July 27, 2022

Ensysce Biosciences Announces Positive Bioequivalence (BE) Study Data of Novel "TAAP" Opioid PF614 and Provides Timing of Corporate Update Call

~ BE Study of PF614 Represents Critical Progress Toward FDA Approval ~
~ Supports the 505(b)(2) Regulatory Path for Clinical Development of PF614 ~

SAN DIEGO, CA / ACCESSWIRE / July 27, 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, announced today the data from the Part B, Bioequivalence (BE) arm of the PF614-102 study examining the Company's novel Trypsin-Activated Abuse-Protected (TAAP) Opioid, PF614.

The BE study follows the successful completion of the multi-ascending twice-daily dosing study of PF614 and compared the release of oxycodone from PF614 versus OxyContin® administered to subjects in both fasted and fed states. This data is critical to understand future prescribing criteria for PF614 as an agent bioequivalent to OxyContin and therefore may be developed through the 505(b)(2) regulatory path as defined by the FDA.

Dr. Nily Osman, Chief Medical Officer of Ensysce, commented, "We continue to be highly encouraged by our progress towards bringing to market this important therapeutic option for pain management, especially the finding that the fed or fasting state has little effect on oxycodone absorption from PF614 in contrast to other commercial products. This may prove important for those ill patients lacking appetite when requiring pain medication. The completion of this study is a critical milestone for Ensysce and we believe a major step toward providing physicians a safer option to alleviate the suffering of patients."

Commenting on the Company's progress, Dr. Lynn Kirkpatrick, CEO of Ensysce, stated, "We have made strong advances across our clinical development of PF614 and are extremely pleased with the positive data from this BE study as we believe it positions PF614 to be a safer alternative to OxyContin. We are building the foundation of clinical data to support PF614 in a New Drug Application to realize our mission of bringing a unique pipeline of safer products onto the market and helping the millions who experience severe pain."

In the BE study arm conducted in healthy volunteers (n=57), pharmacokinetics of oxycodone released from PF614 100 mg capsule was determined when taken with high-fat high-calorie (HFHC) meal, as well as in the fasted state, compared with OxyContin 40 mg dosed with an HFHC meal and in the fasted state.

PF614 100 mg capsule administration produced oxycodone peak plasma concentrations

(C_{max}: mean 49.56 and 59.72 ng/mL;) under fasted or fed conditions respectively after a median 6.0 hours (T_{max}: Range 2 - 8h). Mean area under the concentration versus time curve (AUC_{inf}) under each condition was 571 h*ng/mL (fasted) and 652 h*ng/mL (fed). Variability in C_{max} and AUC_{0-inf} of oxycodone under fasting versus fed were 20% and 14% respectively.

Following OxyContin 40 mg tablet administration under fasting conditions, peak plasma concentrations and AUC of oxycodone (C_{max}: mean 47.90 ng/mL; AUC_{inf}: mean 510 h*ng/mL) were noted after a median 4.4 hours (T_{max}: Range 2 - 6 h). Under fed conditions, the oxycodone mean C_{max} was 67.55 ng/mL and the AUC_{inf} was 584 h*ng/mL. Variability in C_{max} and AUC_{inf} of oxycodone following OxyContin administration under fasting versus fed condition were 41% and 14%, respectively.

It was found that PF614 conformed to the FDA bioequivalence acceptance criteria for the area under the curve (AUC) and maximal blood concentration (C_{max}) when compared to OxyContin under both fasted and fed conditions.

The Company believes that the BE data from this study will support the 505(b)(2) regulatory path for clinical development of PF614, an abbreviated pathway to FDA approval. This pathway allows reference to available safety and clinical data from an approved product, and the BE data established by this study will move PF614 closer to registration. This positive BE data should allow the company to move to discussing Phase 3 plans with the agency at an end-of-Phase 2 meeting in 2023.

PF614 is designed as an abuse-protective agent with trypsin-activated abuse protection (TAAP). TAAP chemical modification inactivates the active ingredient in Ensysce's opioid products including PF614 and provides abuse protection and resistance to manipulation and other forms of recreational drug abuse. This study builds on the safety and pharmacokinetic results of the initial PF614 Phase 1 and 1b (Part A) studies and is designed to improve the understanding of how PF614 compares to currently available commercial products.

As previously announced, the clinical study PF614-102 entitled "A Phase 1b, Randomized, 2-Part Single-Center Study to Evaluate the Pharmacokinetics (PK) and Safety of Multiple-Ascending Oral Doses (MAD) of PF614 and the Food Effect and Bioavailability/BE of Single Oral Doses of PF614 Relative to OxyContin in Healthy Adult Subjects" was conducted by Matthew Johnston, MD, PRA Health Sciences, Salt Lake City, Utah.

Corporate Update Call

Management will host a corporate update conference call on Wednesday, August 17, 2022, at 11:00am ET to provide a corporate update and review the recently discussed results from the BE study of PF614. The call will conclude with Q&A from participants. An accompanying presentation will be posted prior to the call to the Company's investor relations website.

Date: Wednesday, August 17, 2022
Time: 11:00am ET
U.S. Dial-in: 1-877-407-0792
International Dial-in: 1-201-689-8263
Conference ID: 13731880

Webcast: ENSC Corporate Update Call

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 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 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.

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