Zynerba Pharmaceuticals Inc.; Researchers Submit Patent Application, "Synthentic Transdermal Cannabidiol For The Treatment Of Focal Epilepsy In Adults", for Approval (USPTO 20190083388)

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FULL TEXT

2019 APR 8 (NewsRx) -- By a News Reporter-Staff News Editor at Biotech Business Week -- From Washington, D.C., NewsRx journalists report that a patent application by the inventors Gutterman, Donna (Raleigh, NC); Sebree, Terri (Gladwyne, PA); Smith, Theodore (Tubac, AZ); Messenheimer, John (Moncure, NC), filed on September 18, 2018, was made available online on March 21, 2019.

The patent's assignee is Zynerba Pharmaceuticals Inc. (Devon, Pennsylvania, United States).

News editors obtained the following quote from the background information supplied by the inventors:

"Cannabinoids are a class of chemical compounds found in the Cannabis plant. The two primary cannabinoids contained in Cannabis are cannabidiol, or CBD, and 49-tetrahydrocannabinol, or THC. CBD lacks the psychoactive effects of THC. Studies have shown that CBD can be used to treat disorders such as epilepsy, arthritis, and cancer.

"Epilepsy is a disease characterized by an enduring predisposition to generate seizures and by the neurobiological, cognitive, psychological and social consequences of the condition. An epileptic seizure is a transient occurrence of signs and/or symptoms due to abnormal excessive or synchronous neuronal activity in the brain. The seizures in epilepsy may be related to a genetic disorder or a brain injury such as trauma or stroke, but most often the cause is unknown. There are more than 200,000 cases of epilepsy in the United States per year.

"Generalized epilepsy affects both hemispheres of the brain from onset. Focal epilepsy (formerly called partial onset seizures) are seizures that affect only one hemisphere or lobe of the brain initially. Symptoms of focal epilepsy vary depending on which hemisphere or lobe of the brain the seizure occurs."

As a supplement to the background information on this patent application, NewsRx correspondents also obtained the inventors' summary information for this patent application: "The present disclosure relates to a method of reducing seizure frequency in a subject having epilepsy, including transdermally administering an effective amount of cannabidiol (CBD) to the subject wherein the seizure frequency is reduced.

"The seizure frequency can be reduced by 25%. In some embodiments, the seizure frequency is reduced by 30%. The seizure frequency can be reduced by 50%. The seizure frequency can be reduced by 65%. The reduction in seizure frequency can be a reduction from a baseline seizure frequency prior to the administration of an effective amount of CBD. In some embodiments, the reduction in seizure frequency is measured by weekly seizure reduction. In some embodiments, the reduction in seizure frequency is measured by seizure frequency per 28 day period. In some embodiments, the reduction in seizure frequency is measured by monthly seizure frequency.

"In some embodiments focal onset seizures (formerly known as partial onset seizures) in adults are reduced. An adult is a subject who is eighteen (18) years of age or older. In some embodiments focal aware seizures (formerly known as simple partial seizures) are reduced. Focal impaired awareness seizures (formerly known as complex partial seizures) can be reduced. Focal impaired awareness with generalized tonic-clonic seizures (formerly known

