May 9, 2023

Ensysce Biosciences Announces Successful Completion of Ground-Breaking Study on Overdose Protection

~ Represents Major Milestone Towards Launch of PF614-MPAR ~

~ PF614-MPAR on Track to be the First Drug to Protect Against Overdose ~

SAN DIEGO, CA / ACCESSWIRE / May 9, 2023 /Ensysce Biosciences, Inc. (NASDAQ:ENSC), clinical-stage biotech company applying transformative chemistry to improve prescription drug safety, today announced completion of PF614-MPAR-101, a clinical study examining the Company's first pain medication with overdose protection, PF614-MPAR. The final Part B of the study examined dose escalation of PF614-MPAR from 25 to 200 mg (1 to 8 dose units) and showed that PF614-MPAR successfully reduced opioid delivery when three or more doses are consumed simultaneously.

We believe PF614-MPAR is the first drug which can limit opioid exposure when too many pills are swallowed, protecting against overdose. In our PF614-MPAR-101 study, the data showed that a 25 mg dose of PF614-MPAR, delivered oxycodone as designed for what may be a prescribed dose of one to two capsules. Importantly, when administering three or more capsules simultaneously, the amount of opioid released and absorbed into the circulation diminished as compared to the unprotected PF614, thereby substantially reducing the risk of overdose.

Opioids are used widely for the treatment of severe pain, for example, in patients fighting cancer and for post-operative pain. Opioids are highly effective but carry a significant risk of abuse, addiction and overdose. Overdoses with opioids continue to be a major issue which may occur due to inadvertent over-use, or purposefully when family members find drugs to experiment with in the medicine cabinet.

According to Dr. William Schmidt, Chief Medical Officer of Ensysce Biosciences, "This first-in-human demonstration of MPAR's unique ability to reduce the adverse consequences of excessive opioid consumption is a major step towards Ensysce's goal of making safer prescription drugs. If approved by the FDA, PF614-MPAR could represent a true game-changer for the treatment of severe pain, and could validate our MPAR™ technology for application to a range of other medications."

"This successful outcome brings us closer to the launch of the first opioid with overdose protection," said Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce Biosciences. "PF614-MPAR is potentially a first-in-class agent designed to treat severe pain while not only reducing the ability to abuse for recreational purposes but also to provide protection from overdose. The results showed that our patented technology MPAR™, which ‘switches off' the active drug release, can limit delivery when excess was consumed. Our next step is to

clearly define the drug product for all planned dose strengths to optimize effects across our planned dose range. The PF614-MPAR-101 study is particularly important as a proof-of-concept for the base MPAR™ technology which we believe could be used to control delivery of many other drug classes where there may be a narrow therapeutic range. We are excited to explore this further with other therapies as it may help to save many lives in the future."

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage biotech 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 in the process of developing a unique, tamper-resistant treatment option for pain that minimizes the risk of both opioid drug abuse and accidental or intentional 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.

Ensysce Biosciences Company Contact:

Lynn Kirkpatrick, Ph.D.
Chief Executive Officer
(858) 263-4196

Ensysce Biosciences Investor Relations Contact:
Shannon Devine
MZ North America
Main: 203-741-8811
ENSC@mzgroup.us

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