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Ensysce Biosciences Achieves Successful Completion of Part A of Multiple-Ascending Dose (MAD)/Bioequivalents (BE) Trial for its Next Generation Opioid, PF614

SAN DIEGO, Jan. 04, 2022 (GLOBE NEWSWIRE) -- Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ: ENSC, OTC: ENSCW), a clinical-stage biotech company with novel technologies that may provide new hope for those in severe pain, today announced that it has successfully completed Part A of the previously announced clinical study PF614-102, "A Phase 1b, Randomized, 2-Part Single-Center Study to Evaluate the Pharmacokinetics (PK) and Safety of Multiple-Ascending Oral Doses (MAD) of PF614 and the Food Effect and Bioavailability/Bioequivalence (BE) of Single Oral Doses of PF614 Relative to OxyContin in Healthy Adult Subjects," conducted by Matthew Johnston, MD, PRA Health Sciences, Salt Lake City, Utah.

The Part A of the trial evaluated three dose levels of PF614 delivered orally, twice daily for five days to healthy subjects. Additional study participants received OxyContin at three comparable dose levels. Following completion of each cohort, a positive review from the trial's independent Safety Review Committee allowed the trial to proceed to the next dose level. All three dose levels have now been successfully completed.

With this successful completion of the MAD portion, the Company is progressing to the BE stage of the study. Fully analyzed MAD data is expected in the first quarter of 2022, with the BE study results to follow in the second quarter. Safety and PK data is scheduled to be presented at the 2022 Pain Therapeutic Conference to be held in London, UK, in May 2022.

Dr. Lynn Kirkpatrick, CEO, commented, "The final enrollment of the last cohort of subjects and positive safety review at the highest dosage level, represent a significant milestone for Ensysce. We believe we are well on our way to finding a safe and effective treatment for severe pain, which, if successful, delivers a major impact on the current abuse of prescription pain medications. We are eager to begin the second phase of the two-part study and anticipate having results by the end of the second quarter of 2022."

Dr. William Schmidt, Chief Medical Officer added, "The MAD phase of the trial exceeded our expectations, and further advances the possibility of bringing our 'next generation' opioids to the market. PK data confirmed similar dose-proportionate increases in plasma oxycodone following PF614 and OxyContin and there were no unexpected adverse events in either the PF614 or OxyContin dose groups. This creates a strong foundation for our mission of developing unique platforms to stop abuse and overdose of prescription drugs."

PF614 is designed as a delayed onset oxycodone prodrug with trypsin-activated abuse protection (TAAP). TAAP chemical modification inactivates the active ingredient in Ensysce's opioids products including PF614. This provides abuse deterrence, resistance to manipulation and other forms of recreational drug abuse, while providing a high degree of pain relief for those in severe pain. This study builds on the safety and pharmacokinetic results already seen in the prior Phase 1 study and improves the understanding of how PF614 compares to currently available commercial products.

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 new class of powerful, tamper-proof opioids that prevent both drug abuse and overdoses. Ensysce's products are anticipated to provide safer options to treat severe pain and assist in preventing deaths caused by opioid abuse, reducing the human and economic cost. 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.

Forward-Looking Statements

Statements contained in this press release that are not purely historical may be deemed to be forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Without limiting the foregoing, the use of words such as "may," "intends," "can," "might," "will," "expect," "plan," "possible" and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinic and not approved and there can be no assurance that the clinical programs will be successful in demonstrating safety and/or efficacy, that Ensysce will not encounter problems or delays in clinical development, or that any product candidate will ever receive regulatory approval or be successfully commercialized. All forward-looking statements are based on estimates and assumptions by Ensysce's management that, although Ensysce believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Ensysce expected. In addition, Ensysce's business is subject to additional risks and uncertainties, including among others, the initiation and conduct of preclinical studies and clinical trials; the timing and availability of data from preclinical studies and clinical trials; expectations for regulatory submissions and approvals; potential safety concerns related to, or efficacy of, Ensysce's product candidates; the availability or commercial potential of product candidates; the ability of Ensysce to fund its continued operations, including its planned clinical trials; the dilutive effect of stock issuances from our fundraising; and Ensysce's and its partners' ability to perform under their license, collaboration and manufacturing arrangements. These statements are also subject to a number of material risks and uncertainties that are described in Ensysce's most recent quarterly report on Form 10-Q and current reports on Form 8-K, which are available, free of charge, at the SEC's website at www.sec.gov. Any forward-looking statement speaks only as of the date on which it was made. Ensysce undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required under

applicable law.

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