Fampridine-SR is a sustained-release tablet formulation of the investigational drug fampridine (4-aminopyridine, or 4-AP). Data collected in laboratory studies found that Fampridine-SR can improve the communication between damaged nerves, which may result in increased neurological function.

Nasdaq: ACOR

Founded: 1995

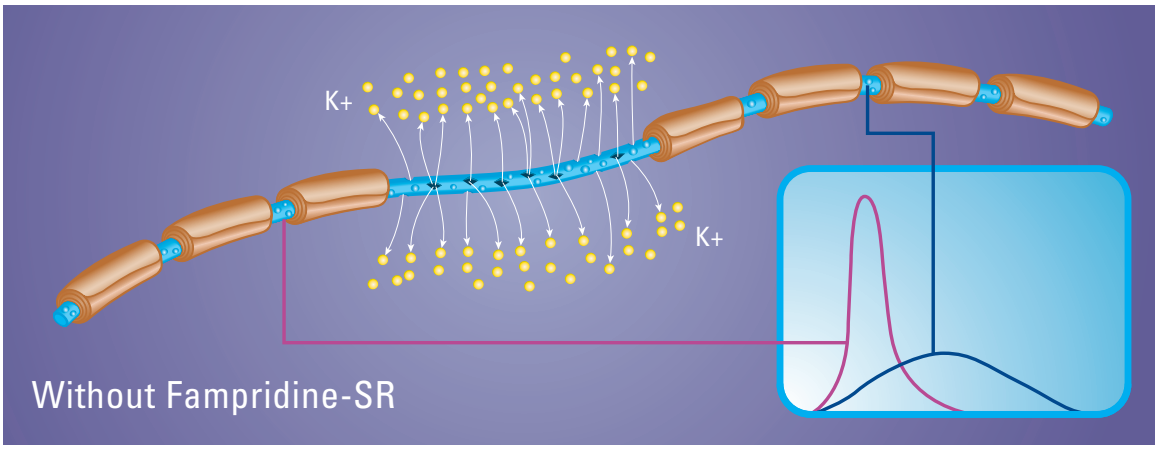
Mission:
Develop and market therapies to restore neurological function in people with spinal cord injury, multiple sclerosis and related conditions of the nervous system.

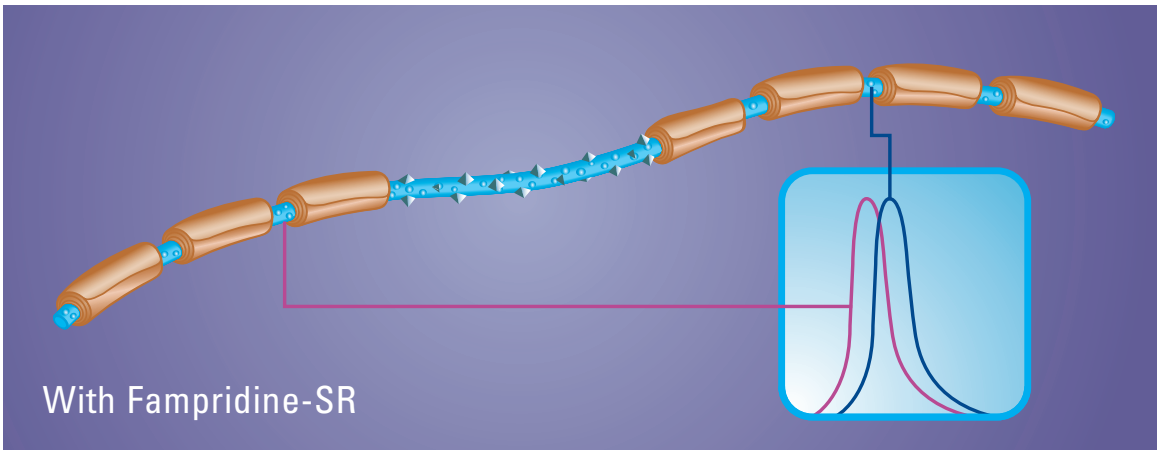
Located:
Hawthorne, NY

Fampridine-SR Mechanism of Action

A nerve cell has one extension called an axon, which it uses to communicate via electrical signals to other nerve cells. All but the smallest axons have a special covering of a fatty substance called myelin that acts as insulation to preserve and speed these nerve signals, much like the insulating cover of an electrical cord helps preserve the transmission of electricity.

In a condition such as multiple sclerosis (MS), the myelin becomes damaged and the axon cannot effectively transmit electrical impulses. Specifically, the damaged myelin exposes channels in the membrane of the axon, which allow potassium ions to leak from the axon, dissipating the electrical current. Fampridine-SR blocks these exposed channels, and helps the electrical signals to pass through areas of damage.





Fampridine-SR enhances the transmission of the electrical signals that a nerve cell's axon conveys. In MS or SCI the myelin (orange) can become damaged and lost, exposing the axon (blue). Without this insulating myelin sheath, axons "short circuit" and cannot transmit motor or sensory impulses, indicated in red. Fampridine-SR helps prevent the axonal short circuits by blocking channels in the axon that leak potassium ions (K+). With the channels blocked, the electrical signals can continue past the damaged section of the axon (blue).

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Fampridine-SR in Multiple Sclerosis

In June 2008, Acorda announced positive results from its second positive Phase 3 clinical trial of Fampridine-SR on walking ability in people with MS. This trial was conducted under a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration (FDA).

A significantly greater portion of Fampridine-SR Timed Walk Responders had a consistent improvement in walking speed, the study's primary outcome, compared to people taking placebo (42.9 percent vs. 9.3 percent) as measured by the Timed 25-Foot Walk ($p<0.001$) (for an explanation of the Response Analysis used in this trial, see the box to the right). Additional measures in this study were consistent with the results of the first Phase 3 Fampridine-SR trial, including improvement in the 12-Item Walking Scale (MSWS-12), a self-rated assessment of walking disability, in Timed Walk Responders compared to non-responders. Increased response rate on the Timed 25-Foot Walk was seen across all four major types of MS. This study was open to people with all types of MS and participants were permitted to remain on a stable regimen of their current medications, including interferons.

Study participants in the last Phase 2 and both Phase 3 MS trials were eligible to enroll in extension studies and receive ongoing treatment with Fampridine-SR. In the longest-running study, 52% (92 of 177) of those who enrolled in the study are still participating after 4.2-4.8 years. In the other two studies, 69% (186 of 269) and 86% (185 of 214) remain enrolled after 2.3-3.1 years and 7-17 months, respectively.

Acorda submitted a New Drug Application for Fampridine-SR to the FDA on January 30, 2009.

Fampridine-SR Response Analysis

People's MS symptoms vary greatly depending upon the activity of their disease on any given day. To account for this inherent variability in MS patients' conditions, Acorda developed a "response analysis" to try to more precisely assess whether improvements in function resulted from drug effect or disease variability. A "Timed Walk Responder" in the trial was defined as a participant whose walking speed during the majority of the on-drug visits was faster than the participant's fastest speed recorded during non-drug visits.

Fampridine-SR Safety Profile

Adverse events observed in the second Phase 3 trial were largely consistent with the safety profile observed in previous studies of Fampridine-SR in people with MS. The most common adverse events (incidence ≥ 2% and at a rate greater than the placebo rate) for Fampridine-SR in MS patients were: urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, and back pain. Seizure has been reported in a small number of cases, and appears to be dose-related. Seizure incidence with Fampridine-SR at 10mg twice a day is within the rates reported for placebo-treated groups in long-term controlled studies of interferon drugs in MS patients.

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