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Ensysce Biosciences Reports Continued Positive Progress in Groundbreaking Trial on PF614-MPAR, Comments on Current Landscape for Pain Treatment

~ Positive Enrollment Progress and Safety Data ~

~ FDA Attention Establishes Momentum in the Pain Treatment Space ~

SAN DIEGO, CA / ACCESS Newswire / February 5, 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 continued subject enrollment and successful dosing augmenting the progress of its second clinical trial to evaluate PF614-MPAR for overdose protection.

In the current study of PF614-MPAR-102, data showed that a 100 mg dosage form of PF614-MPAR provides overdose protection when a greater-than-prescribed dose is consumed at one time. The study has continued with successful enrollment of the highest dosing cohort of 5 times the 100 mg dose unit. Importantly, adverse events have been limited, thus far verifying the favorable safety profile of PF614 and PF614-MPAR as a novel class of opioids to treat severe pain. The uniqueness of PF614-MPAR, a combination opioid with oral overdose protection resulted in the FDA's Breakthrough Therapy designation in 2024.

Dr. Lynn Kirkpatrick, CEO of Ensysce, stated, "Our progress in developing the only opioid with overdose protection is encouraging and data now confirms overdose protection across a dosage range of 25 to 100 mg for our PF614-MPAR drug product. Additionally, we are optimistic about the recent regulatory attention on pain treatment, evident in the latest approval of a NaV1.8 inhibitor. This product may contribute to pain management for those individuals who cannot tolerate NSAIDs, an area that has seen little innovation over the last few decades. Based on data reported so far, we believe NaV1.8 inhibitors will be an important addition for moderate pain currently treated with NSAIDs and COX-2 analgesics. However, to effectively treat severe acute and chronic pain, our team and expert advisors believe the market for a safe opioid remains open to an innovative solution, and we believe PF614 plus PF614-MPAR will be this solution."

Dr. William Schmidt, Chief Medical Officer of Ensysce, added, "We are pleased that the FDA's approval of new products for pain is emerging in this area of high unmet need, where different patients require differing approaches. We believe the most severe and chronic pain will still require products with opioid-like efficacy. We believe we've addressed this goal with the unique value proposition of abuse resistance and overdose protection in Ensysce's lead

products PF614 and PF614-MPAR."

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.

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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