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Ensysce Biosciences Receives Notice of Award for Year Three of Multi-Year NIDA Grant for the Clinical Development of its Next Generation Opioid Products with Overdose Protection

Company's Proprietary TAAP Prodrug Delivery and Overdose Technology Aims to Stem The Opioid Abuse Epidemic

SAN DIEGO, July 08, 2021 (GLOBE NEWSWIRE) -- [Ensysce Biosciences, Inc.](#) (NASDAQ: ENSC) ("Ensysce" or "the Company"), a clinical stage biotech company with proprietary technology platforms to reduce the economic and social burden of prescription drug abuse and overdose, today announced receipt of the 3rd year award of a multi-year grant from the National Institute on Drug Abuse (NIDA). This award will provide \$2.8 million to initiate a Phase 1 study of the first MPARTM overdose protection product in the U.S., PF614-MPAR. This brings the total support of NIDA to \$8.0 million. An additional \$2.8 million award for year four is pending.

"We are honored to receive the UH3 award titled 'PF614 MPAR Abuse Deterrent opioid prodrug with overdose protection: Pre-Clinical Development and Phase 1 Clinical Trial' from the National Institute on Drug Abuse, which provides us with additional resources to continue our work to bring PF614-MPARTM into clinical development," said Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce Biosciences. "Importantly, our next-generation opioid platform is highly differentiated from currently marketed opioid products and designed to significantly reduce abuse potential and overdose protection. We remain focused on our commitment to stem the prescription drug abuse epidemic and look forward to bringing our unique pipeline of products to the industry, which will ultimately provide safer options for both prescribers and patients."

PF614-MPARTM is designed as an extended-release oxycodone prodrug with both [trypsin-activated abuse protection \(TAAP\)](#) and overdose protection through multi-pill abuse resistance (MPARTM) technology. TAAP chemical modification inactivates the active ingredient in PF614 to provide abuse deterrence, and the combination with the trypsin inhibitor, nafamostat, in MPARTM provides the additional layer of overdose protection. The MPARTM overdose protection has been demonstrated in animals and the Phase 1 study with PF614 is being conducted to further validate the MPARTM overdose protection technology. The Phase 1 study trial, "A 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. Maricer Escalon MD, MS, MBA at Quotient

Sciences.

“This award further confirms Ensysce’s important TAAP and MPAR™ technology, which has been recognized by NIH, NIDA and the Federal Government,” said Dr. William Schmidt, Chief Medical Officer of Ensysce. “We remain committed to addressing the significant unmet needs in the marketplace, and look forward to advancing our pipeline of opioid TAAP and MPAR™ products to combat the opioid crisis.”

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; 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 definitive proxy statement/prospectus relating to the recently completed business combination with Leisure Acquisition Corp., which is 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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