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Ensysce Biosciences Completes Significant Milestone, Dosing First Subjects in Breakthrough Therapy PF614-MPAR Trial

~ Landmark Overdose Protection Clinical Trial of PF614-MPAR ~

~ Expects Early Interim Data in 1Q 2025 ~

SAN DIEGO, CA / ACCESSWIRE / November 26, 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 that it has treated its first group of subjects in the PF614-MPAR-102 study. PF614-MPAR received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) and had its development bolstered by the recent $14 million multi-year award from the National Institute on Drug Abuse (NIDA).

Dr. Lynn Kirkpatrick, CEO of Ensysce, was quoted, "Overdose from prescription drugs is still a major societal issue and Ensysce may have the first opioid that can reduce deliberate and accidental overdoses. My team has made this program a priority as we continue to collaborate with Quotient Sciences using their Translational Pharmaceutics® platform. We are delighted with the speed at which Quotient has executed the trial start-up activities and advanced into subject dosing as we aim to receive early interim data in the first quarter of 2025. We look forward to completing this highly important three-part trial and generating additional evidence to conduct productive discussions with the FDA on the path to registration for the first overdose-protected opioid."

Dr. Bill Schmidt, Chief Medical Officer of Ensysce, commented, "Clinical data from our initial study demonstrated the unique overdose protection built into PF614-MPAR, which led to the FDA designation of Breakthrough Therapy, a first for an opioid drug product. We believe this second study will further build on our initial data and aid in bringing PF614-MPAR and a new generation of safer analgesics to the market to alleviate suffering and bring relief to those who experience severe pain."

The trial ‘A Single and Multiple Dose Study to Evaluate the Pharmacokinetics of Oxycodone and PF614 when PF614 capsule is Co-Administered with Nafamostat as a combination Immediate Release solution and Extended-Release Capsule Formulation in Healthy Subjects', is designed to evaluate the full dosage range of PF614-MPAR, study food effects and to conduct a multi-ascending dose study.

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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