January 31, 2024

Ensysce Biosciences Announces Positive End of Phase 2 Meeting with FDA for PF614 to Treat Severe Pain

~ PF614 Phase 3 Program Expected to Begin Enrollment in Mid-2024 ~

SAN DIEGO, CA / ACCESSWIRE / January 31, 2024/ Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC), a clinical-stage company applying transformative chemistry to improve prescription drug safety, today announced the completion of a constructive End of Phase 2 meeting with the Food and Drug Administration (FDA) regarding its lead 'Next Generation' analgesic, PF614. The meeting facilitated an affirmation of the Company's non-clinical program and enabled an exchange of constructive ideas regarding Ensysce's Phase 3 clinical trial designs for PF614.

As previously announced, the Company has performed five clinical studies to evaluate the safety, abuse potential and efficacy of PF614 for the treatment of severe pain. The clinical data has demonstrated that PF614 was bioequivalent to OxyContin for delivering oxycodone, meaning one could easily substitute PF614 for OxyContin in patients with pain. However, PF614 was found to have a longer half-life than OxyContin. Ensysce believes that the longer twelve-hour half-life could improve the pain-relieving qualities of PF614, reduce opioid-related adverse events, and provide true twice daily dosing. Evaluation of both nasal (insufflation) and oral abuse-potential studies met key endpoints that showed PF614 had significantly lower scores for "Overall Drug Liking" and willingness to "Take Drug Again" than the oxycodone comparator.

Additionally, PF614 showed significant analgesic activity in a recent study that measured the time-of-onset of pain-relief in healthy volunteers. The study confirmed the prior clinical pharmacokinetic studies that measured oxycodone blood levels following oral administration of PF614 and showed that Ensysce's TAAP chemical approach delivers strong analgesia. This study was key to the design of the Company's Phase 3 clinical protocols and positive discussions with the FDA.

"We are appreciative of the guidance provided by the FDA to help us properly position PF614 as we progress through clinical trials and supporting studies in order to mitigate the risk of regulatory hurdles in our go-to market plan," commented Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce. "The successful outcome of the End of Phase 2 meeting with the FDA signifies a major step in the regulatory approval process of PF614. In addition, the results and analysis from our Phase 2 study have informed our strategy and design of Phase 3 studies expected to begin in the second half of 2024. In summary, as we advance to Phase 3 trials of PF614, we have gained further conviction that we are creating the "Next Generation" of opioid analgesic care with a safer option for patients in moderate-to-severe pain."

Dr. William Schmidt, Chief Medical Officer of Ensysce added, "PF614 is the key opioid component of the Company's PF614-MPAR 'next-generation' combination product with overdose protection that received the FDA's Breakthrough Therapy Designation, as announced on January 23, 2024. This designation illustrates the innovative approach Ensysce has adopted in the development of this family of novel opioids."

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.

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