Approval for Duopa™ to Treat Parkinson’s Disease

The U.S. Food and Drug Administration has approved AbbVie’s Duopa™ enteral suspension for the treatment of motor fluctuations for individuals with advanced Parkinson’s disease. Duopa is administered using a small, portable infusion pump that delivers carbidopa and levodopa directly into the small intestine for 16 continuous hours via a procedurally placed tube.

In the advanced stages of Parkinson’s disease, patients may experience “off” time (i.e., periods of poor mobility, slowness, and stiffness). In addition, spontaneous emptying of the stomach becomes delayed and unpredictable, which can affect the timing of when orally administered medicines leave the stomach and are absorbed in the small intestine. Duopa provides patients with the same active ingredients as orally administered carbidopa and levodopa immediate release, but is delivered in a suspension that goes directly into the small intestine. This administration is intended to bypass the stomach.

The Duopa approval is based on a phase 3, 12-week, double-blind, double-placebo, active control, parallel group, multicenter trial (N = 71) that compared the efficacy and safety of Duopa to oral, immediate-release (IR) carbidopa–levodopa tablets in patients with advanced Parkinson’s disease. The study showed that Duopa significantly reduced daily (per 16 waking hours) mean “off” time at 12 weeks by 4 hours, which resulted in an average of 1.9 fewer hours of “off” time when compared to carbidopa–levodopa IR tablets. Treatment with Duopa was also associated with an improved mean “on” time (i.e., periods when medication is working and symptoms are controlled) without troublesome dyskinesia (i.e., uncontrolled movement that does not interfere with normal daily activities), which resulted in an average of 1.9 more hours of “on” time when compared to carbidopa–levodopa IR tablets.

New Therapeutic Treatment for Pre-Dementia

The Alzheimer’s Drug Discovery Foundation announced a $900,000 grant to AgeneBio, a pharmaceutical company developing innovative therapies for neurological and psychiatric diseases. The grant will support the initiation of a U.S. Food and Drug Administration (FDA)-registered phase 3 clinical trial of AGB101, a new therapeutic treatment for amnestic mild cognitive impairment (aMCI). aMCI is a condition in which memory is worse than expected for an individual’s age and is considered the pre-dementia stage of Alzheimer’s disease.

AGB101 is a proprietary formulation of low-dose levetiracetam given to patients at approximately one fifteenth of the dose most commonly prescribed for epilepsy. This therapeutic agent has been commercialized for more than one decade and offers a well-characterized safety profile at 15 times the expected dose.

AGB101 is the first and only treatment to target hippocampal hyperactivity—a condition characteristic of the aMCI stage of Alzheimer’s disease. The phase 3 trial will build on studies in both animal models and patients with aMCI that have demonstrated the importance of reducing hippocampal hyperactivity to restore the brain function necessary to maintain cognitive function and memory.

aMCI is believed to affect between 10% and 20% of individuals 65 and older. There is currently no FDA-approved therapy for patients in this pre-dementia stage of Alzheimer’s disease, representing an important unmet clinical need.


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