August 8, 2023

Ensysce Biosciences Announces IRB Approval of Key Study Protocol

~ Approval of Study Represents Progression Toward Full Phase 3 Evaluation of PF614 ~

~ Study to Assess PF614 Time of Onset for Severe Pain Relief ~

SAN DIEGO, CA / ACCESSWIRE / August 8, 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 Investigational Review Board ("IRB") approval of PF614-201 protocol, 'A Randomized, Double-Blind, Placebo-Controlled Crossover Study of PF614 on Analgesic Response in the Cold Pressor Test in Healthy Male Subjects.'

The study will be conducted at Dr. Vince Clinical Research (DVCR) in Overland Park, Kansas, and is designed to confirm time of onset for pain relief by PF614.

Dr. Bill Schmidt, Chief Medical Officer of Ensysce, commented, "The approval of this study protocol represents yet another key milestone that brings us one step closer to our full Phase 3 evaluation of 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. Over the last year, we have been able to rapidly progress the clinical development of PF614 by establishing its bioequivalence to OxyContin and by showing it has limited desirability for use by recreational drug users, both of which we believe will lead to favorable labeling claims. This new study will be critical for understanding the optimal prescribing options for surgical patients. Additionally, we have been accumulating safety data for PF614 which will be important for our regulatory submissions in the future. We remain dedicated to bringing to market this new generation of pain products to alleviate the suffering of those who experience severe pain."

Dr. Lynn Kirkpatrick, CEO of Ensysce offered, "We believe that the features of PF614 are a game changer for the treatment of severe pain. We expect that the requirement for exposure to trypsin and the chemically designed release kinetics will separate PF614 from other marketed oxycodone drug products. Recently, we reported that PF614 is bioequivalent to OxyContin yet has a longer lasting half-life, consistent with true twice-daily dosing. These features, along with its reduced abuse potential, are intended to provide superior pain relief that may be needed following some types of surgery. We look forward to conducting this trial and expect results in late 2023."

About Ensysce Biosciences
Ensysce Biosciences is a clinical-stage company applying transformative chemistry to improve prescription drug safety. 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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