as complex partial with generalized tonic-clonic seizures) can be reduced.
"The subject can have a high seizure frequency. The epilepsy can be drug resistant epilepsy (formerly known as refractory epilepsy).
"In some embodiments, the method also includes administering at least one anti-epileptic drug selected from the group consisting of levetiracetam, carbamazepine, topiramate, lamotrigine, lacosamide, clonazepam, valproate, phenytoin, eslicarbaazepine, clobazam, and oxcarbazepine. Anti-epileptic drugs can be, for example, anticonvulsants. The CBD transdermal gel can be used as an adjunctive therapy with the at least one anti-epileptic drug. In some embodiments, the CBD transdermal gel can be used as an adjunctive therapy with two or three anti-epileptic drugs. The CBD transdermal gel can also be used as a monotherapy.
"In some embodiments, the CBD is (-)-CBD. The CBD can be synthetic CBD. The CBD can be pure CBD.
"The effective amount of CBD can be between about 195 mg and about 780 mg total daily. The CBD can be administered in a single daily dose. In some embodiments, the CBD is administered in two daily doses.
"In some embodiments, the effective amount of CBD is 195 mg in divided daily doses. The effective amount of CBD can be 390 mg in divided daily doses. In some embodiments, the effective amount of CBD is 585 mg in divided daily doses. The effective amount of CBD can be 780 mg in divided daily doses.
"The effective amount of CBD can be provided in a 97.5 mg single use sachet. In some embodiments, the effective amount of CBD is provided in a 195 mg single use sachet. The effective amount of CBD can be provided in a 390 mg single use sachet.
"The CBD is formulated as a gel. In some embodiments, the CBD is formulated as a permeation enhanced gel. The gel can contain 4.2% (wt/wt) CBD or 7.5% (wt/wt) CBD.
"In some embodiments, the transdermal preparation can be a cream, a salve or an ointment. The CBD can be delivered by a bandage, pad or patch.
"Transdermally administering an effective amount of CBD can reduce an intensity of at least one adverse event relative to orally administering CBD. The at least one adverse event can be somnolence, psychoactive effects, liver function, GI related adverse events, diarrhea, decreased appetite, fatigue, pyrexia, vomiting, lethargy, upper respiratory tract infection, convulsion, or combinations thereof. In some embodiments, transdermally administering an effective amount of CBD reduces an intensity of at least one adverse event by about 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95% relative to orally administering CBD.
"In some embodiments, the subject is an adult, i.e., eighteen (18) years of age or older.
"In some embodiments, the reduction in seizure frequency occurs after three months. The reduction in seizure frequency can occur after twelve (12) weeks. In some embodiments, the reduction in seizure frequency occurs after 6 months. The reduction in seizure frequency can occur after 24 weeks.
"The present disclosure relates to a method of reducing seizure frequency in a subject having epilepsy. The method includes transdermally administering a first effective amount of cannabidiol (CBD) to the subject for a time period, wherein the seizure frequency is reduced. The method also includes transdermally administering a second effective amount of CBD to the subject after the time period, wherein the second effective amount of CBD is less than the first effective amount of CBD and wherein the reduced seizure frequency is maintained.
"The time period can be twelve (12) weeks. The time period can be twenty four (24) weeks."
The claims supplied by the inventors are:
"1. A method of reducing seizure frequency in a subject having epilepsy, the method comprising: transdermally administering an effective amount of cannabidiol (CBD) to the subject wherein the seizure frequency is reduced.
"2. The method of claim 1, wherein the seizure frequency is reduced by 30%.
"3. The method of claim 1, wherein the seizure frequency is reduced by 50%.
"4. The method of claim 1, wherein focal onset seizures in adults are reduced.
"5. The method of claim 1, wherein focal aware seizures are reduced.
"6. The method of claim 1, wherein focal impaired awareness seizures are reduced.

"7. The method of claim 1, wherein focal compared awareness with generalized tonic-clonic seizures are reduced.
"8. The method of claim 1, wherein the subject has a high seizure frequency.
"9. The method of claim 1, wherein the epilepsy is drug resistant epilepsy.
"10. The method of claim 1, administering at least one anti-epileptic drug selected from the group consisting of levetiracetam, carbamazepine, topiramate, lamotrigine, lacosamide, clonazepam, valproate, clobazam, phenytoin, eslicarbaazepine, and oxcarbazepine.
"11. The method of claim 1, wherein the CBD is (-)-CBD.
"12. The method of claim 1, wherein the effective amount of CBD is between about 195 mg and about 780 mg total daily.
"13. The method of claim 1, wherein the effective amount of CBD is 195 mg in divided daily doses.
"14. The method of claim 1, wherein the effective amount of CBD is 390 mg in divided daily doses.
"15. The method of claim 1, wherein the effective amount of CBD is 585 mg in divided daily doses.
"16. The method of claim 1, wherein the effective amount of CBD is 780 mg in divided daily doses.
"17. The method of claim 1, wherein the effective amount of CBD is provided in a 97.5 mg single use sachet.
"18. The method of claim 1, wherein the effective amount of CBD is provided in a 195 mg single use sachet.
"19. The method of claim 1, wherein the effective amount of CBD is provided in a 390 mg single use sachet.
"20. The method of claim 1, wherein the CBD is formulated as a gel.
"21. The method of claim 20, wherein the CBD is formulated as a permeation enhanced gel.
"22. The method of claim 1, wherein the CBD is administered in a single daily dose.
"23. The method of claim 1, wherein the CBD is administered in two daily doses.
"24. The method of claim 1, wherein the CBD is a synthetic CBD.
"25. The method of claim 1, wherein the CBD is a pure CBD.
"26. The method of claim 1, wherein transdermally administering an effective amount of CBD reduces an intensity of at least one adverse event relative to orally administering CBD.
"27. The method of claim 26, wherein the at least one adverse event is selected from the group consisting of somnolence, psychoactive effects, liver function, and GI related adverse events.
"28. The method of claim 1, wherein the subject is an adult."
For additional information on this patent application, see: Gutterman, Donna; Sebree, Terri; Smith, Theodore; Messenheimer, John. Synthentic Transdermal Cannabidiol For The Treatment Of Focal Epilepsy In Adults. Filed September 18, 2018 and posted March 21, 2019. Patent URL: http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.html&r=1&f=G&l=50&s1=%2220190083388%22.PGNR.&OS=DN/20190083388&RS=DN/20190083388
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