



July 16, 2020

As the First ALS Treatment in Indonesia RADICAVA has been approved first in ASEAN countries

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Hiroaki Ueno), announced today that edaravone (Indonesia name: RADICAVA; Japan names: RADICUT[®] inj.30mg) was approved by Indonesia FDA for an intravenous treatment for amyotrophic lateral sclerosis (ALS) on July 8, 2020.

RADICAVA is the first ALS treatment in Indonesia as there had been no drug available for the treatment of ALS. MTPC is in the process of filing applications for approval of edaravone in the ASEAN countries, and Indonesia is the first country to approve edaravone.

PT Mitsubishi Tanabe Pharma Indonesia which is MTPC's manufacture and sales subsidiary in Indonesia has filed the application and will also market RADICAVA in Indonesia.

Edaravone was approved for the treatment of ALS in Japan, June 2015, followed by South Korea, U.S., Canada, Switzerland and China.

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. While the cause for the majority of cases is not well understood but may involve genetic and environmental factors. It is one of the most well-known neuromuscular diseases, affecting approximately two in 100,000 people worldwide. In Asian countries including the ASEAN countries, there are various research reports and some countries have no affecting rate*. Indonesia consists of numerous islands, therefore, the actual number of ALS patients including potential patients is not clear at this point. With the approval of RADICAVA as an opportunity, further progress is expected in the clinical practice and research of intractable neurological diseases including ALS.

MTPC will strive to deliver edaravone to patients fighting against ALS all over the world.

*Amyotrophic lateral sclerosis and motor neuron syndromes in Asia.
Shahrizaila N, et al. J Neurol Neurosurg Psychiatry. 2016 Aug;87(8):821-30.

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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, Labour 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, Switzerland in January 2019 and China in July 2019.

■ About PT Mitsubishi Tanabe Pharma Indonesia

PT Mitsubishi Tanabe Pharma Indonesia (MTID) was established in July 1970 and is manufacturing and sales subsidiary of MTPC. Its Headquarters is in Jakarta, sales bases in 13 locations throughout Indonesia, and production bases in Bandung in Indonesia. In addition to the ASEAN countries, MTID supplies products to Hong Kong, Sri Lanka, Brazil, Pakistan, and other countries. With the objective of increasing production capacity and further improving quality, MTID constructed a new formulation building in Bandung, which began operating in January 2015.