January 25, 2023

Ensysce Biosciences Announces Initiation of Final Stage of Groundbreaking Opioid Overdose Protection Phase 1 Study

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

SAN DIEGO, CA / ACCESSWIRE / January 25, 2023 /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 the initiation of the final stage of the Phase 1 study of PF614-MPAR. PF614-MPAR is the overdose protectionversion of its lead product, PF614, and this keystudy is being conducted in healthy subjects by Dr. Maria Bermudez MD, at Quotient Sciences, Miami, Florida.

PF614, a TAAP™ prodrug of oxycodone, has a number of safety features designed to reduce abuse, including its extended-release profile that has been shown to reduce ‘drug liking' in recreational drug users. Additionally, its requirement for exposure to the enzyme trypsin to release oxycodone reduces the ability of recreational users to chew, crush and snort, or manipulate and inject to change the opioid release profile. The combination product PF614-MPAR has another layer of safety, with an added trypsin inhibitor to prevent overdose.

PF614-MPAR is designed to provide optimal pain relief at prescribed doses. Accidental or intentional overdose is designed to be limited by the overdose protection built into each capsule with the addition of Ensysce's formulated trypsin inhibitor, nafamostat. With MPAR™ (Multi-Pill Abuse Resistance) technology, the target dose of one or two prescribed PF614-MPAR capsules will release the expected concentration of oxycodone required to provide pain relief as intended. However, when three or more capsules are taken, exceeding the target dose, the increased exposure to nafamostat progressively inhibits the release of oxycodone from the excess PF614 ingested. This allows the inactive drug to pass through the body, thus averting an overdose.

The recently completed initial stage of the trial sought to optimize PF614-MPAR (the PF614/nafamostat combination) for both release rate and ratio of the combination. Data from the trialdemonstrated that PF614-MPAR could deliver oxycodone similarly toPF614, which was the goal of the study. In line with expectations, the results of the study demonstrated that an overdose of PF614-MPAR would result in diminished oxycodone release and uptake as compared to an equivalent amount of PF614. In the final stage of the study, the selected PF614-MPAR formulation will be evaluated by measuring oxycodone release from increasing dose units delivered to a group of healthy subjects.

Dr. Lynn Kirkpatrick, CEO of Ensysce, commented, "We are committed to improving the

lives of patients suffering from severe pain by providing safe and efficacious products. We believe that TAAP™ and MPAR™ can be built into many medications and our initial focus on pain is just one step toward transforming several drug classes.PF614-MPAR is an opioid pain product designed to provide two layers of safety, one to reduce abuse and the second to prevent overdose. We believe PF614-MPAR may be the first opioid product to prevent all four common methods of opioid abuse - chewing, snorting, injecting and oral overdose. The current study is aimed at confirming that our approach to limiting opioid release with our combination oxycodone product, PF614-MPAR, may save lives."

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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SOURCE: Ensysce Biosciences Inc.

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