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Ensysce Biosciences Announces FDA Guidance on the Clinical Development Pathway for PF614

~ Acute pain indication may be appropriate, with potential to significantly shorten development path ~

SAN DIEGO, CA / ACCESSWIRE / November 14, 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 focused on reducing abuse and overdose, today announced that it received written guidance from the FDA that an acute pain indication may be appropriate for the Company's lead Trypsin Activated Abuse Protection (TAAP™) product, PF614.

The FDA guidance, while not binding, states that the Company's proposed clinical development approach of conducting at least two adequate and well-controlled clinical trials in two different pain models comparing PF614 to placebo and to another immediate release (IR) opioid, such as IR oxycodone, appears reasonable to support a new drug application for PF614 for an acute pain indication. The FDA guidance also provides additional guidance with respect to the non-clinical studies and clinical trials planned by the Company.

The Company believes that the clinical development pathway of PF614 for an acute pain indication will reduce the development timeline and be more cost-effective than initially pursuing a chronic pain indication for PF614. Acute and sub-acute pain indications, based on the recent CDC guidelines, are defined as pain lasting a duration of less than one or three months respectively. The Company intends to pursue development of FP614 for acute indications while continuing development of PF614 for use in chronic pain (pain lasting a duration of more than three months).

"As a result of the FDA guidance, we now intend to initially pursue clinical development of PF614 for an acute pain indication while continuing with our chronic pain development pathway. We believe that the longer half-life of PF614 compared to OxyContin may ultimately prevent acute pain from becoming chronic pain by better controlling severe pain on a day-to-day basis," said Dr. Lynn Kirkpatrick, CEO of Ensysce. "We look forward to completing our human abuse potential studies and moving toward initiation of Phase 3 analgesic efficacy studies in the coming year."

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 (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 overdose. Our 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 costs. 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.

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.