Zynerba Pharmaceuticals Launches Phase 2 Clinical Trial of ZYN002 CBD Gel for Treatment of Osteoarthritis

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DEVON, Pa., Sept. 06, 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 that it has initiated a Phase 2 clinical trial, STOP (**S**ynthetic **T**ransdermal Cannabidi**o**l for the Treatment of Knee **P**ain due to Osteoarthritis (OA)), of ZYN002 cannabidiol (CBD) gel. ZYN002 CBD gel is the first and only patent-protected, synthetic CBD that is formulated as a permeation-enhanced gel for transdermal delivery.

“In the US, there are approximately 31 million people who suffer from osteoarthritis, many of whom are not receiving adequate relief from current therapies,” said Armando Anido, Chairman and Chief Executive Officer of Zynerba. “In preclinical models, cannabidiol has demonstrated the ability to significantly reduce pain and inflammation associated with OA. ZYN002 may offer an effective treatment alternative to NSAIDs and narcotic opioids with an improved safety profile.”

The STOP clinical trial is a Phase 2 multi-center, double-blind, placebo-controlled, multi-dose clinical trial designed to evaluate the efficacy and safety of ZYN002 in patients with knee pain due to OA. Up to 300 patients will be enrolled in the clinical trial and will be followed for two weeks during a baseline phase, which includes a one-week washout period. After completion of the baseline phase, patients will be randomized 1:1:1 to receive either 250 mg of ZYN002 4.2% CBD gel every 12 hours, 125 mg of ZYN002 4.2% CBD gel every 12 hours or placebo gel every 12 hours for 12 weeks. The primary endpoint of the study is the change from baseline in the weekly mean of the 24-hour average worst pain score. The Company expects to report topline results in the first half of 2017.

About ZYN002 CBD Gel
Zynerba’s ZYN002 CBD gel is the first and only synthetic CBD that is formulated as a patent-protected permeation-enhanced gel. Phase 2 clinical studies are ongoing in adults with refractory epilepsy and in knee pain associated with osteoarthritis. Phase 2 clinical studies in patients with Fragile X Syndrome (FXS) are expected to begin in the second half of 2016. ZYN002 is a clear, permeation-enhanced gel that is designed to provide consistent, controlled drug delivery transdermally with convenient 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 in vitro study.

About Osteoarthritis
Osteoarthritis is a degenerative joint disease that leads to wear and tear of the joints and affects the cartilage, joint lining, ligaments and bone. It is the most common form of joint disease and tends to occur most often in the hand joints, spine, hip, knees and great toes. It is characterized by the breakdown of the joint cartilage, bony changes in the joints and deterioration of the tendons and ligaments leading to pain and inflammation of the joint lining. Approximately 31 million patients in the US suffer from osteoarthritis.

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 clinical study of ZYN002 CBD gel in refractory epilepsy patients with focal seizures. In August 2016, the STOP trial in patients with knee pain due to OA was initiated. A Phase 2 study in Fragile X syndrome (FXS) is expected to initiate in the second half of 2016. Zynerba is also developing ZYN001, which utilizes a synthetically manufactured pro-drug of THC. A Phase 1 clinical study for ZYN001 is planned to begin in the second half of 2016. 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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