December 15, 2021

Ensysce Biosciences Announces First Patients Enrolled in Phase 1 Study of PF614-MPAR™, its unique technology platform to provide opioid overdose protection

SAN DIEGO, Dec. 15, 2021 (GLOBE NEWSWIRE) -- Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ: ENSC, OTC: ENSCW), a clinical-stage biotech company with novel technology platforms that may provide new hope for those in severe pain, today announced that the first patients have been enrolled in the Phase 1 study of PF614-MPAR™, the first product utilizing the Company's MPAR™ platform designed to reduce opioid overdose.

Designed to provide safety and pharmacokinetic data on the combination of PF614 and nafamostat, the study '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', is being conducted by Dr. Maria Bermudez MD, at Quotient Sciences.

PF614-MPAR™ is a combination product of Ensysce's PF614, a trypsin-activated abuse protection (TAAP) oxycodone prodrug and nafamostat, a trypsin inhibitor. This combination provides both abuse and overdose protection to the opioid product that the Company believes is unique in the industry. MPAR™ is designed to prevent drug overdose by inhibiting the activation of a TAAP prodrug when more than prescribed doses are taken. The MPAR™ combination technology is the first platform that the Company expects may prevent all four common methods of abuse – injecting, chewing, inhaling, and oral overdose.

"The initiation of this study represents a significant step toward minimizing overdoses and deaths from prescription opioids," said Dr. Lynn Kirkpatrick, CEO of Ensysce Biosciences. "Opioid abuse and overdose are causing significant and long-lasting impacts on the quality of life for sufferers and their families."

Dr. Kirkpatrick concluded: "Ensysce's mission is to launch its first-in-class opioids, PF614 and PF614-MPAR™ with the intent of providing protection against both abuse and overdose. Drug overdose deaths hit record levels in 2021. With our current clinical study of PF614, a TAAP opioid with abuse protection, progressing through bioequivalence and planned human abuse liability studies, this additional study of PF614-MPAR™ with added overdose protection will enhance our dual-prong approach to provide safer solutions to patients and prescribers."

“Enrollment of the first patients in the clinical trial for PF614-MPAR™ is a critical milestone for this potentially transformative pain treatment option,” said Ensysce’s Chief Medical Officer Dr. William Schmidt. “The clinical data coming from this trial will guide our MPAR™ drug product development. We intend to use the data to provide the building blocks to design a second trial at the end of 2022 to fully demonstrate the lifesaving overdose protection of our MPAR™ technology.”

About Ensysce Biosciences
Ensysce Biosciences, San Diego, CA 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 new class of powerful, tamper-proof opioids that prevent both drug abuse and overdoses. Ensysce’s products are anticipated to provide safer options to treat severe pain and assist in preventing deaths caused by opioid abuse, reducing the human and economic cost. 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,” 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 Investor Relations Contact:
Gateway Investor Relations

Alex Thompson, Matt Glover
(949) 574-3860
Ensysce@gatewayir.com

Source: Ensysce Biosciences Inc.