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Ensysce Biosciences Inc. Receives Fast Track Designation for PF614, BIO-MD™ Abuse Deterrent Extended Release Oxycodone Prodrug

SAN DIEGO--(BUSINESS WIRE)-- Ensysce Biosciences is pleased to announce that the FDA has granted Fast Track designation for the development of PF614 for management of moderate to severe chronic pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. A drug that receives Fast Track designation is eligible for:

- More frequent meetings with FDA to discuss PF614 development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met
- Rolling Review, meaning that Ensysce can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed.

PF614 is an extended-release oxycodone prodrug designed with a two-step enzyme activation process that provides abuse deterrent properties and limiting its use to oral administration. A recently completed Phase 1 trial “A Phase 1, Single-Center, Dose-Escalation Study to Determine the Safety and Pharmacokinetics of a Single Oral Dose of PF614 in Healthy Subjects Compared to OxyContin®” demonstrated the safety and the extended release characteristics of this prodrug approach to opioid delivery. Ensysce prodrugs are contrasted from current and emerging opioid technologies in that they do not require an elaborate formulation to confer parenteral and nasal abuse-deterrence.

“Ensysce is pleased the FDA recognizes that PF614 meets the Fast Track criteria and will contribute to deterring opioid abuse. We are focused on the rapid development of PF614 and our product pipeline designed to overcome abuse and overdose of prescription drugs,” said Dr. Lynn Kirkpatrick, CEO, Ensysce Biosciences. “Our prodrug approach, BIO-MD™ is well differentiated from abuse-deterrent formulations of existing opioid drugs that have been marketed for the past few years. While all abuse-deterrent formulations have been able to reduce some forms of abuse, they still contain substantial quantities of bioavailable opioids

that can be extracted and abused by all routes of administration. Since PF614 is a unique 2-step prodrug that is completely inactive until it is metabolized in the small intestine after oral administration, we believe that BIO-MD™ and the combination MPAR™ overdose protection products are unique in the field."

About Ensysce Biosciences:

Ensysce Biosciences, San Diego CA, is an integrated drug delivery company for both small and large molecules, using prodrug technology and single walled carbon nanotubes respectively. The BIO-MD™ prodrug abuse deterrent and MPAR™ overdose resistant pain platforms, with worldwide intellectual patent protection, eliminate the ability to abuse opioid products by the non-oral route, the fastest growing drug problem in the US that leads to billions in healthcare costs annually.

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