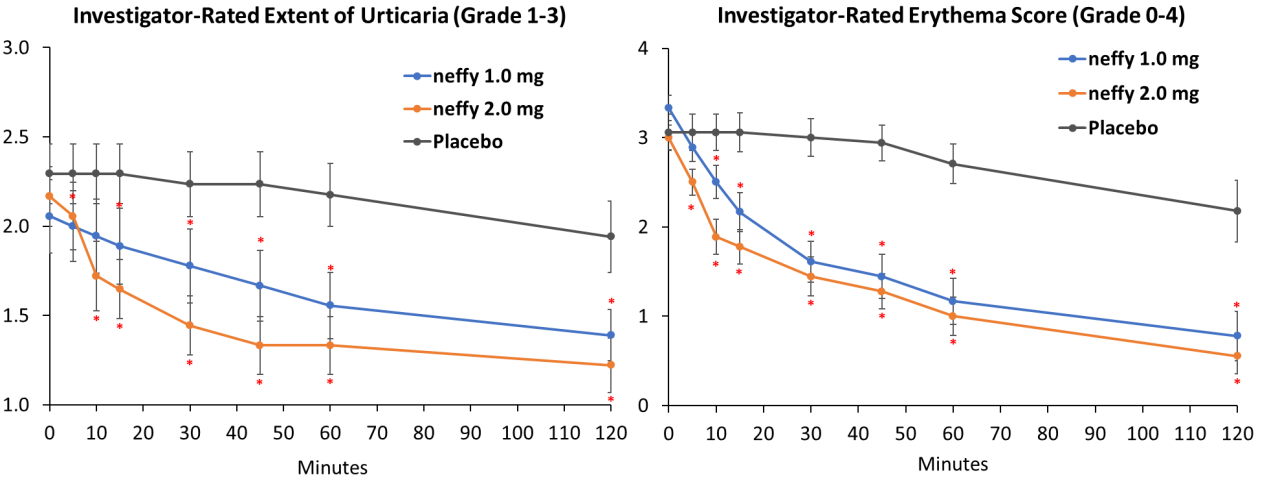
The EPI-U01 study was a randomized, placebo-controlled, cross-over study evaluating the safety and efficacy of epinephrine nasal spray in patients with chronic spontaneous urticaria (CSU) treated with chronic medications who were still experiencing flares. This oral presentation includes data analysis from 18 adult patients as of the cut-off date who enrolled in this study and returned to the clinical site while experiencing a flare, where they were randomized to receive either a single treatment of 1 mg or 2 mg ***neffy*** or placebo in a crossover design.

All subjects had flares with pruritus and hives scores greater than or equal to 2 on a 3 point severity scale, despite all patients having been treated with antihistamines or Xolair.

Results from *neffy* efficacy study in urticaria



* p<0.05 based on pair t-test of 1 mg vs. placebo and 2 mg vs. placebo (n = 17 subjects)



* p<0.05 based on pair t-test of 1 mg vs. placebo and 2 mg vs. placebo (n = 17 subjects)

There was no meaningful difference in efficacy on patient-reported itch severity score, patient-reported hives severity score, investigator-related extent of urticaria, or investigator-reated erythema score between 1 mg and 2 mg ***neffy*** doses, indicating that the 1 mg dose may be sufficient to activate the beta-2 adrenergic receptors responsible for stopping the mast cell degranulation and allergic mediator release that leads to an urticaria flare.

neffy was well-tolerated, with adverse events reported in 8 subjects, which were all mild or moderate in severity. The most common adverse event reported was nasal discomfort in 5 subjects. There were no serious adverse events.

"This study adds to the wealth of data supporting the efficacy and safety of ***neffy*** in the treatment of type I allergic reactions," said **Sarina Tanimoto, M.D., Ph.D.**, Chief Medical Officer and Co-Founder of ARS Pharma. "Urticaria is not only a standalone type I allergy disease, but also represents the most frequent symptom observed during type I allergic reactions including anaphylaxis. The improvement in urticaria symptoms almost immediately after dosing ***neffy*** demonstrated its rapid onset of action, and is consistent with the previously reported responses on pharmacodynamic markers of efficacy in as little as one minute after dosing."

Unmet need in urticaria and role of *neffy*

Urticaria is a skin disorder driven by mast cell degranulation and histamine release, which causes itchy wheals (hives) and angioedema, or both. In the United States, the annualized incidence is approximately 5 million cases (1.56 per 100,000).[2] Less than 40% of cases become chronic urticaria, which can last for several years before spontaneous remission occurs.

Antihistamines are the first-line therapy for treatment of urticaria, but 20 to 25% of acute urticaria cases[1], and 50% of chronic urticaria cases[3] are non-responsive to antihistamines. These non-responsive patients on stable therapy regimens can experience exacerbations or flares several times a year among acute cases, and even several times a week[4], including up to 3 or 4 emergency room visits, among chronic urticaria cases.[5] Angioedema is also a co-occuring symptom in about 33 to 67% of these patients.[6] There are currently no approved community use treatments for acute flares experienced by urticaria patients on chronic regimens of antihistamines. ***neffy*** may provide episodic symptomatic relief of these acute flares or exacerbations to improve the quality of life of urticaria patients. Patients would have the option to quickly resolve exacerbations or flares at home without escalating to chronic use of systemic biologics that may have more serious side effects and benefit-risk considerations, or having to visit the emergency room for further treatment.

Next steps for *neffy* development in urticaria

ARS Pharma plans to initiate a placebo-controlled outpatient urticaria study in patients treated with antihistamines who experience frequent acute flares later in 2024 followed by the potential initiation of a single pivotal efficacy study in 2025. This would follow the anticipated FDA approval of ***neffy*** for allergic reactions (Type I) including anaphylaxis in the second half of 2024.

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 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 Pharma 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***® (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 ARS Pharma's planned urticaria outpatient study and the timing thereof; the potential pivotal study and the timing thereof; ***neffy*** potentially being a game-changing therapeutic advance in the treatment of urticaria and offering patients a treatment option to address existing gaps in the efficacy of currently available antihistamines or biologics; 1 mg dose of ***neffy*** potentially being sufficient to activate the beta-2 adrenergic receptors; the potential approval of ***neffy*** and the timing thereof; 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," "could," "indicate," "may," "plans," "will," "potential" 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***; the results of the clinical trials may not support the approval of ***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; 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 September 30, 2023, filed with the Securities and Exchange Commission on November 9, 2023. This document can also be accessed on ARS Pharma's web page at ir.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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