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Ensysce Biosciences Inc. Initiates Phase 1 Clinical Trial to Study PF614, BIO-MD™ Prodrug of Oxycodone

SAN DIEGO--(BUSINESS WIRE)-- Ensysce Biosciences is pleased to announce the treatment of the first two patients with PF614, a two-step extended-release oxycodone prodrug designed to have abuse deterrent properties that limit its use to oral administration. The 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®” is being conducted by Dr. Daniel Dickerson, MD, PhD, of PRA Health Sciences, Lenexa KS. This single ascending dose (SAD) study will treat up to 6 cohorts of 8 healthy male and/or female subjects randomized to take PF614 or OxyContin to evaluate safety and the pharmacokinetic profile of PF614 as compared to OxyContin.

PF614 is a trypsin-activated BIO-MD™ extended-release oxycodone prodrug with inherent abuse deterrence since it is pharmacologically and chemically inert until activation by pancreatic trypsin. The initial activation is followed by a second non-enzymatic cyclization and cleavage, producing free oxycodone and providing PF614 with extended release characteristics. Ensysce’s product pipeline includes immediate-release (IR) or extended-release (ER) prodrugs with timed activation of opioids and stimulants that present challenges for duration of action and abuse-deterrence. Additionally, Ensysce’s combination MPAR™ products combine the BIO-MD™ prodrugs with trypsin inhibitors, providing overdose protection. The MPAR™ technology has been demonstrated with PF329, an extended-release hydromorphone prodrug in a Phase 1 clinical study. Ensysce prodrugs are contrasted from current and emerging opioid technologies in that they do not require elaborate formulation to confer parenteral and nasal abuse-deterrence.

“Ensysce is pleased to bring PF614 into clinical development. We are focused on continuing to develop our opioid pipeline designed to significantly reduce abuse potential,” said Dr. Lynn Kirkpatrick, CEO, Ensysce Biosciences. “Our prodrug approach, BIO-MD™ is well differentiated from the formulation alterations that have been marketed for these products. 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. This Phase 1 clinical trial for the BIO-MD™ abuse

deterrent oxycodone prodrug, PF614 will provide data beginning at the end of 2016.

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