ARS Pharmaceuticals announces FDA acceptance of NDA for neffy® (epinephrine nasal spray) for the Treatment of Allergic Reactions (type I) including Anaphylaxis

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- ***neffy*** *has potential to be the first non-injectable medicine indicated to treat allergic reactions (type I) including anaphylaxis in the U.S., if approved*

SAN DIEGO – October 21, 2022 – ARS Pharmaceuticals, Inc. announced today that the U.S. Food and Drug Administration (FDA) has accepted for review ARS' New Drug Application (NDA) for ***neffy*** for the emergency treatment of allergic reactions (type I) including anaphylaxis in adults and children ≥30 kg (66 lbs). If approved by the FDA, *neffy* would be the first non-injectable treatment available to patients with allergic reactions (type I) including anaphylaxis.

The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date that is anticipated in mid-2023.

"The FDA acceptance of our NDA for ***neffy*** is a major milestone in our efforts to bring to patients the ability to deliver epinephrine with comparable pharmacokinetics to an intramuscular injection, but in a needle-free and simple to administer nasal spray," said Richard Lowenthal, President and CEO of ARS Pharmaceuticals. "We appreciate that the FDA recognizes the potential clinical benefit of this novel approach to treating patients with severe allergies and look forward to working with the FDA during this process, with the goal of potentially changing the treatment paradigm for the millions of patients with or at-risk for severe allergic reactions (type I)."

The NDA submission to the FDA was based on data from four primary registration studies supporting that a 2 mg intranasal dose of ***neffy*** met all clinical endpoints recommended by regulators and that its 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 500 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.

About Allergic Reactions (Type I) 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 Pharmaceuticals is 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.richardl77.sg-host.com.

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