

September 8, 2021



Ensysce Biosciences Announces Treatment of First Cohort for Subjects in Clinical Study of its Next Generation Opioid, PF614

Company Commences Second Study of Trypsin Activated Abuse Protected (TAAP) Opioid, PF614, on September 7, 2021

SAN DIEGO, Sept. 08, 2021 (GLOBE NEWSWIRE) -- Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ: ENSC, OTC: ENSCW), a clinical-stage biotech company with proprietary technology platforms to reduce the economic and social burden of prescription drug abuse and overdose, today announced that it has enrolled the first cohort of subjects in a clinical study PF614-102 entitled "A Phase 1b, Randomized, 2-Part Single-Center Study to Evaluate the Pharmacokinetics and Safety of Multiple-Ascending Oral Doses of PF614 and the Food Effect and Bioavailability/Bioequivalence of Single Oral Doses of PF614 Relative to OxyContin in Healthy Adult Subjects." The study is being conducted by Matthew Johnston, MD, PRA Health Sciences, Salt Lake City, Utah.

PF614 is designed as an extended-release oxycodone prodrug with [trypsin-activated abuse protection \(TAAP\)](#). TAAP chemical modification inactivates the active ingredient in Ensysce's opioids products including PF614 and provides abuse deterrence, resistance to manipulation and other forms of recreational drug abuse, while providing a high degree of pain relief for those in severe pain. This study will build on the safety and pharmacokinetic results of the initial Phase 1 study, and may lead to an understanding of how PF614 compares to currently available commercial products.

"Finding a safe and effective treatment to address the opioid crisis is a pressing health priority," said Dr. William Schmidt, Chief Medical Officer of Ensysce. "This study will be an important step toward achieving our goal of developing the next generation of opioid products for patients in chronic pain."

"This important study, to demonstrate how PF614 compares to OxyContin, may lead to the ability to use the 505(b)(2) regulatory path to registration, and the more seamless commercialization of this highly innovative approach to reduce opioid abuse." said David Kovacs, VP of Public Policy. "I joined this team because I believe these products may provide an opportunity to change the course of this huge societal problem."

Dr. Lynn Kirkpatrick, CEO of Ensysce Biosciences, commented: "Our mission is to transform pain treatment and provide a critical solution to the opioid crisis. We believe our approach can contribute to making opioid pain relief a more acceptable therapeutic option in the future, and we remain focused on our commitment to stem the prescription drug abuse

epidemic by bringing our unique pipeline of products to the industry, which will ultimately provide safer options for both prescribers and patients.”

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 most recent Form S-4 and Ensysce’s definitive proxy statement/prospectus relating to the recently completed business combination with LACQ. 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 Company Contact

Lynn Kirkpatrick, Ph.D.
Chief Executive Officer
(858) 263-4196

Ensysce Biosciences Investor Relations Contact:

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



Source: Ensysce Biosciences Inc.