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Ensysce Biosciences Completes Scale Up Manufacture of PF614 to Support Phase 3 Studies

~ Positioning Company to Commence Commercialization Strategy ~

SAN DIEGO, CA / ACCESSWIRE / September 14, 2023 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC), a clinical-stage company applying transformative chemistry to improve prescription drug safety, today announced that two scale up manufactures have been completed for the Company's lead drug candidate PF614, a next generation pain medicine to treat severe pain. The success of the scaled manufacturing work has positioned the Company to begin its commercialization strategy consistent with timeline expectations.

As a result of the positive progress on its clinical milestones, Ensysce has commenced the next phase of development, including planning its phase 3 studies and increasing its manufacturing capacity in line with commercial readiness. The previous clinical milestones met for PF614 over the past year include PF614 delivered oxycodone in an equivalent manner to Oxycodin to treat severe pain (defined as ‘bioequivalence'), yet notably PF614 had significantly lower scores of "Drug Liking" and ‘Take Drug Again' than its oxycodone comparator in two different recreational drug abuse studies indicating that it was less likely to be abused by drug users.

Using two different Contract Manufacturing Organizations, Veranova and Purisys LLC, Ensysce has completed the manufacture of over 10 kilograms of the active pharmaceutical ingredient that will be used for the final stages of non-clinical studies, the final clinical trials that will lead to filing its New Drug Application and drug product manufacture. It is intended that Purisys LLC will continue to support the Company's larger scale commercial manufacture going forward.

Dr. Lynn Kirkpatrick, CEO of Ensysce said, "We continue to make advancements towards the final clinical trials as evident in our ability to scale our manufacturing and progress on clinical trials to date. We have found the drug substance to be robust and stable which has allowed us to press forward with our last stage clinical plans. Today, we can confidently state, we believe we have a product with equivalent efficacy to OxyContin yet with many advantages that will make it desirable to prescribe for severe pain."

About PF614

PF614 is a Trypsin Activated Abuse Protected (TAAP^{TM}) product designed as a delayed onset extended-release oxycodone prodrug. TAAP^{TM} 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.

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. 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 annual report on Form 10-K 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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