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Ensysce Biosciences Awarded $5.3 Million in Continued NIDA Support to Advance Breakthrough Opioid Overdose Protection

~ PF614-MPAR Moving to Next Stage of Development, Finalizing Drug Formulation ~

~ Funds Accelerate Path Towards Commercialization ~

SAN DIEGO, CA / ACCESS Newswire / June 4, 2025 /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 was awarded the second $5.3 million installment of a $15 million, three-year grant from the National Institute on Drug Abuse (NIDA)[1]. This continued support will accelerate the clinical and non-clinical development of PF614-MPAR, a next-generation opioid designed to offer powerful pain relief while dramatically reducing the risk of overdose.

PF614-MPAR, which has earned the FDA's prestigious Breakthrough Therapy designation, is uniquely engineered using Ensysce's proprietary TAAP™ (Trypsin-Activated Abuse Protection) and MPAR® (Multi-Pill Abuse Resistance) technologies. These platforms enable PF614-MPAR to maintain therapeutic efficacy while offering built-in overdose protection - even when doses exceed prescribed amounts, whether accidentally or intentionally.

The first year of NIDA funding, together with outside capital raised, enabled a series of promising clinical studies that validated PF614-MPAR's ability to prevent overdose. This next phase of funding which began on June 1, 2025, will focus on optimizing the final drug formulation, undertaking further clinical evaluation while preparing to move to commercialization. Ensysce plans to engage with the FDA in the coming months to align on full development plans based on the robust data generated to date.

Dr. Lynn Kirkpatrick, CEO of Ensysce, commented, "Our initial clinical results confirm what we set out to achieve - a safer opioid that can offer what we believe is real protection in overdose scenarios. PF614-MPAR is the only opioid product to receive FDA Breakthrough Therapy status, a testament to its potential impact. NIDA's continued support is a powerful endorsement of our mission to deliver innovative, life-saving solutions for pain management. With these additional funds, we're accelerating toward commercialization and look forward to working closely with the FDA on our next steps."

[1]The research is supported by the National Institute on Drug Abuse of the National Institutes of Health under Award Number UO1DA059791.

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, 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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