Cannabidiol gel reduces seizures in children with severe epilepsy, Australasian trial shows

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A cannabidiol gel has been shown to reduce epileptic seizures in children in a clinical trial conducted in New Zealand and Australia.

The gel, which is applied to the skin as a transdermal treatment, was found to reduce the number of focal impaired awareness and convulsive seizures experienced by children with severe epilepsy by up to 58 percent between month two and month six of being treated. At month five, 63 percent of children had a reduction of seizures by at least 50 percent.

The phase II clinical trials of the product, which is being developed by US company Zynerba Pharmaceuticals, took place in Wellington and Melbourne, with a total of 48 children enrolled, 24 in each centre.

Professor Lynette Sadleir, a pediatric neurologist at the University of Otago, Wellington, and Professor Ingrid Scheffer, a pediatric neurologist at the University of Melbourne, were the two principle investigators in the trial.

Professor Sadleir says the product offers new hope for children and adolescents experiencing severe epileptic seizures, who currently have few effective options for treatment.

The phase II clinical trial assessed the product's safety and efficacy in children and adolescents with Developmental and Epileptic Encephalopathies. These are the most difficult to treat epilepsies, and include the conditions Dravet Syndrome and Lennox-Gastaut syndrome. Patients with Developmental and Epileptic Encephalopathy have frequent severe seizures as well as severe cognitive and behavioral impairment.

Professor Sadleir says the gel not only reduced the number of epileptic seizures the children had, but also led to a reported improvement in behavioral and cognitive symptoms. It was also very well tolerated.

"These conditions are the most challenging and poorly controlled of all epilepsy disorders, and have a tremendous impact on the families involved.

"Zygel offers the prospect of these children attending school more frequently, and holds out the hope of a more normal life for their families.

"It can be difficult for children with disabilities to take drugs by mouth, but there is presently no other way to give these children anti-seizure medicines. This gel will be the first anti-seizure medicine that will not have to be given by mouth."

Zynerba says it intends to seek a meeting with the US Food and Drug Administration likely in the first half of next year, to discuss the clinical pathway to

approving the product.

About the BELIEVE 1 clinical trial

The six-month BELIEVE 1 clinical trial was an open-label multi-dose Phase II trial designed to evaluate the safety and efficacy of Zygel in children and adolescents. A total of 48 patients between the ages of three and 16 years were enrolled in the trial.

Provided by University of Otago