FDA approves epidiolex for severe forms of epilepsy

June 28 2018

(HealthDay)—The U.S. Food and Drug Administration has approved

Epidiolex (cannabidiol) oral solution for treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome for patients age 2 years and older.

The rare, genetic Dravet syndrome appears during the first year of life with frequent fever-related seizures; other types of seizures arise later, and status epilepticus may occur. Lennox-Gastaut syndrome begins in childhood and is characterized by multiple seizure types. Frequent seizures begin in early childhood, usually between ages 3 and 5.

The effectiveness of Epidiolex was examined in three randomized, double-blind, placebo-controlled clinical trials involving 516 patients with Lennox-Gastaut or Dravet syndrome. When taken with other medications, Epidiolex reduced the frequency of seizures compared with placebo. The most common side effects observed in patients treated with Epidiolex were sleepiness, sedation and lethargy; elevated liver enzymes; decreased appetite; diarrhea; rash; fatigue, malaise, and weakness; insomnia, sleep disorder, and poor sleep quality; and infections.

"In addition to another important treatment option for Lennox-Gastaut patients, this first-ever approval of a drug specifically for Dravet patients will provide a significant and needed improvement in the therapeutic approach to caring for people with this condition," Billy Dunn, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research, said in a statement.

More information: More Information