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Ensysce Biosciences Announces Initiation of Second Human Abuse Potential Study, Being Conducted by DVCR

~ Oral Opioid Abuse Being Explored for PF614 ~

~ Data From Trial Supports Abuse Deterrent Labeling, Designed to Measure the Potential for Drug Liking ~

SAN DIEGO, CA / ACCESSWIRE / September 22, 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 initiation of PF614-104, '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.' The study is being conducted by Dr. Brad Vince, from Dr. Vince Clinical Research (DVCR), at one of the most innovative and technologically advanced clinical pharmacology units, newly constructed and recently opened in Overland Park, Kansas. This study is designed to test and confirm that PF614 will have less potential for drug liking versus immediate release oxycodone at equivalent drug dosages.

Dr. Bill Schmidt, Chief Medical Officer of Ensysce, commented, "This is the second Human Abuse Potential (HAP) study of PF614 to be conducted this year demonstrating the Company's rapid advancement in the development of our lead drug candidate. Such studies are critical for the abuse deterrent labeling of any new opioid drug product and this study serves as an important step in establishing that PF614 is differentiated from current products on the market. PF614 is a chemically modified oxycodone that requires exposure to endogenous human trypsin in the small intestine to activate to relieve severe pain, and this requirement is key to the abuse deterrence of PF614. We remain dedicated to bringing to market a responsible 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 reduce the liking qualities of the product, ultimately deterring drug abusers from taking, or sourcing PF614. We also believe the requirement for exposure to trypsin and the chemically designed release kinetics of PF614 will separate PF614 from other marketed oxycodone drug products. Our recent report that PF614 is bioequivalent to OxyContin demonstrates that the chemical modification of PF614 is likely to provide the same pain-relieving properties, yet with longer pain relief than OxyContin since PF614 has been shown to have a longer half-life consistent with true twice-daily dosing. We are looking forward to working with DVCR to conduct this study and reporting the data from this trial, expected in early 2023."

The PF614-104 study will examine the desirability of three doses of PF614 versus a current marketed equivalent and 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.'

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

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