May 23, 2022

Ensysce Biosciences Announces Initiation of First Human Abuse Potential Study

~ Nasal Opioid Abuse Being Explored for PF614 ~

~ Data From Trial Expected in September 2022 ~

SAN DIEGO, CA / ACCESSWIRE / May 23, 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 and performance focused on reducing abuse and overdose, today announced the initiation of PF614-103, 'A Randomized, Double-blind, Placebo- and Active-Controlled Crossover Study to Evaluate the Intranasal Abuse Potential of PF614 Compared with Immediate-Release Oxycodone and Placebo in Non-Dependent Recreational Opioid Users' is being conducted by Dr. Glen Apseloff, from Ohio Clinical Trials. This trial is designed to test and confirm that manipulating and snorting PF614 will not allow the drug abuser to achieve that desired state of euphoria.

Dr. Nily Osman, Chief Medical Officer of Ensysce, commented, "Our progression of PF614 though clinical development is rapidly advancing with the initiation of this Human Abuse Potential (HAP) study. This is an important step in establishing that, unlike the current opioid analgesics on the market, which can be manipulated and abused through nasal inhalation, PF614 does not carry this risk. PF614 is developed utilizing Ensysce's proprietary drug delivery technology that works with endogenous human trypsin in the small intestine, and as such substantially reduces the risk of misuse, abuse, and diversion through inhaled and IV routes by those who use recreational drugs. We remain dedicated to bringing to market a responsible analgesia solution that will alleviate suffering for those who experience severe pain."

Dr. Lynn Kirkpatrick, CEO of Ensysce offered, "We believe the features of PF614 will make it unattractive to those who wish to enjoy opioids for recreation. We have already demonstrated that PF614 requires exposure to trypsin to become activated to release oxycodone, and we have designed this process to match the release of oxycodone from the marketed product, OxyContin CR. Since the trypsin enzyme is found only in the small intestine and not in nasal passages, we believe most drug abusers will not experience the same effect as they do with snorting other opioid products. We are looking forward to reporting the data from this trial and expect to do so in September of this year."

PF614-103 study will examine the pharmacokinetic and pharmacodynamic (e.g., Maximum Drug Liking and Take Drug Again) of PF614 versus crushed oxycodone and placebo in recreational drug users. Eligible subjects will receive each of the following 3 treatments (1 per treatment period) in a randomized, double-blind, crossover manner, following a fasting period of at least 8 hours: PF614 100 mg; Crushed oxycodone HCl IR 40 mg; Placebo powder. The primary outcome measures will be the maximum effect (Emax) for 'Drug Liking.'

About Ensysce Biosciences

Ensysce Biosciences, based in San Diego, CA is a clinical-stage biotech company using its two novel 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 seeking to develop next-generation, tamper-proof opioids that prevent both drug abuse and overdoses. Ensysce's products are anticipated to provide safer options to treat severe pain and assist in preventing deaths caused by opioid abuse, reducing the human and economic costs. The platforms are covered by an extensive worldwide intellectual property portfolio encompassing a wide array of prescription drugs. For more information, please visit www.ensysce.com.

Forward-Looking Statements

Statements contained in this press release that are not purely historical may be deemed to be forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Without limiting the foregoing, the use of words such as "may," "intends," "can," "might," "will," "expect," "plan," and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinical development and are not approved and there can be no assurance that the clinical programs will be successful in demonstrating safety and/or efficacy, that Ensysce will not encounter problems or delays in clinical development, or that any product candidate will ever receive regulatory approval or be successfully commercialized. All forward-looking statements are based on estimates and assumptions by Ensysce's management that, although Ensysce believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Ensysce expected. In addition, Ensysce's business is subject to additional risks and uncertainties, including among others, the initiation and conduct of preclinical studies and clinical trials; the timing and availability of data from preclinical studies and clinical trials; expectations for regulatory submissions and approvals; potential safety concerns related to, or efficacy of, Ensysce's product candidates; the availability or commercial potential of product candidates; the ability of Ensysce to fund its continued operations, including its planned clinical trials; the dilutive effect of stock issuances from our fundraising; and Ensysce's and its partners' ability to perform under their license, collaboration and manufacturing arrangements. These statements are also subject to a number of material risks and uncertainties that are described in Ensysce's most recent annual report on Form 10-K and current reports on Form 8-K, which are available, free of charge, at the SEC's website at www.sec.gov. Any forward-looking statement speaks only as of the date on which it was made. Ensysce undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required under applicable law.

Ensysce Biosciences Company Contact:
Lynn Kirkpatrick, Ph.D.
Chief Executive Officer
(858) 263-4196

Ensysce Biosciences Investor Relations Contact:
Shannon Devine
MZ North America

Main: 203-741-8811
ENSC@mzgroup.us

SOURCE: Ensysce Biosciences Inc.

View source version on accesswire.com:
https://www.accesswire.com/702190/Ensysce-Biosciences-Announces-Initiation-of-First-Human-Abuse-Potential-Study