January 4, 2023

Ensysce Biosciences Announces Successful Completion of Clinical Portion of Oral Human Abuse Potential Trial

Data Expected in March 2023

SAN DIEGO, CA / ACCESSWIRE / January 4, 2023 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC, OTC: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 PF614-104, 'A Randomized, Double-Blind, Placebo- and Active-Controlled, Crossover Study to Evaluate the Oral Abuse Potential of PF614 Compared with Oxycodone Immediate-Release Tablets, and Placebo in Non-Dependent Recreational Opioid Users' (ClinicalTrials.gov: NCT05571345) being conducted by Dr. Vince Clinical Research.

This is the second human abuse potential (HAP) study completed for PF614, a controlled-release oxycodone TAAPä prodrug, following completion of an intranasal HAP study in August 2022. HAP studies are critical for gaining abuse-deterrent labeling as outlined by the FDA. The trial was designed to evaluate abuse potential in non-dependent, recreational drug users, including measures of "drug liking" and whether study participants would "take drug again." Orally administered PF614 was compared to immediate-release oxycodone HCl. The global opioid epidemic is primarily driven by individuals abusing opioids through manipulation of currently marketed products. PF614 is designed to maintain its extended-release (ER) profile even after being subjected to common methods of manipulation, including chewing and crushing the product prior to oral administration.

Dr. Lynn Kirkpatrick, CEO of Ensysce, commented, "Release of the active ingredient in PF614 requires exposure to trypsin, which is found only in the small intestine and not in the mouth, the nose, or blood stream, so simple manipulation of PF614 will not result in oxycodone release. We are looking forward to reporting the final data from this oral PF614-104 trial and expect to do so by the end of the first quarter."

Dr. William Schmidt, Chief Medical Officer of Ensysce, stated, "We believe that this oral HAP study will provide critical data to differentiate PF614 from other oxycodone ER products that can be abused through crushing and chewing to convert to immediate release products. This study along with our previously reported positive nasal HAP study represents two essential steps toward achieving success in bringing PF614 to the market. It is the goal of Ensysce to fill an important unmet need of providing safer options for pain management, ultimately alleviating patient suffering from severe pain."

The PF614-104 study examined the 'Drug Liking' as well as pharmacokinetic release of oxycodone from each test agent, including PF614 (50, 100 and 200 mg doses), oxycodone HCl (40 mg), and placebo, all administered orally in a blinded rotation among 32 recreational

drug users. The primary outcome measure is the maximum effect (Emax) for ‘Drug Liking.' Data from the clinical trial is expected to be released in March 2023.

About PF614

PF614 is a TAAP™ product designed as a delayed onset ER oxycodone prodrug. TAAP™ chemical modification inactivates the active ingredient in Ensysce's products including PF614 until they are swallowed. This provides abuse deterrence, resistance to manipulation and other forms of recreational drug abuse, while providing a high degree of pain relief for those who require opioid analgesics for 24/7 round-the-clock severe pain. This study builds on the safety and pharmacokinetic results already seen in the prior clinical studies and improves the understanding of how PF614 compares to currently available commercial products.

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage biotech company using its proprietary technology platforms to develop safer prescription drugs. Leveraging its Trypsin Activated Abuse Protection (TAAPä) and Multi-Pill Abuse Resistance (MPAR™) platforms, 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, reducing the human and economic costs. 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," "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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