September 17, 2018

Ensysce Biosciences Receives Multi-Year NIDA Grant to Study and Deliver Opioid Overdose Protection

The promise of a solution to 2 major health crises; opioid abuse and opioid overdose

SAN DIEGO--(BUSINESS WIRE)-- Ensysce Biosciences Inc. today announced receipt of Notice of Award from the National Institute on Drug Abuse (NIDA), a four year award to undertake the pre-clinical and clinical development of the company's opioid overdose protection platform MPAR™ (Multi Pill Abuse Resistance). The first two years of the grant will provide $4.285 million to complete the IND enabling studies to bring the first MPAR™ overdose protection product into clinical studies in the U.S. With the IND submission, additional funds of up to approximately $5 million will be available for the Phase 1 clinical trial.

TAAP abuse protection: Ensysce's TAAP (Trypsin Activated Abuse Protection) is a first in class platform that provides abuse deterrence to several CNS active prescription drugs, including opioid products. The prodrugs are activated in a 2-step, enzyme mediated reaction only after oral administration. This process removes the patient's ability to abuse the drug by inhalation or through kitchen chemistry and intravenous injection. Ensysce recently completed a Phase 1 trial with its lead TAAP oxycodone prodrug, PF614. The trial results in 60 subjects randomized to receive PF614 or OxyContin™, showed over 90% efficient release of oxycodone from PF614 and an improved safety profile over OxyContin™.

MPAR overdose protection: The Ensysce overdose protection platform, MPAR™, is a combination product that diminishes the activation of the TAAP prodrugs when more than the prescribed doses are administered. The combination of TAAP and a trypsin inhibitor in these MPAR products reduces activation to active opioid when increasing doses are consumed, therefore preventing overdose.

As prescriptions for opioids have risen sharply over the last two decades, rates of addiction and overdose deaths have dramatically increased. Drug overdose deaths are now the leading cause of accidental death in the U.S., exceeding deaths caused by motor vehicles and estimated at 116 fatalities per day. Abuse Deterrent Formulation (ADF) opioids have not stemmed this epidemic as all formulations developed so far can be cracked and abused. Ensysce's TAAP opioid MPAR™ products may be the first to provide the promise of true abuse and overdose protection. Preliminary research into the TAAP agents demonstrated no ability to crack or abuse the agents, with studies directed and reviewed by Pinney Associates.

"This award provides the opportunity for Ensysce to progress its TAAP opioid MPAR™ overdose platform rapidly," said Dr. Kirkpatrick, CEO of Ensysce Biosciences. "Our mission is to eliminate or reduce opioid abuse and overdose; our TAAP technology combined with

our overdose resistant MPAR™ products could help save countless lives. We are proud to work with NIDA on this unique approach."

"This NIDA award to Ensysce Biosciences is the recognition by NIH, NIDA and the Federal Government of the exceptional value of the Ensysce TAAP MPAR™ technology, and will address the significant unmet needs in the marketplace, for true opioid abuse and overdose protection," said Dr. William Schmidt, Ensysce Biosciences Chief Medical Officer. "We look forward to advancing Ensysce's pipeline of opioid TAAP and MPAR™ products to clinical trials and on to commercialization to combat the opioid crisis, a top priority of our government."

About Ensysce Biosciences:

Ensysce has an extensive worldwide intellectual property portfolio, including a portfolio covering a wide array of prescription drug prodrug compositions to overcome abuse, especially for the highly abused opioid and ADHD products, as well as delivery technology developed at Rice University by Nobel Laurate, Dr. Richard Smalley, for the use of SWCNT for therapeutic applications and delivery of large biologics. **www.ensysce.com**

View source version on businesswire.com:
https://www.businesswire.com/news/home/20180917005181/en/

Ensysce Biosciences Inc.
Lynn Kirkpatrick, PhD, 858-242-1553
CEO
www.ensysce.com

Source: Ensysce Biosciences Inc.