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Ensysce Biosciences Announces Completion of Enrollment for Groundbreaking Opioid Overdose Protection Study

~ Data Demonstrates Exceptional Safety Profile of PF614-MPAR, the Industry's First Overdose Protection Pain Product ~

SAN DIEGO, CA / ACCESSWIRE / March 22, 2023 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC), a clinical-stage biotech company applying transformative chemistry to improve prescription drug safety, today announced the completion of enrollment in the final stage of the Phase 1 study, PF614-MPAR-101. This study was conducted by Dr. Maria Bermudez MD, at Quotient Sciences, Miami, Florida.

PF614-MPAR is the overdose protectionderivative of the Ensysce lead product PF614 and holds the promise of protecting against multiple forms of abuse and overdose, an industry first. The added layer of overdose protection is made possible by combining PF614 with a trypsin inhibitor, nafamostat, to prevent overdose if too many pills are swallowed.

The combination product, 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. This product, if approved, could herald a new class of treatment for the most severe forms of pain, with built-in protection in each capsule against the issues which plague traditional opioids.

Overdose deaths in the US remain out of control, with the latest figures from the National Institute on Drug Abuse showing over 106,000 deaths in 2021, averaging over 250 deaths per day. Safer opioids to treat severe pain while providing protection against abuse and overdose are vital to reverse this tragic trend. Prescription opioid overdose deaths result when patients ingest too many pills accidentally, and often when younger people get unintended access to the prescription products.

The first stage of the study, reported previously, manufactured and tested a number of nafamostat formulations allowing determination of the final PF614 and nafamostat combination composition. The results for both safety and pharmacokinetics demonstrated that MPAR overdose protection may be achieved with the selected nafamostat formulation.

This last stage of the trial was conducted to confirm that the selected PF614/nafamostat composition would allow oxycodone release and hence pain relief at the prescribed dose of one to two capsules yet would reduce oxycodone release if three or more capsules were taken. The data demonstrates that the safety profile has been exceptional to date, with limited adverse events noted at any of the dose levels. Further data from the trialis expected

in the second quarter of 2023 when the pharmacokinetic data will be provided to demonstrate how the PF614-MPAR formulation performed to diminish oxycodone release at excess dose units.

Dr. Maria Bermudez, PI of the study from Quotient Sciences commented, "This is the most interesting Phase 1 study I have been involved with. I have been impressed by the positive data that has been generated, it is encouraging to be able to contribute to a solution to one of this century's biggest health crises. I look forward to the final results from the study."

"Ensysce is committed to improving the lives of patients suffering from severe pain by providing safe and effective products which give confidence to prescribers and patients," stated Dr. Lynn Kirkpatrick, CEO of Ensysce. "I am very excited at the potential of PF614-MPAR. It is not often that we get the chance to fundamentally transform care. TAAP™ and MPAR™ can be built into many medications and our initial PF614-MPAR could be a huge step toward transforming pain management. We believe that this landmark study confirms the safety of our approach and the safety of our first product with overdose protection, PF614-MPAR. Overdoses are still going up and we are potentially only a few years away from having a solution to prescription opioid overdose."

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage biotech company using its proprietary technology platforms to develop safer prescription drugs. Leveraging TAAP™ and MPAR™, the Company is in the process of developing a unique, tamper-proof treatment option for pain that minimizes the risk of both drug abuse and overdoses. 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.

Definitions

‘TAAP': trypsin-activated abuse protection - designed to protect against prescription drug abuse.

‘MPAR': multi-pill abuse resistance - designed to protect against abuse and accidental overdose.

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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