Zynerba Pharmaceuticals Initiates ZYN001 Phase 1 Clinical Program

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Phase 1 results will inform potential Phase 2 studies in patients with fibromyalgia and neuropathic pain, planned to start in 2H17

Study includes single rising dose and multiple rising dose evaluations

DEVON, Pa., June 26, 2017 (GLOBE NEWSWIRE) -- Zynerba Pharmaceuticals, Inc. (NASDAQ:ZYNE), a clinical-stage specialty pharmaceutical company dedicated to developing and commercializing innovative transdermal synthetic cannabinoid treatments, today announced that it has initiated its ZYN001 Phase 1 clinical program to study the company's patent-protected, pro-drug of tetrahydrocannabinol (THC) delivered via a transdermal patch. This study will assess single and multiple rising doses of several formulations of ZYN001 to identify the optimal dose to take into Phase 2 studies.

"The initiation of the ZYN001 clinical program is an important milestone for the Company, as we now have two clinical stage assets which upon approval may address serious unmet medical needs in a variety of disease settings," said Armando Anido, Chairman and Chief Executive Officer of Zynerba. "We believe that ZYN001 will be important in a number of pain indications, given THC's known impact on pain transmission and analgesic effect in patients suffering from chronic pain. Our state-of-the-art transdermal patch delivery offers unique advantages to patients, including the potential for more consistent, sustained delivery and better tolerability of THC."

This first in man study is a randomized, double-blind, placebo-controlled Phase 1 trial. First, the safety, tolerability and pharmacokinetic profile of a single dose of ZYN001 versus placebo will be evaluated. Several formulations and patch wear times ranging from 24 hours to 7 days will be assessed in up to 48 healthy subjects. Based on results from the single dose portion of this trial, two formulations will be evaluated in multiple patch applications for 14 days in up to 32 healthy subjects who will be randomized 3:1 to ZYN001 or placebo. The goal is to deliver constant levels of THC to optimize efficacy while minimizing CNS side effects. With the successful completion of this single and multiple dose study, a Phase 2 program for ZYN001 in fibromyalgia and neuropathic pain is planned to start in the second half of 2017.

About ZYN001 THC Pro-Drug Patch
ZYN001 is a synthetic pro-drug of THC in a state-of-the-art drug-adhesive matrix transdermal patch, and is being developed for patients with fibromyalgia and peripheral neuropathic pain. THC is a CB1 agonist which acts at many sites along pain transmission pathways, and has been shown to have an analgesic effect in chronic pain models. A pro-drug is a drug administered in an inactive or less active form and designed to enable more effective delivery, which is then converted into an active form through a normal metabolic process. Transdermal patches allow drugs to be absorbed through the skin directly into the systemic blood circulation, avoiding first-pass liver metabolism and potentially enabling lower dosage levels of active pharmaceutical ingredients, a more controlled, consistent delivery of drug with a higher bioavailability and potentially lower incidence of CNS side effects.

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 March 2017, the Company completed enrollment in 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, the most common form of epilepsy in adults. Also in March 2017, 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 osteoarthritis was fully enrolled. In June 2017, the Company completed target enrollment in its exploratory Phase 2 FAB-C (Treatment of Fragile X Syndrome Anxiety and Behavioral Challenges with CBD) clinical trial in children with Fragile X syndrome. Zynerba is also developing ZYN001, which utilizes a synthetically manufactured pro-drug of THC. A Phase 1 clinical study for ZYN001 was initiated in the second quarter 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. In addition, the Company's cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated. 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. This list is not exhaustive and these and other risks are described in the Company's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q 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.

Zynerba Contacts
Jim Fickenscher, CFO and VP Corporate Development
484.581.7483
fickenscherj@zynerba.com

Will Roberts, VP Investor Relations and Corporate Communications
484.581.7489
robertsw@zynerba.com

Primary Logo

Zynerba Pharmaceuticals, Inc.