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Ensysce Biosciences Announces Major Milestone for Opioid Use Disorder Program

~ Selects Lead Candidate with Abuse Deterrence and Improved Safety Profile to Treat Opioid Use Disorder ~

SAN DIEGO, CA / ACCESSWIRE / June 6, 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 misuse, abuse and overdose, today announced the achievement of a critical milestone in its opioid use disorder (OUD) program with the selection of a lead drug candidate to move into Investigational New Drug (IND) enabling studies. Designed with the application of Ensysce's TAAP platform to reduce the abuse profile, lead candidate PF9001 has shown lower potential for cardiovascular side effects associated with traditional methadone opioid use disorder (OUD) treatments. This work has been supported by a multi-year Helping to End Addiction Long-Term (HEAL) award of up to $15 million granted by the NIH and National Institute on Drug Abuse (NIDA).

Dr. Lynn Kirkpatrick, CEO of Ensysce said, "We are pleased that the adaptability of our TAAP technology platform has demonstrated benefits in therapeutic indications beyond pain and ADHD. Our novel approach to produce drug candidates whose activity can be turned on and off through the control of trypsin activation is an attractive advantage for new drug development. As we expand our product pipeline to include OUD, we look forward to bringing PF9001 into human clinical studies within the next 12 to 18 months. The significant funding from NIDA and the HEAL program, with a focus on the reduction of drug abuse and addiction, has been instrumental in our achievement of this critical milestone, and we appreciate their continued support."

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 (TAAPä) and Multi-Pill Abuse Resistance (MPAR®) platforms, the Company is developing a unique, tamper-proof treatment option for pain that minimizes 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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