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# Ensysce Biosciences Initiates Pivotal Phase 3 Study of PF614 - A Next-Generation Opioid - Designed to Deliver Powerful Pain Relief and Reduce Abuse

***~ FDA Protocol Review Completed ~***

***~ Rho, Inc. Selected as Clinical Research Partner ~***

**SAN DIEGO, CA / ACCESS Newswire / July 16, 2025 /** Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage pharmaceutical company pioneering novel solutions for severe pain with built-in abuse and overdose protection, today announced the initiation of its pivotal Phase 3 study of PF614, the Company's lead product candidate.

This landmark study, PF614-301, *'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'* is designed to demonstrate PF614's ability to effectively manage post-surgical pain while protecting from abuse and offering patients what is believed to be a safer alternative to conventional opioids. The study aims to confirm that PF614 delivers powerful pain relief and facilitates the transition to non-opioid out-patient care.

To execute this critical program, Ensysce has partnered with Rho, Inc., a leading Clinical Research Organization with extensive expertise in central nervous system (CNS) disorders and pain studies. Over the past five years, Rho has successfully managed more than 90 neurology and psychiatry trials at over 840 sites, guiding programs from first-in-human trials to regulatory approval - making them an ideal partner for Ensysce's transformative mission.

"In our view, this is more than a partnership. It's a coordinated effort to execute a pivotal study, and a significant step toward redefining pain therapy." said Dr. Lynn Kirkpatrick, CEO of Ensysce. "Our goal is to deliver a new class of opioids that delivers relief from severe pain while protecting patients from the dangers of abuse. We believe PF614 can set a new standard of safety for millions of patients who depend on these medications for a good quality of life."

**About Ensysce Biosciences**
Ensysce Biosciences is a clinical-stage pharmaceutical company disrupting the pain treatment landscape with its proprietary **Trypsin-Activated Abuse Protection (TAAP™)** and **Multi-Pill Abuse Resistance (MPAR®)** platforms. By engineering opioids with intrinsic safeguards against tampering, misuse, and overdose, Ensysce aims to offer safer, life-saving options for patients in need of powerful pain relief. Learn more at: 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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