neffy® (epinephrine nasal spray) – Expanded indication

- On March 5, 2025, ARS Pharmaceuticals announced the FDA approval of neffy (epinephrine nasal spray), **for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients aged 4 years and older who weigh 15 kg or greater**.
    - Neffy was previously approved for this indication in adult and pediatric patients who weigh 30 kg or greater.
- In addition to the expanded indication, the FDA approved a new 1 mg/0.1 mL nasal spray.
    - Neffy is also available as a 2 mg/0.1 mL nasal spray.
- The use of neffy is supported by extrapolation from the clinical pharmacology studies in adults that compared the pharmacokinetic/pharmacodynamic profile of neffy to epinephrine injection products with established safety and effectiveness for this indication and clinical pharmacology data in pediatric patients aged 4 years and older who weigh 15 kg or greater.
- The recommended dose of neffy for patients weighing 15 kg to less than 30 kg is one spray of neffy 1 mg.
    - 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.
- ARS Pharmaceuticals is expected to launch neffy 1 mg by the end of May 2025.