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Ensysce Biosciences Receives Positive FDA Feedback on PF614 Manufacturing Approach

~ FDA Response Streamlines Path to Commercial Production of PF614~

SAN DIEGO, CA / ACCESS Newswire / November 20, 2025 / Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage pharmaceutical company pioneering next-generation pain and central nervous system therapeutics designed to minimize abuse and overdose risk, today announced that the Food and Drug Administration (FDA or Agency) provided Written Responses to a meeting request.

Ensysce had requested guidance on its approach to the manufacture of PF614, wanting to understand the appropriateness of regulatory starting materials (RSMs) and specifications for PF614 drug substance and the RSMs.

In its written responses, the Agency agreed with all of Ensysce's proposed plans. These responses provide Ensysce with a direct path to commercial production of PF614, which is currently being initiated with its manufacturing partner, Purisys, LLC, a subsidiary of Noramco, LLC.

Dr. Jeff Millard, Chief Operating Officer of Ensysce who lead the CMC effort stated "We are extremely pleased with the FDA's feedback, which validates our approach and enables us to accelerate PF614's path to market. This milestone brings us closer to providing safer pain relief options for patients in need."

"The feedback from the FDA now provides us with a clear path to scaling our manufacture of PF614 for its commercial production," said Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce. "PF614 is our TAAP™ oxycodone analogue and the leading product in our Next Generation Analgesic pipeline of TAAP™ and MPAR® products. We are exceptionally pleased that our meeting package was so well received and that we are aligned with the FDA requirements for producing this novel therapeutic that is designed to alleviate moderate to severe pain while providing what we believe are safer qualities for the general public who require this level of pain relief."

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 quarterly report on Form 10-Q 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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