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Ensysce Biosciences Continues Collaboration to Advance the Clinical Development of Innovative Overdose Protection Platform

New Study to Confirm Overdose Protection Across Full Dosage Range of Breakthrough Therapy Opioid PF614-MPAR

SAN DIEGO, CA / ACCESSWIRE / May 20, 2024 /Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical stage pharmaceutical company developing innovative solutions for severe pain relief while reducing the potential for opioid abuse and overdose, today announced the renewal of its collaboration with Quotient Sciences to undertake the study PF614-MPAR-102 to examine and evaluate the full commercial dose range of the PF614-MPAR drug product.

PF614-MPAR is the Company's Multi-Pill Abuse Protection (MPAR) unique combination opioid product which shuts off opioid release when too many pills are ingested, thereby stopping deliberate or accidental overdose. This ground-breaking technology has the potential to save many lives and was recently granted Breakthrough Therapy designation by the U.S. Food & Drug Administration (FDA).

The Phase 1b study, PF614-MPAR-102, will evaluate opioid release following administration of PF614-MPAR at doses of 25 mg, 50 mg and 100 mg delivered twice daily for 5 days to verify both overdose protection and effective delivery of oxycodone. The study will apply the Quotient Sciences Translational Pharmaceutics® platform to manufacture and test the PF614-MPAR drug product to expedite the clinical study process.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, remarked, "My team is delighted to continue our partnership with Quotient Sciences and the use of their unique approach to drug product optimization. Our aim is to provide prescribers and patients with an innovative, safer choice to treat severe pain and reduce substantial concern of overdose. As prescription opioid overdoses remain a critical issue in America, the resultant regulatory restrictions are now causing supply issues for patients in severe pain. The potential benefits of our MPAR platform were highlighted by Dr. Rick Dart at the PAINWeek conference in 2023."

About Breakthrough Therapy

Breakthrough Therapy is a rarely used designation, having been granted to fewer than 300 drugs since the category was established in 2012. It is designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial

improvement over available therapies.

About Quotient Sciences

Quotient Sciences is a global drug development and manufacturing accelerator that supports companies across the drug development pathway. They provide integrated contract research, development, and manufacturing services for many of the leading global pharma and biotech companies, bringing deep expertise and insight to the development process. The Quotient partnership was instrumental in aiding the development of the first PF614-MPAR 25 mg dosage form using their unique "Translation Pharmaceutics®" process.

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage 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 developing unique, tamper-proof treatment options for pain that minimize the risk of both drug abuse and overdose. 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.

Definitions

TAAP: trypsin activated abuse protection - designed to protect against prescription drug abuse.

MPAR: multi-pill abuse resistance - designed to protect against abuse and accidental overdose.

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, possible Nasdaq delisting; 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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