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Ensysce Biosciences Announces First Cohort Dosing in Bioequivalence (BE) Study of Novel "TAAP" Opioid

BE Study of PF614 Provides Critical Step toward FDA Approval

SAN DIEGO, Jan. 10, 2022 (GLOBE NEWSWIRE) -- Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ: ENSC, OTC: ENSCW), a clinical-stage biotech company with two novel technology platforms designed to provide relief for those suffering with severe pain while protecting against abuse and overdose, announced today the initiation and first dosing in the Bioequivalence (BE) trial of the novel Trypsin Activated Abuse Protected (TAAP) Opioid, PF614.

The BE study follows the successful completion of the multi-ascending twice daily dosing study of PF614 and will compare PF614 versus OxyContin in subjects in both fasted and fed states. This data will be critical to understand future prescribing criteria for PF614. If successful, upon completion of the BE study the Company believes that the data will support the 505(b)(2) regulatory path for clinical development of PF614, an abbreviated pathway to FDA approval. This pathway allows reference to available safety and clinical data from an approved product, and the BE data established by this study will move PF614 closer to registration.

Dr. William Schmidt, Chief Medical Officer of Ensysce, commented, "We continue to be encouraged by our progress towards bringing our lead 'next generation' opioid to market. The completion of this study will be a critical milestone for Ensysce and a major step toward providing safer options for doctors and patients."

Commenting on the Company's progress, Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, stated, "As we enter 2022 with strong progress across our clinical stage pipeline, we are looking forward to the data from this BE study in the second quarter of the year to position PF614 as our first commercial candidate. We believe that we have the foundation in place to realize our mission of bringing a unique pipeline of products onto the market and helping the millions who experience severe pain."

PF614 is designed as an abuse protective agent with trypsin-activated abuse protection (TAAP). TAAP chemical modification inactivates the active ingredient in Ensysce's opioids products including PF614 and provides abuse protection, resistance to manipulation and other forms of recreational drug abuse. This study will build on the safety and pharmacokinetic results of the initial Phase 1 and 1b studies and is designed to improve the understanding of how PF614 compares to currently available commercial products.

As previously announced, the clinical study is PF614-102 entitled "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/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.

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.

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