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Ensysce Biosciences Inc. Publishes Manuscript Describing the in Vitro Abuse Deterrence of Oxycodone Prodrug, PF614

SAN DIEGO--(BUSINESS WIRE)-- Ensysce Biosciences is pleased to announce the publication in the latest issue of the Journal of Opioid Management, **In vitro and in vivo assessment of the abuse potential of PF614, a novel BIO-MD™ prodrug of oxycodone Vol 13, No 1 (2017): January/February pg 39-49,** by Kirkpatrick, et al**.** This publication describes how the Ensysce Bio-activated Molecular Delivery (BIO-MD™) prodrug platform provides tamper- and abuse deterrence to opioid products. This prodrug approach reduces the intravenous and nasal abuse potential of PF614, through requiring a two-step activation process following oral administration. PF614 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. Unlike other existing abuse deterrent formulations of oxycodone, the extended-release profile of PF614 cannot be accelerated by chewing or extraction to a pharmacologically active substance.

The success of this ‘chemical barrier to abuse’, has been demonstrated in the recently completed 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®” conducted by Dr. Daniel Dickerson, MD, PhD, of PRA Health Sciences, Lenexa, KS. This single ascending dose study treated 6 cohorts of 8 healthy male and/or female subjects randomized to take PF614 as an oral solution or OxyContin in tablet form. The endpoints evaluated safety and the pharmacokinetic profile of PF614 as compared to OxyContin. The Ensysce prodrugs are contrasted from current and emerging opioid technologies in that they do not require elaborate formulations to confer parenteral and nasal abuse-deterrence.

“Ensysce is pleased to have this peer reviewed publication describing the properties of PF614 and the BIO-MD™ platform. Additionally, with the completion of our Phase 1 clinical trial, we now have a clear demonstration that our prodrug approach provides efficient oral delivery of opioid products. We believe our BIO-MD™ products can have tremendous impact in stemming the abuse of these commonly prescribed pain medications,” said Dr. Lynn Kirkpatrick, CEO, Ensysce Biosciences. “Our BIO-MD™ prodrug approach is well differentiated from other abuse deterrent formulations.”

About Ensysce Biosciences:

Ensysce Biosciences, San Diego, CA, is developing the BIO-MD™ prodrug technology for abuse deterrence and the MPAR™ combination platform for overdose protection, to curb prescription drug abuse that leads to billions in healthcare costs annually in the US.

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