Zynerba Pharmaceuticals Announces Initiation of STAR 2 Open-Label Extension Clinical Trial for ZYN002 CBD Gel in Adult Refractory Epilepsy Patients

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DEVON, Pa., Nov. 02, 2016 (GLOBE NEWSWIRE) -- Zynerba Pharmaceuticals, Inc. (NASDAQ:ZYNE), a clinical-stage specialty pharmaceutical company dedicated to the development of innovative transdermal synthetic cannabinoid treatments, today announced the enrollment of the first patients into the STAR 2 (**S**ynthetic **T**ransdermal C**a**nnabidiol for the T**r**eatment of Epilepsy) clinical trial, an open-label extension trial which allows patients who have completed the STAR 1 clinical trial to receive treatment with ZYN002 CBD gel for up to 52 weeks.

"STAR 2 is designed to provide additional tolerability and safety information for ZYN002 CBD gel for up to 52 weeks, which we believe will establish that ZYN002 CBD gel is well-tolerated over long-term use," said Armando Anido, CEO of Zynerba. "Enrollment in STAR 1 is continuing and we plan to report top line results in the first half of 2017."

STAR 2 is a multi-center, open-label Phase 2 clinical trial in which epilepsy patients with refractory focal seizures who complete the STAR 1 study will receive treatment with ZYN002 for up to 52 weeks. The patients will receive 195 mg of CBD in ZYN002 4.2% gel every 12 hours. After two weeks, the investigators will have the option to reduce the dose to 97.5 mg of CBD in ZYN002 4.2% gel every 12 hours based upon the patient's response. The clinical trial is being conducted at the same 14 sites in Australia and New Zealand as the STAR 1 clinical trial.

About ZYN002 CBD Gel
Zynerba's ZYN002 CBD gel is the first and only synthetic CBD formulated as a patent-protected permeation-enhanced gel and is being studied in refractory epilepsy, Fragile X syndrome and osteoarthritis. ZYN002 is a clear, permeation-enhanced gel that is designed to provide consistent, controlled drug delivery transdermally with twice-daily dosing. Transdermal therapeutics are absorbed through the skin directly into the systemic circulation, avoiding first-pass liver metabolism and potentially enabling lower dosage levels of active pharmaceutical ingredients and rapid and reliable absorption with high bioavailability. In addition, transdermal delivery avoids the gastrointestinal tract and potential stomach acid degradation of CBD into THC (associated with psychoactive effects), as demonstrated in a Zynerba-sponsored in vitro study.

About Zynerba Pharmaceuticals, Inc.
Zynerba Pharmaceuticals (NASDAQ:ZYNE) is a clinical-stage specialty pharmaceutical company focused on developing and commercializing proprietary next-generation synthetic cannabinoid therapeutics formulated for transdermal delivery. Zynerba is developing therapeutic candidates based on proprietary transdermal technologies that, if successfully developed, may allow sustained, consistent and controlled delivery of therapeutic levels of two cannabinoids: cannabidiol (CBD), a non-psychoactive cannabinoid, and tetrahydrocannabinol (THC). Transdermal delivery has the potential to reduce adverse effects associated with oral dosing. ZYN002, the Company's CBD gel, is the first and only synthetic CBD formulated as a patent protected permeation-enhanced gel. In June 2016, the company initiated the Phase 2 STAR 1 (Synthetic Transdermal Cannabidiol for the Treatment of Epilepsy) clinical trial of ZYN002 CBD gel in refractory epilepsy patients with focal seizures. In August 2016, the Phase 2 STOP (Synthetic Transdermal Cannabidiol for the Treatment of Knee Pain due to Osteoarthritis) clinical trial in patients with knee pain due to OA was initiated. A Phase 2 clinical trial in Fragile X syndrome (FXS) is expected to initiate by year-end 2016. Top line results from all three Phase 2 clinical trials are planned to report in the first half of 2017. Zynerba is also developing ZYN001, which utilizes a synthetically manufactured pro-drug of THC. A Phase 1 clinical trial for ZYN001 is planned to begin in the first half of 2017. Learn more at www.zynerba.com and follow the Company on Twitter at @ZynerbaPharma.

Cautionary Note on Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the Company's current expectations. For example, there can be no guarantee that the Company will obtain approval for ZYN002 or ZYN001 from the U.S. Food and Drug Administration (FDA) or foreign regulatory authorities; even if ZYN002 or ZYN001 are approved, the Company may not be able to obtain the label claims that it is seeking from the FDA. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: the success, cost and timing of the Company's product development activities, studies and clinical trials; the success of competing products that are or become available; the Company's ability to commercialize its product candidates; the size and growth potential of the markets for the Company's product candidates, and the Company's ability to service those markets; the Company's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of the Company's product candidates; and the Company's expectations regarding its ability to obtain and adequately maintain sufficient intellectual property protection for its product candidates. These and other risks are described in the Company's periodic reports, including the annual report on Form 10K, quarterly reports on Form 10Q and current reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission and available at www.sec.gov. Any forward-looking statements that the Company makes in this press release speak only as of the date of this press release. The Company assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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