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Ensysce Biosciences Announces Completion of Clinical Portion of Overdose Protection Trial PF614-MPAR-101-Part A

~ Completion of Trial Represents Continuing Progress Towards Development of the Industry's First Overdose Protection Pain Product ~

SAN DIEGO, CA / ACCESSWIRE / December 5, 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 that it has successfully completed the clinical portion of study PF614-MPAR-101 Part A, entitled 'Single-Dose Study to Evaluate the Pharmacokinetics of oxycodone and PF614, when PF614 Solution is Co-Administered with Nafamostat, as an Immediate-Release Solution and/or Extended-Release (ER) Capsule Formulations in Healthy Subjects', being conducted by Dr. Maria Bermudez MD, at Quotient Sciences, Miami Florida.

Dr. Lynn Kirkpatrick, CEO of Ensysce, commented, "Overdose with opioids is a societal crisis. Hundreds of Americans die each day due to deliberate and accidental overdoses. PF614-MPAR is designed to provide two layers of safety, one to reduce casual abuse and the second to prevent accidental overdose. We are looking forward to reporting the final data from this part of the trial and expect to do so by the end of this month."

"We believe the data from this trial will allow us to define the exact ratio of PF614 and nafamostat in PF614-MPAR that will be necessary to provide optimal pain relief with overdose protection. We are expanding the study in a Part B in 2023 in order to confirm the overdose protection with escalating dose units," continued Dr Kirkpatrick. "It has been a pleasure partnering with Quotient Sciences, using their Translational Pharmaceutics platform to perform the clinical portion of this unique study with both abuse and overdose protection in the same medication to treat severe pain."

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

'PF614 TAAP': trypsin activated abuse protection - designed to protect against prescription drug abuse.

'PF614-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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