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Ensysce Biosciences Submits Phase 3 Protocol to the FDA

Phase 3 Study to Assess PF614 Efficacy in Treating Post-Surgical Pain

SAN DIEGO, CA / ACCESSWIRE / September 19, 2024 /Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage pharmaceutical company developing innovative solutions for severe pain relief while reducing the potential for opioid abuse and overdose, today announced it has submitted to the FDA its PF614-301 protocol of the study, "A Multicenter, Randomized, Double-Blind, Placebo-and Active-Controlled Study to Evaluate the Efficacy and Safety of PF614 for the Treatment of Moderate to Severe Pain after Abdominoplasty". Included in the Phase 3 study is the Company's statistical analysis plan for review and input by the FDA.

The study, once finalized with the FDA, will be conducted through four to six clinical sites in the United States, and is designed to assess the analgesic efficacy of PF614 compared to placebo in subjects with moderate-to-severe pain following abdominoplasty. Additionally, Ensysce will evaluate PF614 versus an active comparator, the use of rescue medication and the safety and tolerability of PF614.

Dr. Bill Schmidt, Chief Medical Officer of Ensysce, commented, "The review of this study protocol represents another key milestone that brings us one step closer to executing the last clinical phase of evaluation for PF614. We anticipate the results of this Phase 3 trial will continue to prove the positive qualities of PF614 over existing oxycodone products. We remain dedicated to bringing PF614, a ‘next-generation opioid', to market."

Dr. Lynn Kirkpatrick, CEO of Ensysce, offered, "We believe that the features of PF614 will be a game changer for the treatment of short-term severe pain. The fact that PF614 delivers the pain-relieving qualities of OxyContin but lasts twice as long, should alleviate the common problem of recurring breakthrough pain between dosing. In parallel with its reduced abuse potential, PF614 is anticipated to offer this market a superior pain product. We look forward to conducting this trial and expect results in late 2025."

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.

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