May 5, 2022

Ensysce Biosciences Announces New Clinical Results from Trials PF614-102 and PF614-MPAR-101

~ Results confirmed the safety and longer-lasting profile of PF614 versus OxyContin and provides first human data showing the potential for overdose protection with MPAR~

~ Announces corporate update call timing ~

SAN DIEGO, CA / ACCESSWIRE / May 5, 2022 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") **(NASDAQ:ENSC, OTC:ENSCW)**, a clinical-stage biotech company applying transformative chemistry to improve prescription drug safety and performance with a current focus on reducing abuse and overdose, today presented results from the clinical trials PF614-102 and PF614-MPAR-101 at the SMi Pain Therapeutics meeting in London, UK.

PF614-102

The multi-ascending dose study (MAD) study examined 3 dose levels of PF614, a novel TAAP prodrug of oxycodone and the Company's lead candidate in Phase 2 development for the treatment moderate to severe pain. The MAD study evaluated PF614 delivered as an oral solution or as 100 mg capsules. The healthy volunteer study was designed to evaluate the safety and pharmacokinetics of five days of treatment with twice daily doses of PF614 to equivalent doses of OxyContin, the extended-release abuse deterrent formulation of oxycodone. The results of the study show the longer-lasting half-life of PF614 versus OxyContin as seen in the prior Phase 1 single-ascending dose study of PF614 oral solution versus OxyContin. The pharmacokinetic data demonstrated that PF614 has a delayed onset and extended activity after delivery, with a time to maximal drug concentration of 5.8 hour similar to Oxycontin's 4.5 hour. A distinguishing feature of PF614 is its terminal half-life which on Day 5 ranged from 13.75 to 28.4 hour as compared to 4.5 to 7.8 hour for OxyContin. We believe this data confirms the findings from our Phase 1 study that demonstrate PF614 should provide true twice daily dosing.

The safety data for the study also showed that PF614 performed similarly to OxyContin with no test article serious adverse events recorded. Treatment emergent adverse events (TEAE) were limited and opioid related.

The second part of the PF614-102 study, the bioequivalence (BE) arm, continues to be analyzed and as reported previously it is anticipated that this BE data will be available at the end of the second quarter of 2022.

PF614-MPAR-101

PF614-MPAR-101 overdose protection study examined PF614 administered orally alone or in combination with the trypsin inhibitor nafamostat (MPAR) to healthy volunteers. This data demonstrated how the combination product PF614-MPAR could reduce the trypsin activation and reduce the release of oxycodone in a simulated overdose situation. It also demonstrated the PF614 in the systemic circulation (simulated injection) did not convert to oxycodone. We believe this is the first step to identifying the first MPAR drug product that will be marketed in the coming years.

Dr. William Schmidt, Senior VP of Clinical Development, commented, "The results of the 102 study are in-line with our expectations, and we are eager to continue making progress towards bringing our lead ‘next generation' opioid to market. The results from this clinical trial represent a critical milestone for Ensysce confirming our previous findings that were highly encouraging, and a significant step towards our mission of providing safer, effective options for doctors and patients. We were also highly enthused by the first MPAR data as it is confirmation that our approach for overdose protection is a possibility - not just a hope."

Dr. Lynn Kirkpatrick, Chief Executive Officer, added, "We believe with these study results we have added to an already strong foundation of data supporting our novel approach to delivering pain relief, and begin to realize our stated mission - providing abuse and overdose protection where needed. It is exciting to see the first human data for MPAR, and as the study progresses, we feel our solidification of a final drug product is possible. We entered 2022 with clear progress against our clinical stage pipeline and this data further positions the Company for continued successes. We look forward to reviewing the data in further detail and sharing with all Ensysce' constituents in the coming weeks, ultimately this is a step towards value creation for our shareholders."

Corporate Update Call

Management will host a corporate update conference call on Tuesday, May 17, 2022, at 11:00am ET to provide a corporate update and review the recently discussed results from Clinical Trail PF614-102. The call will conclude with Q&A from participants. An accompanying presentation will be posted prior to the call to the Company's investor relations website.

Date: Tuesday, May 17, 2022

Time: 11:00am ET

U.S. Dial-in: 1-877-407-0792

International Dial-in: 1-201-689-8263

Conference ID: 13729812

Webcast: ENSC Corporate Update Call

Please dial in at least 10 minutes before the start of the call to ensure timely participation. A playback of the call will be available through Tuesday, May 17, 2022. To listen, call 1-844-512-2921 within the United States and Canada or 1-412-317-6671 when calling internationally. Please use the replay pin number 13729812.

About Ensysce Biosciences

Ensysce Biosciences, based in San Diego, CA is a clinical-stage biotech company using its two novel 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 developing next-generation, 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 costs. The platforms are covered by an extensive worldwide intellectual property portfolio encompassing a wide array of prescription drugs. 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 annual report on Form 10-K 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:
Shannon Devine
MZ North America

Main: 203-741-8811
ENSC@mzgroup.us

SOURCE: Ensysce Biosciences Inc.

View source version on accesswire.com:
https://www.accesswire.com/700301/Ensysce-Biosciences-Announces-New-Clinical-Results-from-Trials-PF614-102-and-PF614-MPAR-101