Zynerba Pharmaceuticals Presents Data on Zygel™ at the American Society of Clinical Psychopharmacology Annual Meeting

June 1, 2022

– Poster presentation highlights design enhancements incorporated into pivotal RECONNECT trial –

– Oral presentation demonstrates long-term safety and potential effectiveness of Zygel in children and adolescents with Fragile X syndrome –

DEVON, Pa., June 01, 2022 (GLOBE NEWSWIRE) -- Zynerba Pharmaceuticals, Inc. (Nasdaq: ZYNE), the leader in innovative pharmaceutically-produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders, is presenting an oral podium presentation and a poster presentation at the American Society of Clinical Psychopharmacology Annual Meeting (ASCP 2022), being held May 31 – June 3, 2022, in Scottsdale, Ariz. Copies of the presentations are available on the Zynerba corporate website at http://zynerba.com/publications/.

"The RECONNECT trial provides us with an opportunity to confirm the positive results observed in a population of responders in our CONNECT-FX trial and further evaluate the effect of Zygel on behaviors associated with Fragile X syndrome (FXS)," said Armando Anido, Chairman and Chief Executive Officer of Zynerba. "Furthermore, the interim results from the open-label extension trial support the long-term safety and potential effectiveness of Zygel in children and adolescents with FXS, with the greatest improvements seen in those with complete methylation of their *FMR1* gene, the population for the primary efficacy analysis in RECONNECT."

The presentation titled, "*Long-Term Safety and Sustained Efficacy of ZYN002 Cannabidiol Transdermal Gel in Children and Adolescents with Fragile X Syndrome (ZYN2-CL-017)*," includes data demonstrating that in the ongoing long-term safety and efficacy trial of Zygel in children and adolescents with FXS, improvement was seen in Social Avoidance in the full population, with the greatest improvement in patients with complete methylation of their *FMR1* gene. Patients with complete methylation, who match the primary efficacy population in the ongoing confirmatory trial, RECONNECT, achieved and maintained clinically meaningful change in Social Avoidance, supporting one of the key design enhancements for RECONNECT. Zygel was well-tolerated with long-term administration with up to 38 months of exposure.

The poster titled, "*RECONNECT (ZYN2-CL-033): Design of a Phase 3 Trial of ZYN002 Cannabidiol Transdermal Gel in Children and Adolescents with Fragile X Syndrome Based Upon Learnings from CONNECT-FX (ZYN2-CL-016) Completed During SARS-COV-2 Pandemic*," describes how learnings from CONNECT-FX, the first randomized, double-blind, placebo-controlled trial of Zygel in the treatment of FXS, shaped the design of RECONNECT. In addition to the primary endpoint of the RECONNECT trial being measured in patients who have a completely methylated *FMR1* gene, the treatment period of the trial has been extended by four weeks and an additional weight-based dose has been added for participants weighing greater than 50kg. RECONNECT is expected to provide key data to determine the effectiveness of Zygel in FXS while using a design intended to reduce the burden of participation in a clinical trial for families with children and adolescents with FXS.

About Zygel

Zygel is the first and only pharmaceutically-manufactured cannabidiol formulated as a patent-protected permeation-enhanced clear gel, designed to provide controlled drug delivery into the bloodstream transdermally (i.e. through the skin). Recent studies suggest that cannabidiol may modulate the endocannabinoid system and improve certain behavioral symptoms associated with neuropsychiatric conditions. Zygel is an investigational drug product in development for the potential treatment of behavioral symptoms associated with Fragile X syndrome (FXS), autism spectrum disorder (ASD), and 22q11.2 deletion syndrome (22q). The Company has received orphan drug designation for cannabidiol, the active ingredient in Zygel, from the FDA and the European Commission in the treatment of FXS and by the FDA for the treatment of 22q. Additionally, Zygel has been designated a Fast Track development program for treatment of behavioral symptoms of FXS.

About RECONNECT

RECONNECT is a randomized, double-blind, placebo-controlled, multiple-center efficacy and safety trial of Zygel administered as a transdermal gel to children and adolescents ages 3 through 17 with Fragile X syndrome. For more information regarding participation visit www.fragilexhelp.com.

About Zynerba Pharmaceuticals, Inc.

Zynerba Pharmaceuticals is the leader in innovative pharmaceutically-produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders. We are committed to improving the lives of patients and their families living with severe, chronic health conditions including Fragile X syndrome, autism spectrum disorder, and 22q11.2 deletion syndrome. Learn more at www.zynerba.com and follow us 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. 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 Company's cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated; the Company's expectations, projections and estimates regarding expenses, future revenue, capital requirements, incentive and other tax credit eligibility, collectability and timing, and availability of and the need for additional financing;

the Company's ability to obtain additional funding to support its clinical development programs; the results, cost and timing of the Company's clinical development programs, including any delays to such clinical trials relating to enrollment or site initiation; clinical results for the Company's product candidates may not be replicated or continue to occur in additional trials and may not otherwise support further development in a specified indication or at all; actions or advice of the U.S. Food and Drug Administration, the European Medicines Agency and other foreign regulatory agencies may affect the design, initiation, timing, continuation and/or progress of clinical trials or result in the need for additional clinical trials; the Company's ability to obtain and maintain regulatory approval for its product candidates, and the labeling under any such approval; the Company's reliance on third parties to assist in conducting pre-clinical and clinical trials for its product candidates; delays, interruptions or failures in the manufacture and supply of the Company's product candidates 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; the Company's expectations regarding its ability to obtain and adequately maintain sufficient intellectual property protection for its product candidates; and the extent to which health epidemics and other outbreaks of communicable diseases, including COVID-19, could disrupt our operations or adversely affect our business and financial conditions. 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.

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