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Ensysce Biosciences Announces Data from PF614-MPAR-101-Part A Successfully Demonstrating Opioid Overdose Protection

~ PF614-MPAR will be the Industry's First Overdose Protection Pain Product ~

SAN DIEGO, CA / ACCESSWIRE / December 19, 2022 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC)(OTC PINK:ENSCW), a clinical-stage biotech company applying transformative chemistry to improve prescription drug safety to reduce abuse and overdose, today announced data demonstrating the overdose protection of its drug product, PF614-MPAR from the clinical study being conducted in Healthy Subjects by Dr. Maria Bermudez MD, at Quotient Sciences, Miami, Florida.

PF614-MPAR is designed to provide optimal pain relief at prescribed doses. Accidental or intentional overdose is limited by the overdose protection built into each capsule with the addition of Ensysce's formulated nafamostat ingredient. With MPAR technology, one or two PF614-MPAR capsules taken as prescribed will release the expected concentration of oxycodone required to provide pain relief as intended. However, when three or more capsules are taken, the increased exposure to nafamostat inhibits the trypsin-mediated release of oxycodone from the excess PF614 ingested, allowing the inactive parent drug to pass through the body unmodified. The recently completed Part A of the trial allowed the optimization of the nafamostat formulation by evaluating the PF614/nafamostat combination for both release rate and ratio of the combination. Data from the trial was able to show that in healthy subjects we could deliver oxycodone similarly with PF614 and PF614-MPAR, which was the goal of the study. Additionally, and as anticipated, the results of the study demonstrated that a large overdose of PF614-MPAR would result in diminished oxycodone release and uptake as compared to an equivalent amount of an unprotected opioid. In early 2023, the final formulation selected from this study will be evaluated as increasing dose units of PF614-MPAR in a group of healthy subjects in Part B of the study.

Dr. Lynn Kirkpatrick, CEO of Ensysce, commented, "PF614-MPAR is an opioid pain product designed to provide two layers of safety, one to reduce casual abuse and the second to prevent accidental overdose. We believe the data we present today demonstrates that our approach to limiting opioid release with our combination oxycodone product, PF614-MPAR, may save lives."

Continued Dr Kirkpatrick, "This unique study of a product with both abuse and overdose protection in the same medication is the first step in providing an opioid to treat severe pain while limiting the potential for abuse or overdose."

MPAR™ (Multi-Pill Abuse Resistance) is designed to prevent drug overdose by inhibiting the activation and release of opioid when more than prescribed doses are taken. PF614 is a TAAP™ (Trypsin Activated Abuse Protection) prodrug of oxycodone designed to reduce abuse of this opioid pain medication. TAAP™ chemical modification inactivates the active ingredient in Ensysce's products until they are swallowed and exposed to a digestive enzyme, trypsin. PF614 requires exposure to trypsin, which safely turns ‘on' the release of oxycodone. The PF614-MPAR has additional protection of an added trypsin inhibitor, nafamostat, to turn ‘off' the release of oxycodone in an overdose situation. The MPAR™ combination technology of a TAAP prodrug and a trypsin inhibitor is the first platform that the Company expects may prevent all four common methods of opioid abuse - chewing, inhaling, injecting and oral 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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