



PRESS RELEASE

Epinephrine Nasal Spray in Development for Treatment of Anaphylaxis Shows Promise as Potential Alternative to Intramuscular Injection

PHOENIX, June 14, 2018 (GLOBE NEWSWIRE) -- Allergy sufferers who experience anaphylaxis—an acute, life-threatening allergic reaction requiring urgent treatment—may soon have a new delivery option for receiving a timely dose of epinephrine to avoid a potentially fatal outcome.

INSYS Therapeutics, Inc. (NASDAQ:INSY), a leader in the development, manufacture and commercialization of pharmaceutical cannabinoids and spray technology, announced today that its investigational epinephrine nasal spray showed promise in an early clinical trial as a potential needle-free, non-invasive and easy-to-use alternative to intramuscular injection for the treatment of anaphylaxis.

In a pharmacokinetics study involving 60 people with seasonal allergies, preliminary results showed that the bioavailability of the company's novel, proprietary formulation of epinephrine delivered intranasally was similar to that of intramuscular injection with EpiPen® (0.3 mg). The study also demonstrated rapid drug absorption with the epinephrine nasal spray.

“If the results of the initial study are borne out in a subsequent trial, this epinephrine nasal spray may become a viable alternative for patients with food allergy, venom allergy or other causes of anaphylaxis who must be prepared to treat it rapidly and effectively when it occurs,” said Dr. David Fleischer, an associate professor of pediatrics at the University of Colorado School of Medicine and Children's Hospital Colorado who served as an advisory board physician. “Because epinephrine is the first-line treatment for anaphylaxis, having other effective delivery options, such as a needleless alternative, may be attractive to patients and healthcare providers, as well as parents, school nurses, first responders and emergency department staff.”

“This is an exciting milestone for people affected by severe allergies who might be seeking an alternative delivery mechanism for epinephrine,” said Saeed Motahari, president and chief executive officer of INSYS Therapeutics. “Given that epinephrine is on the FDA shortage list, we look forward to working closely with the agency to determine the optimal path to making this investigational novel drug delivery system available to those in need.”

According to the Mayo Clinic, more than 200,000 cases of anaphylaxis occur each year in the United States. The World Allergy Organization estimates that up to two percent of the global population—as many as 150 million people worldwide—will experience anaphylaxis during their lifetime.

About INSYS

INSYS Therapeutics is a specialty pharmaceutical company that develops and commercializes innovative drugs and novel drug delivery systems of therapeutic molecules that improve patients' quality of life. Using proprietary spray technology and capabilities to develop pharmaceutical cannabinoids, INSYS is developing a pipeline of products intended to address unmet medical needs and the clinical shortcomings of existing commercial products. INSYS is committed to developing medications for potentially treating addiction to opioids, opioid overdose, epilepsy and other disease areas with a significant unmet need.

Forward-Looking Statements

This news release contains forward-looking statements including our belief in the potential for our proprietary formulation of epinephrine delivered intranasally to become an alternative to intramuscular injection of epinephrine as a treatment for anaphylaxis. These forward-looking statements are based on management's expectations and assumptions as of the date of this news release. Actual results may differ materially from those in these forward-looking statements as a result of various factors, many of which are beyond our control. These factors include, but are not limited to, risk factors described in our filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended Dec. 31, 2017 and subsequent updates that may occur in our Quarterly Reports on Form 10-Q. Forward-looking statements speak only as of the date of this news release, and we undertake no obligation to publicly update or revise these statements, except as may be required by law.

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