August 27, 2024

Ensysce Biosciences Announces IRB Approval for Key MPAR Study

Next Clinical Trial of FDA Breakthrough Therapy PF614-MPAR Supported by $14 Million Federal Government Grant

SAN DIEGO, CA / ACCESSWIRE / August 27, 2024 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC), a clinical-stage pharmaceutical company developing innovative solutions for severe pain relief while reducing the potential for opioid abuse and overdose, today announced that it has received Investigational Review Board ("IRB") approval of the PF614-MPAR-102 protocol, 'A Single and Multiple Dose Study to Evaluate the Pharmacokinetics of Oxycodone and PF614 when PF614 capsule is Co-Administered with Nafamostat as a combination Immediate Release solution and Extended-Release Capsule Formulation in Healthy Subjects.' Ensysce has continued its collaboration with Quotient Sciences to conduct this second clinical study of MPAR using their Translational Pharmaceutics® platform.

Dr. Bill Schmidt, Chief Medical Officer of Ensysce, commented, "The approval of this study protocol represents another key milestone towards completing the clinical development of our first-in-class opioid with both abuse and overdose protection. Clinical data from our initial study demonstrated the unique overdose protection built into PF614-MPAR, which led to the FDA designation of Breakthrough Therapy. PF614-MPAR is the only opioid to receive such recognition and one of only ~300 drugs ever approved for this designation. We remain dedicated to bringing to market a new generation of safer products to alleviate the suffering of those who experience severe pain."

Dr. Lynn Kirkpatrick, CEO of Ensysce, offered, "We are pleased to have IRB approval that allows us to quickly start this second clinical study of PF614-MPAR. This program not only has FDA support but is also supported by the National Institute on Drug Abuse with today's announcement of a $14 million multi-year award to Ensysce. This award allows us to complete this clinical trial and necessary non-clinical studies for both PF614 and the combination with nafamostat. Additionally, the Breakthrough Therapy designation of PF614-MPAR permits frequent interactions with the FDA which are pivotal to maintain a relatively smooth path to registration. We look forward to initiating this three-part trial immediately and expect to announce first data in mid-2025."

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.

About Breakthrough Therapy Designation

Breakthrough Therapy is a rarely used designation, having been granted by the FDA to fewer than 300 drugs since its introduction 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.

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.

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