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Ensysce Biosciences Announces FDA Breakthrough Therapy Designation Granted for PF614-MPAR

~ FDA acknowledges significant potential impact of MPAR's oral overdose protection ~

SAN DIEGO, CA / ACCESSWIRE / January 23, 2024 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC), a clinical-stage company applying transformative chemistry to improve prescription drug safety, today announced receipt of notice from the U.S Food and Drug Administration (FDA) that it has granted Breakthrough Therapy Designation (BTD) for PF614-MPAR. A next generation opioid, PF614-MPAR represents a major scientific innovation, as it is what we believe to be the first product with oral overdose protection in any drug class.

BTD is a rarely used designation, having been granted to fewer than 300 drugs. 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.

Prescription overdose deaths in the US remain at a crisis point and the latest figures from the Centers for Disease Control indicate almost two overdose deaths per hour. Safer opioids to treat severe pain while providing protection against abuse and oral overdose are vital to reverse this tragic trend and Ensysce is forging the way with two new opioids in clinical development.

PF614-MPAR is designed to provide optimal pain relief at prescribed doses yet limit accidental or intentional overdose by ‘shutting down' opioid release if too much active drug is consumed. PF614-MPAR could herald a new class of treatment for the most severe forms of pain and could save lives if approved, as each capsule contains built-in protection against both abuse and overdose which plague traditional opioids.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce Biosciences, commented, "We are highly encouraged with the receipt of Breakthrough Therapy Designation by the FDA based on the data we generated in our Phase 1 study, PF614-MPAR-101, that demonstrated our approach can provide protection from taking too many opioids orally. This is unique for the opioids class. We previously received Fast-Track Status for PF614, and this recognition of BTD for PF614-MPAR highlights the advancement we have made with our approach to treating severe pain. BTD facilitates our ability to expedite our programs through the approval processes in an efficient manner, with rolling review of both programs. We believe our goal of bringing the ‘next generation' of analgesics for severe pain to those in need is becoming a reality."

The primary intent of BTD is to develop evidence needed to support approval as efficiently as possible. The designation provides all the features of Fast Track designation including accelerated approval and priority review along with intensive guidance involving senior managers on an efficient drug development program.

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.

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.

Ensysce Biosciences Company Contact:

Lynn Kirkpatrick, Ph.D.
Chief Executive Officer
(858) 263-4196

Ensysce Biosciences Investor Relations Contact:

Shannon Devine
MZ North America
Main: 203-741-8811
ENSC@mzgroup.us

SOURCE: Ensysce Biosciences Inc.