November 30, 2021

Ensysce Biosciences Announces Clinical Trial Progress of its New Class of Opioids

SAN DIEGO, Nov. 30, 2021 (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 the completion of a positive safety review and enrollment of the last cohort of subjects at the highest dose level in the Company’s second study of its Trypsin Activated Abuse Protected (TAAP) Opioid, PF614.

The clinical study is PF614-102 entitled “A Phase 1b, Randomized, 2-Part Single-Center Study to Evaluate the Pharmacokinetics 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.” The study is being conducted by Matthew Johnston, MD, PRA Health Sciences, Salt Lake City, Utah.

In receiving a positive safety review from the trial’s Safety Review Committee, the trial is proceeding as planned and the Company has advanced its trial to the highest dose level. Following the conclusion of the cohort, the Company expects to enter the bioequivalence stage of the study in January 2022, with data expected from the MAD study in the first quarter of 2022 and from the BE study in the second quarter of 2022.

PF614 is designed as a delayed onset oxycodone prodrug withtrypsin-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 will build on the safety and pharmacokinetic results of the initial Phase 1 study and is designed to improve the understanding of how PF614 compares to currently available commercial products.

Dr. William Schmidt, Chief Medical Officer of Ensysce, commented: “We are encouraged by the results of our trials to date. With our expertise in drug development, we are advancing as expected toward bringing our lead ‘next generation’ opioids products to market. Since Ensysce’s inception, we have been committed to, and demonstrated progress in, developing unique platforms to curb abuse and overdose of prescription drugs. While we have made significant progress to date through a disciplined approach to our business, we recognize the urgency in addressing the opioid crisis through the introduction of new technologies. This study is an important step toward achieving our goal of bringing our unique pipeline of products to the industry to provide safer options for prescribers and patients.”

Commenting on the Company’s recent progress, Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, stated: “This year, we have added significant talent to our management team and achieved notable milestones for the organization, positioning us for long-term success. Specifically, our recently strengthened balance sheet provides us with the

necessary resources to advance our lead clinical trial programs, including our PF614-102 bioequivalence study and our nasal and oral human abuse liability studies. Additionally, we received funds for year three of a multi-year grant from the National Institute on Drug Abuse, which provides us with additional resources to continue our clinical development initiatives with our overdose protection platform and its lead product PF614-MPAR™. Looking ahead, we are entering 2022 with encouraging momentum across our clinical stage pipeline, a broadened patent portfolio with additional pipeline candidates for ADHD indications, and an enhanced balance sheet that provides us with the necessary foundation to realize our mission to bring our unique pipeline of products into the over $11 billion US prescription opioid market."

About Ensysce Biosciences

Ensysce Biosciences, San Diego, CA 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," 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.

Ensysce Biosciences Company Contact
Lynn Kirkpatrick, Ph.D.
Chief Executive Officer
(858) 263-4196

Ensysce Biosciences Investor Relations Contact:
Gateway Investor Relations
Alex Thompson, Matt Glover
(949) 574-3860
Ensysce@gatewayir.com

Source: Ensysce Biosciences Inc.