neffy® (epinephrine) – New drug approval

- On August 9, 2024, the FDA announced the approval of ARS Pharmaceuticals neffy (epinephrine), for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater.

- Neffy is the first epinephrine product for the treatment of anaphylaxis that is not administered by injection.

- The approval of neffy is based on four studies in 175 healthy adults, without anaphylaxis, that measured the epinephrine concentrations in the blood following administration of neffy or approved epinephrine injection products. Results from these studies showed comparable epinephrine blood concentrations between neffy and approved epinephrine injection products.

    - Neffy also demonstrated similar increases in blood pressure and heart rate as epinephrine injection products, two critical effects of epinephrine in the treatment of anaphylaxis.
    - A study of neffy in children weighing more than 66 pounds showed that epinephrine concentrations in children were similar to adults who received neffy.

- Warnings and precautions for neffy include potential altered absorption of neffy in patients with underlying structural or anatomical nasal conditions; risks associated with use of epinephrine in certain coexisting conditions; and allergic reactions associated with sulfite.

- The most common adverse reactions (≥ 2%) with neffy use were 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

- The recommended dosage of neffy is one spray (2 mg of epinephrine) administered into one nostril. In the absence of clinical improvement or if symptoms worsen after the initial treatment, a second dose of neffy may be administered in the same nostril with a second nasal spray starting 5 minutes after the first dose.

    - It is recommended that patients are prescribed and have immediate access to two neffy nasal sprays at all times.

- ARS Pharmaceuticals plans to launch neffy within eight weeks of FDA approval. Neffy will be available as a 2 mg/0.1 mL single-dose nasal spray.