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Ensysce Biosciences Receives $14 Million NIH Grant for Clinical Development of Novel Opioid with Overdose Protection

~ Substantial Award Follows FDA Breakthrough Therapy Designation for PF614-MPAR ~

~ Federal Grant Funding Awarded to Date Now at $40 Million ~

SAN DIEGO, CA / ACCESSWIRE / August 27, 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 receipt of a $14 million multi-year grant from the NIH and National Institute on Drug Abuse (NIDA) for the continued development of PF614-MPAR, an abuse-deterrent opioid with overdose protection that received Breakthrough Therapy designation from the FDA in January 2024. Funding from this award will be available over a period of approximately three years, allowing for the completion of the Phase 1b clinical trial, PF614-MPAR-102. This Phase 1b study is designed to expand the product offering identified in the PF614-MPAR-101 study, the first study to verify the overdose protection of the Multi-Pill Abuse Resistance (MPAR®) platform. Combined, the two studies will help position PF614-MPAR as the first opioid product with oral overdose protection.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce Biosciences, commented, "This non-dilutive award by NIDA is another meaningful vote of support by the federal government for the development of this novel class of opioids with overdose protection. Our initial Phase 1 study of PF614-MPAR demonstrated this approach to treat pain provides protection from taking too many pills orally. With this funding, adding to the two prior grants of over $26 million for the initial work on the MPAR and opioid use disorder (OUD) programs, Ensysce intends to quickly drive PF614-MPAR through clinical development to make its benefits available in a large market where we believe unmet need is high."

PF614-MPAR is designed to provide optimal pain relief at prescribed doses yet limit accidental or intentional overdose by ‘shutting down' opioid release if too much active drug is consumed. PF614-MPAR could herald a new class of treatment for the most severe forms of pain and could save lives, as each capsule contains built-in protection against both abuse and overdose which plague traditional opioids. Safer opioids for severe pain which protect against abuse and oral overdose are vital to address the discouraging statistics from the Centers for Disease Control of almost two overdose deaths per hour. Ensysce is forging the way to reverse this trend with two new opioids in clinical development. The MPAR® technology may also have applications for improving drug safety beyond opioids.

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.

About Breakthrough Therapy Designation

Breakthrough Therapy is a rarely used designation, having been granted by the FDA to fewer than 300 drugs since its introduction in 2012. It is designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies.

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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