September 26, 2023

Ensysce Biosciences Announces Completion of Site Initiation Visit for PF614-201 Clinical Study

~ Study Initiation Brings PF614 One Necessary Step Closer to Phase 3 ~

~ Trial Results Expected Before Year End 2023 ~

SAN DIEGO, CA / ACCESSWIRE / September 26, 2023 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC), a clinical-stage company applying transformative chemistry to improve prescription drug safety, today announced the Site Initiation Visit (SIV) was completed for 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' to evaluate time of onset for PF614. The study is being conducted by Dr. George Atiee at Dr. Vince Clinical Research (DVCR) in Overland, KS.

Dr. Bill Schmidt, Chief Medical Officer of Ensysce, commented, "Each study serves a critical purpose and this new study's importance is grounded in the ability to best determine optimal prescribing options for surgical patients, while also key in preparing for our full Phase 3 evaluation of PF614. We have determined PF614 has reduced abuse potential, has a longer lasting half-life than the current abuse deterrent products, yet is bioequivalent to OxyContin for pain relief, and we believe the features of PF614 will provide superior pain relief that may be needed following some types of surgery."

Dr. Lynn Kirkpatrick, CEO of Ensysce, offered, "The completion of the SIV for this study represents yet another key milestone in our development path for PF614. PF614 is a chemically modified opioid product that requires initial metabolic transformation by trypsin in the small intestine for activation to be able to relieve severe pain in patients who require an opioid-level analgesic. We believe PF614 will be a game changer for the treatment of severe pain and represents a new generation of pain products. We look forward to continuing our progress and conducting this trial with results expected in late 2023."

About Ensysce Biosciences
Ensysce Biosciences is a clinical-stage biotech company using its proprietary technology platforms to develop safer prescription drugs. Leveraging TAAP™ and MPAR™, 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 overdoses. 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.

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