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ASIA EDITION

ARS Pharma receives US FDA approval for first nasal spray to treat anaphylaxis

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Neffy is a single dose nasal spray administered into one nostril



The US Food and Drug Administration (FDA) has approved neffy (epinephrine nasal spray) for the emergency treatment of allergic reactions (Type I), including those that are life-threatening (anaphylaxis), in adult and paediatric patients who weigh at least 30 kilograms (about 66 pounds). The US FDA has granted the approval of neffy to ARS Pharmaceuticals.

Neffy's approval 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.

Neffy is a single dose nasal spray administered into one nostril. As with epinephrine injection products, a second dose (using a new nasal spray to administer neffy in the same nostril) may be given if there is no improvement in symptoms or symptoms worsen. Patients may need to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.