Fampridine Improves Walking Speed and Leg Strength in MS, Announces Drug Company

Acorda Therapeutics (Hawthorne, NY) announced positive results of a Phase 3, controlled clinical trial of Fampridine-SR, an oral drug designed to provide symptomatic relief by compensating for lost nerve conduction. The placebo-controlled study involved 301 patients with all types of multiple sclerosis at 33 sites in the U.S. and Canada. The primary outcome measured was improvement in the time it took to walk 25 feet. According to the company, those on active treatment showed an average increase in walking speed of 25% versus those on inactive placebo.

The company is expected to meet with the U.S. Food and Drug Administration to determine next steps needed to apply for marketing approval. It is not yet clear whether an additional clinical trial will be required.

Fampridine-SR is a sustained-release formula of 4-aminopyridine, which blocks tiny pores, or potassium channels, on the surface of nerve fibers. This blocking ability may improve the conduction of nerve signals in nerve fibers whose insulating myelin coating has been damaged by MS. The first studies of this potassium-blocking approach in people with MS were supported by the National MS Society.

Thirty-five percent of those on active therapy experienced increased walking speed. Other positive outcomes during the 14 weeks of therapy included increased leg strength in those on active treatment, even in some individuals whose walking speed did not improve. Patients that responded to the drug reported feeling less disabled in daily activities requiring mobility.
According to company sources, common adverse events (side effects) experienced more often by those on active treatment included falls, back pain, dizziness, insomnia, fatigue, nausea and balance disorder. Serious adverse events that led to discontinuation of the drug included one case of anxiety and one seizure in a person who developed sepsis from a urinary tract infection. There were no deaths during the treatment phase of the study, but one person died five weeks after the last treatment visit. It is not yet clear what that person died from or whether it was related to therapy.

Participants in this clinical trial were permitted to remain on other medications, including disease-modifying therapies (such as Betaseron, Copaxone, Avonex, Rebif) during the trial, establishing the potential of the drug as a symptomatic management strategy that could be used along with their regular medications.

“If the FDA agrees that Fampridine is safe and effective, it would bring a welcome symptomatic therapy that has potential utility for a large number of people with different types of MS,” said John R. Richert, MD, vice president of research and clinical programs for the National MS Society.

The company plans to release data from this study to the medical community at a medical meeting in the near future. If any individuals have questions about the results, they may call Acorda’s toll-free number: 877-223-5212.

-- Research and Clinical Programs Department