FDA Accepts NDA Filing of First Cannabis Plant-Derived Medicine

On December 28, 2017, GW Pharmaceuticals announced that the US Food and Drug Administration (FDA) had accepted for filing its recently submitted new drug application (NDA) for Epidiolex (cannabinol or CBD), a proprietary cannabinoid product, for both Lennox-Gastaut syndrome and Dravet syndrome. Previously, GW had received rare pediatric disease and orphan drug designations from the FDA for Epidiolex for the treatment of both Lennox-Gastaut syndrome and Dravet syndrome.

Additionally, GW has received priority review designation from the FDA for the Epidiolex filing. The granting of priority review status accelerates the timing of the FDA review of the application compared to a standard review, and is reserved for drugs that may offer major advances in treatment where no adequate therapies currently exist.

“We are pleased with the FDA’s acceptance of our NDA filing with priority review, an action that underscores the unmet need in the LGS and Dravet syndrome populations,” said Justin Gover, GW’s Chief Executive Officer. “We look forward to working with the FDA during the review process to support the case for approval of Epidiolex so as to provide a much needed new treatment option for patients that suffer from these highly treatment-resistant conditions of childhood-onset epilepsy.”

Boston Scientific’s Vercise Deep Brain Stimulation System Receives FDA Approval

Boston Scientific announced on December 11, 2017, that it received US Food and Drug Administration (FDA) approval for the Vercise Deep Brain Stimulation (DBS) System for the treatment of symptoms of Parkinson’s disease.

The approval was based on the INTREPID study, a multicenter, prospective, double-blind, randomized, sham-controlled study of DBS for Parkinson’s disease. The study was conducted in the United States, and enrolled a total of 292 subjects at 23 sites evaluating safety and effectiveness. The INTREPID study met its primary endpoint of mean change in good symptom control during waking hours. Results from the INTREPID study are expected in 2018. The filing was also supported by safety data from the VANTAGE study, a European, multicenter, prospective, single-arm study which treated 40 patients.

“The Vercise DBS System changes the landscape of what physicians can do to help improve the quality of life for people living with Parkinson’s disease,” said Jerry Vitek, MD, PhD, Professor and Chair, Department of Neurology at the University of Minnesota Medical Center in Minneapolis, Minnesota, coordinating principal investigator for the INTREPID study. “This study provides an ability to sculpt the current field in the DBS target using novel technology that offers flexibility in programming. This flexibility allows us to target different regions of the subthalamic nucleus, which we believe will improve outcomes while reducing side effects.”

Thinking Ability and Memory May Improve With Exercise

A new guideline recommendation, released by the American Academy of Neurology, and endorsed by the Alzheimer’s Association, suggests that exercising twice a week may improve thinking ability and memory in people with mild cognitive impairment (MCI). The recommendation was published in the December 27, 2017, online issue of Neurology.

Although MCI is linked to problems with thinking ability and memory, it is not the same as dementia, but is still common with aging. People with MCI have milder symptoms than dementia, however, there is strong evidence that MCI can lead to dementia.

“It’s exciting that exercise may help improve memory at this stage, as it’s something most people can do and of course it has overall health benefits,” said lead author Ronald C. Petersen, MD, PhD, of the Mayo Clinic in Rochester, Minnesota, and a Fellow of the American Academy of Neurology. “Because MCI may progress to
dementia, it is particularly important that MCI is diagnosed early.”

There are currently no FDA-approved medications for the treatment of MCI, and there are no long-term studies that could lead to drugs or dietary changes for the improvement in thinking ability or delay of memory problems in people with MCI.

Worldwide, more than 6% of people in their 60s, and more than 37% of people over 85 years of age have MCI.

**Eating Leafy Greens May Be Tied to Slower Rate of Brain Aging**

A recent study published in *Neurology* (December 20, 2017, online) has found that people who eat at least one serving of green, leafy vegetables a day had slower rates of decline on memory tests and thinking skills than people who rarely or never ate vegetables.

The study followed 961 subjects for an average of 4.7 years. The subjects had an average age of 81 and did not have dementia. Subjects completed a questionnaire about how often they ate certain foods, including how many servings they ate green, leafy vegetables each year. Subjects were also tested for their thinking and memory skills yearly during that time.

Subjects were divided into five groups based on how often they ate green, leafy vegetables. Subjects in the group consuming the most amount of green, leafy vegetables had an equivalence of being 11 years younger in age than those that ate the least amount.

The study also accounted for other factors such as smoking, high blood pressure, obesity, education level and amount of physical and cognitive activities that can affect brain health. Study author Martha Clare Morris, ScD, of Rush Medical Center in Chicago noted that the study does not prove that eating green, leafy vegetables slows brain aging, rather, it only shows an association.

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**CORRECTION**

**Correction from the November/December 2017 issue**

The following changes should have been made to the article “The Prevalence of Migraine and Other Neurological Conditions Among Retired National Football League Players: A Pilot Study” by Randolph W. Evans, MD.

Page 21, fourth paragraph, second sentence should read as follows:

I conducted a retrospective pilot study to investigate the prevalence of migraine and co-morbidities using a convenience sample of 50 retired players seen in my practice.

Page 21, sixth paragraph should read as follows:

An independent review board exemption was obtained, including waiver of informed consent, and data extracted was de-identified. This article is neither endorsed nor authorized by the NFL Concussion Settlement Program, the parties to, or the administrators of that settlement.

Page 22, text under heading “Objectives” should read as follows:

Objectives: To evaluate the one-year prevalence of migraine in a pilot study using a convenience sample of retired NFL players.

Page 24, second column, under heading “Essential tremor and Parkinson’s disease”, third paragraph, second sentence should read as follows:

One player was in his early fifties, and the other was in his seventies.

Page 25, first paragraph, second sentence should read as follows:

The retired players were part of a biased, nonrandom sample and are probably not representative of all retired NFL players.

*Please accept our apology as we strive to ensure our publication meets the highest of standards.*