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Ensysce Biosciences Secures IRB Approval of Final Phase of PF614-MPAR-102 Clinical Study

~ Advances First-in-Class Opioid with Oral Overdose-Protection ~

SAN DIEGO, CA / ACCESS Newswire / April 16, 2026 / Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage pharmaceutical company pioneering next-generation pain and central nervous system therapeutics engineered to minimize abuse and overdose risk, today announced Investigational Review Board (IRB) approval to initiate Part 3 of the PF614-MPAR-102 clinical study, marking the final stage in this study evaluating its novel MPAR® (Multi-Pill Abuse Resistance) overdose-protection technology.

PF614-MPAR, which received Breakthrough Therapy designation from the U.S. FDA following the PF614-MPAR-101 study, represents a fundamentally new approach to opioid safety. Unlike conventional abuse-deterrent formulations, PF614-MPAR is designed to provide active protection against oral overdose-addressing a critical unresolved risk in opioid therapy. PF614-MPAR uses a proprietary chemical control mechanism that maintains therapeutic opioid exposure under prescribed use, while automatically limiting additional opioid release when excessive doses are ingested. This "built-in safety switch" introduces a new therapeutic paradigm: opioids engineered not only for efficacy, but for controlled exposure under conditions of misuse.

Previously published clinical data demonstrate that PF614-MPAR delivers consistent, therapeutic plasma levels under normal dosing conditions, while significantly attenuating increases in opioid exposure at supratherapeutic doses. Part 3 of the PF614-MPAR-102 study is designed to further characterize this protective effect across a range of dosing scenarios.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce stated "Nearly 80,000 lives are lost annually to opioid overdose in the U.S., with prescription opioids contributing meaningfully to this ongoing crisis[1]. MPAR® introduces a new class of chemically engineered opioids designed to actively protect patients, even in cases of dosing errors or misuse. This is a critical step toward establishing a new standard for opioid safety."

The PF614-MPAR-102 study builds on earlier clinical findings and continues formulation development with ongoing support from the National Institute on Drug Abuse (NIDA)[2].

Beyond pain management, Ensysce is seeking to extend the uses of MPAR® across additional therapeutic categories including amphetamines and methadone, with the objective of delivering safer treatments for pain, attention-deficit/hyperactivity disorder (ADHD), and

opioid use disorder.

[1]https://drugabusestatistics.org/opioid-epidemic/

[2]Research supporting this patent was funded by the National Institute on Drug Abuse of the National Institutes of Health under Award Number DA047682.

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage company with a goal of disrupting the analgesic landscape by introducing a new class of highly novel opioids for the treatment of severe pain. 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. 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, possible NASDAQ delisting, 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; continuation of government funding; 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 annual report on Form 10-K and current reports on Form 8-K, 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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