November 16, 2023

Ensysce Biosciences Announces Enrollment Completion for PF614-201 Clinical Study

~ Enrollment Completion Signifies Critical Progress to Phase 3 of PF614 ~

~ Trial Results Expected in December 2023 ~

SAN DIEGO, CA / ACCESSWIRE / November 16, 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 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' has completed enrollment. The goal of this exploratory Phase 2 PF614-201 study is to confirm the approximate time of onset for PF614 analgesic effects prior to initiation of Phase 3 efficacy evaluations.

Dr. Bill Schmidt, Chief Medical Officer of Ensysce, commented, "With completion of enrollment of this study, we will have efficacy data that is complementary to our prior bioequivalence study that evaluated plasma oxycodone exposure levels produced by orally administered PF614. The readout from this time of onset study will inform the final design of our clinical protocols in preparation for our full Phase 3 evaluation of PF614, expected to begin in the first half of 2024. We believe this continued advancement of our lead program, PF614, is grounded by the data we have generated this year showing that PF614 produces significantly longer and safer exposure to analgesic-levels than OxyContin, while concurrently indicating less potential of harmful abuse."

Dr. Lynn Kirkpatrick, CEO of Ensysce, offered, "The successful completion and full patient enrollment in this study is another critical step in maintaining the momentum in our development plans of PF614 towards conducting Phase 3 studies. We expect initial data from this study in December 2023, and remain on track to discuss the results with the FDA during our End of Phase 2 meeting which the FDA recently confirmed will occur at the end of January 2024. The significant interest we've received following our presentation at PAINWeek, and the potential benefits of PF614's analgesic properties and lower abuse liability than other opioid analgesics has solidified our confidence that we are delivering the 'next generation' of analgesics 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

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