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Ensysce Biosciences Announces Publication of Clinical Bioequivalence Manuscript

Publication Details Positive Results of Clinical Study PF614-102

SAN DIEGO, CA / ACCESSWIRE / February 15, 2024 /Ensysce Biosciences, Inc. (NASDAQ:ENSC)(OTC PINK:ENSCW) ("Ensysce" or "Company"), a clinical-stage company applying transformative chemistry to improve prescription drug safety, today announced online publication of its manuscript entitled, *"Clinical evaluation of PF614, a novel TAAP™ prodrug of oxycodone, versus OxyContin® in a multi-ascending dose study with a bioequivalence arm in healthy volunteers"* published online by the open-access medical journal Clinical and Translational Science (CTS) sponsored by the American Society of Clinical Pharmacology and Therapeutics (ASCPT). The article is authored by members of the Ensysce team plus external experts; D. Lynn Kirkpatrick PhD, Cari Evans RN, Linda A. Pestano PhD, Jeffrey Millard PhD, Matthew Johnston MD, Emily Mick PharmD, and William K. Schmidt PhD.

The results from the two-part PF614-102 study are very significant as we believe they demonstrate a clear dose relationship between PF614 and oxycodone, which is the foundation for the FDA submission. The BE arm showed that plasma oxycodone bioequivalence was successfully achieved between 100 mg PF614 and 40 mg OxyContin. PF614 provided similar oxycodone exposures in both fasted and fed states, showing that it can be taken either on an empty stomach or with food, these data highlight PF614's potential advantage compared to other marketed abuse deterrent formulation (ADF) opioids. PF614 also showed a longer (12 hour) half-life, a major patient benefit in severe pain treatment.

This manuscript provides a report of the safety and pharmacokinetics (PK) profile of PF614, a Trypsin-Activated Abuse Protection (TAAP™) oxycodone prodrug designed to reduce recreational drug abuse. PF614 was compared to OxyContin® in healthy subjects in the initial multi-ascending dose arm of the study. Additionally, the manuscript details the second arm which evaluated oxycodone release from PF614 and OxyContin administered to 60 subjects in both a fasted and fed state in order to assess whether PF614 is bioequivalent (BE) to OxyContin. The notable distinction identified in this study between PF614 and OxyContin was the longer half-life of PF614, which provides a benefit to the patient as this is a true twice daily pain treatment. We believe this differentiating feature is critically important as steady blood levels can deliver sustained analgesia throughout the day to prevent breakthrough pain and the need for additional therapeutics.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce Biosciences, commented, "We are pleased that the PF614-102 study not only confirmed findings from our prior Single

Ascending Dose study showing 100 mg of PF614 releases oxycodone with a PK profile comparable to 40 mg of OxyContin, but demonstrated the beneficial qualities of PF614 in contrast to alternative commercially available ADFs including its fed/fasted equivalency and longer half-life. As the clinical data and safety package strengthens for PF614 with each study we complete, we continue to move closer to our goal of bringing the ‘next generation' of analgesics for severe pain to market."

CTS is a peer-reviewed open-access medical journal that highlights original research and helps to bridge laboratory discoveries with the diagnosis and treatment of human disease.

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage 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 developing unique, tamper-proof treatment options for pain that minimize the risk of both drug abuse and overdose. Ensysce's products are anticipated to provide safer options to treat patients suffering from severe pain and assist in preventing deaths caused by medication abuse. 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," "possible," "believe" and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinic and 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 quarterly report on Form 10-Q 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.