

Mitsubishi Tanabe Pharma's ALS drug treats more than 1000 people in three months

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Radicava is the second drug approved to treat ALS in 22 years



Japan's Mitsubishi Tanabe Pharma America, Inc. today announced that more than 1,000 people with amyotrophic lateral sclerosis (ALS) have been treated with RADICAVA[®] (edaravone) since it became available in the U.S. in August as the first FDA-approved treatment option for the disease in more than 20 years.

The U.S. Food and Drug Administration (FDA) approved RADICAVA (edaravone) on May 5, as a treatment option for all adult patients diagnosed with amyotrophic lateral sclerosis (ALS). The FDA approval of the drug is notable not only because it is just the second drug approved to treat ALS in 22 years—the first since riluzole (Rilutek, from Covis Pharma) in 1995—but also because it was approved through the orphan drug program for expedited review and without clinical trials in the United States.

Radicava is given to patients intravenously and can be administered in multiple settings, including an ALS center or through home infusion under the supervision of an HCP. Over the last three months since becoming available in the U.S., more than 300 infusion centers have treated patients, and more than half of patients have received treatment through home infusion providers.

Mr Atsushi Fujimoto, President, Mitsubishi Tanabe Pharma America, said, "Our goal is to help as many people with ALS as possible. This is an important milestone, and we remain keenly focused on continuing to ensure that patients prescribed RADICAVA are able to access this treatment as quickly as possible."

Mr Tomas H. Holmlund, M.D., added, "After decades of waiting for a treatment option, the ALS community is one step closer to managing this devastating disease. This is extremely meaningful to me and to the patients I treat."

ALS, or amyotrophic lateral sclerosis, is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the

body. The progressive degeneration of the motor neurons in ALS eventually leads to their demise. When the motor neurons die, the ability of the brain to initiate and control muscle movement is lost. With voluntary muscle action progressively affected, people may lose the ability to speak, eat, move and breathe.

An estimated 5,000-6,000 Americans are diagnosed each year with ALS. The majority of ALS patients die within two to five years of receiving a diagnosis.