August 23, 2022

Ensysce Biosciences Announces Completion of Clinical Portion of Human Abuse Potential Trial PF614-103

Completion of Clinical Portion Represents Critical Milestone Towards Commercialization

Nasal Opioid Abuse Being Explored for PF614

Data From Trial Expected in September 2022

SAN DIEGO, CA / ACCESSWIRE / August 23, 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 PF614-103, 'A Randomized, Double-blind, Placebo- and Active-Controlled Crossover Study to Evaluate the Intranasal Abuse Potential of PF614 Compared with Immediate-Release Oxycodone and Placebo in Non-Dependent Recreational Opioid Users' being conducted by Dr. Glen Apseloff, from Ohio Clinical Trials, Inc.

This trial is designed to test and confirm that manipulating and snorting PF614 will not result in subjects "liking" the product. Human Abuse Potential (HAP) studies are critical for gaining Abuse Deterrent labeling as outlined by the FDA. The global opioid epidemic is primarily driven by individuals abusing opioids through manipulation of current marketed products by crushing, snorting and through IV injections. Due to the unique mechanism of action of PF614, the FDA has not required Ensysce to perform an IV HAP study. Thus, the nasal HAP study is one of two important HAP studies in the clinical development of PF614. The second is an oral HAP study for which we look forward to providing an update shortly.

Dr. Lynn Kirkpatrick, CEO of Ensysce, commented, "Release of the active ingredient in PF614 requires exposure to trypsin, which is only found in the small intestine and not in the nasal mucosa, so we believe inhalation of PF614 will not result in oxycodone release. Similarly, trypsin is not found in the blood stream, and therefore, PF614 will not convert to the active drug if injected or absorbed into the circulation as shown in our PF614-MPAR-101 study. We are looking forward to reporting the final data from this 103 trial and expect to do so by the end of next month."

Dr. Nily Osman, Chief Medical Officer of Ensysce, stated, "We believe that this nasal HAP study will provide critical data to differentiate PF614 from other oxycodone products commercially available that can be abused through nasal inhalation. This is an essential step forward for Ensysce to bring PF614 to market and provide safer options for pain management for alleviating patient suffering, an important unmet need."

The PF614-103 study examined the pharmacokinetic and pharmacodynamic (e.g., Maximum Drug Liking and Take Drug Again) of PF614 (100 mg) versus crushed oxycodone (40 mg) and placebo, all administered by inhalation in 26 recreational drug users. The primary outcome measure is the maximum effect (Emax) for 'Drug Liking.'

PF614 is a TAAP™ product designed as a delayed onset oxycodone prodrug. TAAP™ chemical modification inactivates the active ingredient in Ensysce's opioids products including PF614. This 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 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 (TAAPTM) 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" 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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