October 31, 2022

Ensysce Biosciences Announces Positive Topline Results of Clinical Study Evaluating Human Abuse Potential of Intranasal Administration of PF614, a TAAP Abuse-Deterrent Oxycodone Extended-Release Product

~ Announces Timing of Corporate Update Call ~

SAN DIEGO, CA / ACCESSWIRE / October 31, 2022 /Ensysce Biosciences Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC)(OTC PINK:ENSCW), a clinical-stage biotech company applying transformative chemistry to improve prescription drug safety focused on reducing abuse and overdose, today announced positive topline results from a human abuse potential (HAP) study for PF614. PF614 is a new class of analgesia, a Trypsin Activated Abuse-Protected oxycodone product. Ensysce's TAAP™ technology is designed to be highly resistant to tampering and abuse as compared to traditional Abuse Deterrent Formulations (ADFs) of oxycodone. The product's abuse-deterrent characteristics are being evaluated in laboratory and clinical studies, consistent with the 2015 FDA Guidance for labeling. The HAP study was designed to test if known recreational drug users "liked" the product and is critical for new drugs in this class. The primary measure in this study, "drug liking," is recommended by the FDA in their Guidance on "Assessment of Abuse Potential of Drugs." This measure is known to correlate with a drug's potential for abuse.

Intranasal administration of PF614 powder from capsule was compared with intranasal administration of crushed oxycodone immediate-release (IR) tablets in non-dependent, recreational opioid users (n=26). The primary endpoint for the study was "drug liking at this moment," measured up to 24 hours after dosing using a visual analogue scale (VAS). In the study, PF614 powder produced significantly lower peak "drug liking" (Emax) when compared with intranasal crushed IR oxycodone ($p = 0.0133$) using the full modified completer population in a 3-period crossover of PF614 vs. crushed oxycodone and placebo. Furthermore, in a first period analysis of initial impressions of each drug, a similarly strong difference was noted between PF614 (n=8) and crushed IR oxycodone (n=10) ($p = 0.0175$), even with this smaller cohort of subjects.

Statistically significant differences in peak effects (Emax) between PF614 and crushed IR oxycodone intranasal were also demonstrated for the secondary endpoint of "take drug again," also using a first period analysis, where PF614 produced only 27% as high an Emax score as crushed oxycodone among recreational drug users ($p < 0.0001$).

"We are very excited about the results of this study as they are consistent with prior findings that we believe demonstrate PF614 may provide unique advantages when compared with currently marketed products," said Dr. Lynn Kirkpatrick, CEO of Ensysce. "We look forward to completing enrollment in our oral HAP program and remain committed to moving soon into Phase 3 analgesic efficacy studies."

Prescription opioids are critical in the management of moderate-to-severe chronic pain. PF614 has a true 12-hour half-life designed chemically to maintain its analgesic effects over a prolonged dosing interval. In contrast, extended-release (ER) ADFs in this category contain high doses of active drug in an extended-release formulation and abusers frequently tamper with these formulations in an attempt to subvert the time-release mechanism and access the entire drug load at once. Many conventional ER formulations are susceptible to tampering techniques such as crushing, chewing, or dissolving the active drug in various solvents. Crushed ER formulations can be used intranasally to achieve high plasma concentrations and maximum euphoric effects. PF614 has been developed using novel trypsin-activated chemistry (not an ER formulation) that occurs only in the gastrointestinal tract. This is expected to provide clinicians and patients with a novel approach to abuse-deterrence that does not alter its release of active drug even if chewed, crushed or dissolved in water.

"There is a significant societal need for safer abuse-deterrent analgesics," said Dr. William Schmidt, Interim Chief Medical Officer and Senior Vice President of Clinical Development of Ensysce. "PF614 demonstrated significantly reduced "drug liking", the primary endpoint, when compared to intranasal crushed immediate-release oxycodone. We believe that the high level of statistical significance with the first period analysis (using roughly 1/3 of the total population on their first drug exposures) and the full modified completer population (after they had experienced all 3 test drugs in a crossover fashion) speaks to the strength of these results. The data from this study is intended to support abuse-deterrent labeling upon final approval of PF614."

Corporate Update Call

Management will host a corporate update conference call on Wednesday, November 16, 2022, at 11:00am ET to provide a corporate update and review the recently discussed results from the HAP study of PF614. The call will conclude with Q&A from participants. An accompanying presentation will be posted prior to the call to the Company's investor relations website.

Date: Wednesday, November 16, 2022
Time: 11:00am ET
U.S. Dial-in: 1-877-407-0792
International Dial-in: 1-201-689-8263
Conference ID: 13734017
Webcast: ENSC Corporate Update Call

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage biotech company using its proprietary technology platforms to develop safer prescription drugs. Leveraging its Trypsin Activated Abuse Protection (TAAP™) and Multi-Pill Abuse Resistance (MPAR™) platforms, the Company is

in the process of developing a unique, tamper-proof treatment option for pain that minimizes the risk of both drug abuse and overdose. Our products are anticipated to provide safer options to treat patients suffering from severe pain and assist in preventing deaths caused by medication abuse, reducing the human and economic costs. The platforms are covered by an extensive worldwide intellectual property portfolio for a wide array of prescription drug compositions. For more information, please visit www.ensysce.com.

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