February 6th, 2019

Swissmedic approves RADICAVA, Japan-originated ALS treatment

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Masayuki Mitsuka), announced today that Edaravone (Swiss name: RADICAVA®; Japan names: RADICUT® BAG for I.V. Infusion 30mg) was approved by the Swissmedic for an indication of amyotrophic lateral sclerosis (ALS), a rapidly progressive, neurodegenerative disease on January 31st. Mitsubishi Tanabe Pharma GmbH (MTPD) as a subsidiary of MTPC has filed to Swissmedic and will commercialize RADICAVA®.

The approval of Swissmedic was based on a clinical trial which the primary endpoint was a measurement utilizing the ALS Functional Rating Scale-Revised (ALSFRS-R), a validated rating instrument for monitoring the progression of disability in patients with ALS in Japan*.
Now there are limited treatment options to treat ALS, therefore MTPC would like to meet ALS patients demand of RADICAVA® in Switzerland.

ALS is an idiopathic neurodegenerative disease in which motor neurons selectively degenerate and vanish. Muscle strength declines throughout the entire body, including the limb, facial, and respiratory muscles, and muscular atrophy progress. Initial symptoms can be subtle, and accordingly it can take 12 to 14 months to be accurately diagnosed. It is one of the most well-known neuromuscular diseases, affecting approximately two in 100,000 people worldwide. An estimated 600 Swiss currently are living with ALS**.

Mitsubishi Tanabe Pharma will strive to deliver edaravone to patients fighting against ALS all over the world.

* Refer to the package insert (clinical trial results) for RADICUT® inj. 30mg ampule and RADICUT® BAG for I.V. Infusion 30mg
**Kathi Schweikert. Amyotrophe Lateralsklerose. Swiss Medical Forum 2015;15(46):1068–1073. http://www.als-schweiz.ch/__/frontend/handler/document.php?id=534&type=42

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<Reference>

■ About edaravone

Edaravone is a free-radical scavenger that was discovered by Mitsubishi Tanabe Pharma. It was approved by the Japanese Ministry of Health, Labor and Welfare in April 2001 as a treatment agent for the acute stage of cerebral infarction. In Japan, it is being marketed under the product name RADICUT®. Edaravone has the effect of scavenging free radicals that arise accompanying cerebral ischemia, controlling the lipid peroxidation reaction, and protecting neurons in the region of the ischemia and the surrounding region. Accordingly, it is thought that edaravone has the effect of scavenging free radicals, which increase in ALS, protecting motor neurons from oxidative stress, and delaying the decline in muscle strength and the progress of muscular atrophy.

For use as a treatment for ALS, edaravone was approved in Japan in June 2015, South Korea in December 2015, US in May 2017, Canada in October 2018. MTPC filed for edaravone to EMA.

■ Mitsubishi Tanabe Pharma GmbH (MTPD)

Headquartered in Dusseldorf, Germany, Mitsubishi Tanabe Pharma GmbH has been founded in 2003 as a subsidiary of Mitsubishi Pharma Europe Ltd. (London/UK). The company in Switzerland, based in Zurich, focuses not only on Radicava®, but also on marketing the direct thrombin inhibitor, Argatra® (argatroban monohydrate).

■ About Mitsubishi Tanabe Pharma Europe Ltd.

Based in London, UK, Mitsubishi Tanabe Pharma Europe Ltd. is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC). Mitsubishi Tanabe Pharma Europe Ltd. is dedicated to research and develop innovative pharmaceutical products that address the unmet medical needs of patients in EU.

http://www.mt-pharma-eu.com/