SRI receives FDA clearance to initiate high-dose naloxone clinical trial

New formulation aims to reduce overdose fatalities caused by fentanyl and other synthetic opioids

MENLO PARK, CA, UNITED STATES, June 10, 2025 /EINPresswire.com/ -- SRI announced today that the U.S. Food and Drug Administration (FDA) authorized the Phase 1 clinical trial of a new naloxone formulation under an Investigational New Drug (IND) application. The trial will evaluate SRI's high-dose naloxone formulation for intravenous and intramuscular use.

Deaths involving synthetic opioids rose by more than 700% between 2015 and 2022, according to the National Center for Health Statistics. SRI is addressing this by developing an injectable formulation of naloxone designed to provide a rapid and sustained reversal of opioid overdose, particularly in cases involving ultra-potent synthetic opioids such as fentanyl, nitazenes, and carfentanil. These are increasingly present in the illicit drug supply and are associated with difficult-to-reverse overdoses using today's naloxone products.

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>
> *Gita Shankar*

"Given the current low-dose naloxone formulations, they're not as effective for the kinds of synthetic opioids we're seeing today," said Gita Shankar, senior director of the Pharmaceutical Sciences Lab at SRI. "Our new formulation is a single high-dose naloxone shot that first responders can inject into victims when there is a risk of death."

When someone overdoses today, it often leads to oxygen deprivation, coma, and even death. Naloxone (also known by the brand name Narcan) can reverse this by blocking receptors in the brain and displacing opioids that are binding to receptors. "The problem is that Narcan lasts about 90 minutes," Shankar said. "It drops off, and opioids can re-bind to those receptors,

resulting in a recurrence of overdose symptoms, and the person can stop breathing again. Giving our higher dose treatment can reduce the effects of a deep overdose."

To address the limitations of current treatments, SRI developed a highly concentrated naloxone formulation that delivers 10 times more naloxone per milliliter than today's products. The formulation is optimized for systemic availability and shelf stability, making it more suitable for emergency use. "In the hands of emergency responders, this has the potential to address the synthetic opioid overdose crisis head-on and save more lives," Shankar concluded.

About SRI
SRI is an independent nonprofit research institute headquartered in Menlo Park, Calif., with a rich history of supporting government and industry. We create and deliver world-changing solutions for a safer, healthier, and more sustainable future. For nearly 80 years, we have collaborated across technical and scientific disciplines to discover and develop groundbreaking products and technologies and bring innovations and ideas to the marketplace. Learn more at www.sri.com.

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