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Ensysce Biosciences Receives Multi-Year NIH HEAL Grant to Develop a Novel Opioid-Use-Disorder (OUD) Medication

Company proprietary TAPP and MPAR overdose technology to aid a most vulnerable patient population.

SAN DIEGO, Calif.--(BUSINESS WIRE)-- Ensysce Biosciences Inc., a clinical stage company, today announced receipt of Notice of Award from the National Institute on Drug Abuse (NIDA) for a $14.5 million five year award to undertake the pre-clinical and clinical development of the company's opioid-use-disorder (OUD) product using its trypsin activated abuse protection (TAAP™) and MPAR™ overdose protection platforms. The first three years of the grant will provide approximately $8.4 Million to complete the IND enabling studies to bring the first OUD MPAR™ overdose protection product into clinical studies in the US. With the IND submission, additional funds of approximately $6.1 million will be available for the Phase 1 clinical trial.

The scale and scope of the OUD problem.

- OUD is a chronic, relapsing illness, associated with significantly increased rates of morbidity and mortality.
- OUD affects more than 2 million Americans.
- Opioids, used medically for pain relief, have analgesic and central nervous system depressant effects as well as the potential to cause euphoria that may lead to OUD. OUD can involve misuse of prescribed opioid medications, use of diverted opioid medications, or use of illicitly obtained opioid products.
- Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them.
- Between 8 and 12 percent develop an OUD.

The most common form of treatment for OUD is with methadone but that agent carries significant risks – one estimate reported that more than 10 people die each day due to methadone overdose. The Ensysce technologies can address these issues and stem the crises before they spiral out of control.

"This award provides the opportunity for Ensysce to apply its TAAP/MPAR™ overdose platform to methadone that has seen a dramatic rise in deaths from its use over the last decade," said Dr. Kirkpatrick, CEO of Ensysce Biosciences. "Our TAAP™ oral prodrug technology and our overdose resistant MPAR™ products, which are unique to the industry, have already demonstrated exceptional clinical results."

"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™ technologies," said Dr. William Schmidt, Ensysce Biosciences Chief Medical Officer. "We look forward to advancing

Ensysce's TAAP/MPAR™ OUD product to clinical trials to combat this part of the opioid crisis."

NIH HEAL Initiative

The National Institutes of Health launched the Helping to End Addiction Long-term Initiative, or NIH HEAL Initiative, in April 2018 to improve prevention and treatment strategies for opioid misuse and addiction and enhance pain management. The NIH HEAL Initiative aims to improve treatments for chronic pain, curb the rates of opioid use disorder and overdose and achieve long-term recovery from opioid addiction. Ensysce's award is one of 375 grant awards across 41 states made by the National Institutes of Health in fiscal year 2019 to apply scientific solutions to reverse the national opioid crisis.

"It's clear that a multi-pronged scientific approach is needed to reduce the risks of opioids, accelerate development of effective non-opioid therapies for pain and provide more flexible and effective options for treating addiction to opioids," said NIH Director Francis S. Collins, M.D., Ph.D., who launched the initiative in early 2018. "This unprecedented investment in the NIH HEAL Initiative demonstrates the commitment to reversing this devastating crisis."

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. **www.ensysce.com**

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