Zynerba Pharmaceuticals Presents Sleep Data from Study of Zygel™ in Children and Adolescents with Both Developmental and Epileptic Encephalopathies (DEE) and Autism Spectrum Disorder (ASD) at the Associated Professional Sleep Societies SLEEP 2021 Annual M

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DEVON, Pa., June 11, 2021 (GLOBE NEWSWIRE) -- Zynerba Pharmaceuticals, Inc. (Nasdaq: ZYNE), the leader in innovative pharmaceutically-produced transdermal cannabinoid therapies for rare and near-rare neuropsychiatric disorders, presented a poster today at SLEEP 2021, the 35th Annual Meeting of the Associated Professional Sleep Societies, LLC. A copy of the poster is available on the Zynerba corporate website at http://zynerba.com/publications/.

The poster titled "*Impact of ZYN002 Cannabidiol Transdermal Gel on Sleep in Children and Adolescents with Developmental and Epileptic Encephalopathies and Comorbid Autism Spectrum Disorder,"* shows that in an open-label Phase 2 trial with patients with developmental and epileptic encephalopathies (DEE), treatment with Zygel™ was associated with improved sleep in children with clinically significant sleep disorders at baseline. Furthermore, the children with both DEE and autism spectrum disorder (ASD) showed more wide-ranging benefits on sleep compared to those with DEE alone.

"Epilepsy and sleep disorders have a bidirectional relationship and co-occur in individuals with ASD. Improvements in sleep may result in better seizure control and behavior in these medically fragile children with DEE," said Joseph M. Palumbo, M.D., LFAPA, MACPsych, Chief Medical Officer of Zynerba. "While these results are exploratory in nature, they are encouraging and warrant confirmation in future clinical trials of Zygel in patients with DEE and/or ASD."

In the open-label Phase 2 trial with Zygel in patients with DEEs aged 3 to ≤17 years, improvements were observed in different aspects of sleep in the two groups. In patients with ASD (n=5), improvements compared to baseline were observed over the 26-week study period in sleep breathing (p=0.018), sleep wake transition (p=0.006) and the total sleep disturbance scale for children (p=0.024). In patients without ASD (n=11), improvement was seen in initiating and maintaining sleep (p=0.033). Zygel was well tolerated in the trial. Most treatment-emergent adverse events were characterized as mild or moderate. Over the 26-week study period, 60.4% participants had ≥1 related adverse event, with 93% mild/moderate severity.

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, 22q11.2 deletion syndrome, and a heterogeneous group of rare and ultra-rare epilepsies known as developmental and epileptic encephalopathies. 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 and 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; the timing and outcome of current and future legal proceedings; 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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