December 14, 2023

Ensysce Biosciences Announces Key Efficacy Data for Lead Analgesic

Results Reinforce Efficacy of PF614 as a Next Generation Analgesic with Significant Pain Intensity Reduction
PF614 Clinical Data Primes FDA Evaluation and Design of Phase 3 Studies in 2024

SAN DIEGO, CA / ACCESSWIRE / December 14, 2023 /Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage company applying transformative chemistry to improve prescription drug safety, today announced that its most recent study has demonstrated crucially important data for PF614 on pain intensity efficacy and speed of onset.

The PF614-201 study, ‘A Randomized, Double-Blind, Placebo-Controlled Crossover Study of PF614 on Analgesic Response in the Cold Pressor Test in Healthy Male Subjects', which completed enrollment in November 2023, demonstrated time-to-efficacy onset for the analgesia effect and significant decrease of pain intensity versus placebo of PF614 at two different dose levels, the first ever measured for this TAAP opioid. The study endpoints matched all previous clinical studies, demonstrating that Ensysce's TAAP chemical approach delivers strong analgesia safely and effectively. This ‘time of onset' study data supports the key elements of our Phase 3 study designs that will allow the Company to affirm its Phase 3 plans and launch strategy for PF614 with the FDA during its End of Phase 2 meeting scheduled in late January 2024.

Dr. Bill Schmidt, Chief Medical Officer of Ensysce, commented, "This study met its primary goal and successfully demonstrated the efficacy for PF614 using a well-established, validated experimental pain model in healthy subjects. We are exceptionally pleased that the measurement of oxycodone blood levels from four earlier studies fully matched the efficacy measured in this Phase 2 study. We believe the insights we've gained regarding the efficacy of PF614 as well as its safety, make us exceptionally positioned to move to the next stage of development for this new class of agents to treat severe pain."

Dr. Lynn Kirkpatrick, CEO of Ensysce, offered, "The successful completion of this study is critical to maintain the progress and development of our lead analgesic, PF614. Today's announced data builds on that from our prior bioequivalence study and shows strong efficacy in pain intensity reduction. The additional benefits of PF614's analgesic properties identified in prior clinical studies align with our target profile. We believe PF614 is the first abuse protective opioid with longer lasting genuine twice daily dosing, which experts describe as a potential revolutionary treatment for severe pain."

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.

Definitions

'TAAP': trypsin activated abuse protection - designed to protect against prescription drug abuse.
'MPAR': multi-pill abuse resistance - designed to protect against abuse and accidental overdose.

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 its 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:
MZ Group North America
Shannon Devine
203-741-8811
ENSC@mzgroup.us

SOURCE: Ensysce Biosciences, Inc.

View the original press release on accesswire.com