October 28, 2022

Ensysce Biosciences Announces First Subjects Dosed in Second Human Abuse Potential Study

~ Critical Study to Support Abuse Deterrent Labeling ~

SAN DIEGO, CA / ACCESSWIRE / October 28, 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 the first subjects dosed in the PF614-104 study, 'A Randomized, Double-blind, Placebo and Active-Controlled, Crossover Study to Evaluate the Oral Abuse Potential of PF614 Compared with Oxycodone Immediate-Release Tablets, and Placebo in Non-Dependent Recreational Opioid Users' (ClinicalTrials.gov Identifier: NCT05571345). The study is being conducted by Drs. Brad Vince and Steven Hull at Dr. Vince Clinical Research (DVCR) in Overland, KS. This study is designed to test and confirm that oral PF614 will have less potential for 'Drug Liking' by recreational drug users versus immediate release oxycodone at equivalent drug dosages.

Dr. Bill Schmidt, Chief Medical Officer of Ensysce, commented, "This second Human Abuse Potential (HAP) study of PF614 is intended to demonstrate our technology's abuse deterrent properties and is critical for the 'abuse deterrent' labeling of any new opioid drug product. This study along with our previous intranasal abuse liability study serve as important steps in establishing that PF614 may be differentiated from current immediate-release and extended-release oxycodone-containing products. PF614 uses the Ensysce TAAP™ technology and requires exposure to endogenous human trypsin in the intestines to trigger a two-step activation process to release active dose levels of oxycodone that is then absorbed systemically. Without exposure to trypsin, PF614 remains essentially inert and is excreted unchanged. This two-step activation is key to the abuse deterrence of PF614 and is ultimately what we believe sets PF614 apart from current marketed opioids. Our focus is on aiding those suffering from severe pain while reducing the fear of opioids."

The PF614-104 study will examine the desirability of three doses of PF614 versus a currently marketed dose of oxycodone HCl and versus placebo in recreational drug users. Eligible subjects will receive five treatments (one per treatment period) in a randomized, double-blind, crossover manner. The primary outcome measure will be 'Drug Liking' and the key secondary endpoint will be 'Take Drug Again.'

Dr. Lynn Kirkpatrick, CEO of Ensysce offered, "This study is vital to our path to commercialization, and we are extremely happy to be working with DVCR to execute this study. We believe that PF614 is a unique drug in the opioid space and this study may provide data that further supports its potential. We look forward to completing this study and reporting the data, expected in early 2023."

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.

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/722703/Ensysce-Biosciences-Announces-First-Subjects-Dosed-in-Second-Human-Abuse-Potential-Study