

FDA Approves Edaravone: A Cause for Celebration in the U.S. ALS Community

The anticipated FDA approval for Edaravone, also known as Radicava, has arrived a full month earlier than expected.

MADISON, WI, UNITED STATES, May 10, 2017 /EINPresswire.com/ -- On May 5, 2017, FDA authorization was granted to Mitsubishi Tanabe Pharma America, Inc. to manufacture and distribute Edaravone, the medication that has already provided systemic benefit to many with Amyotrophic Lateral Sclerosis (ALS) in Japan, India, and smaller patient groups in at least 16 other countries, including the US. The FDA's approval comes one month earlier than originally expected and provides great hope to ALS patients in the US.

ALS Worldwide has firsthand experience enabling compassionate use of Edaravone for ALS patients who sought this medication and were able to manage its challenges. Based upon positive trial results shared by Mitsubishi Tanabe, ALS Worldwide provided the use of this drug to a group of ALS patients beginning in August 2016. Some US and EU patients traveled individually to Japan to bring back a several-month supply for themselves. For others, the organization traveled abroad to import this medication for its compassionate use trial and benefits in the US and other countries, learning the majority of those who began its use have achieved benefits that outweigh the challenges involved in its administration. Edaravone, also known as Radicava, requires a PICC line or Port-A-Cath for daily intravenous (IV) injection. The process can take up to an hour for the daily infusion to be completed. For most patients, this was achieved in-home and soon became an acceptable part of their daily routine.

Edaravone arrives 22 years after the introduction of Rilutek (riluzole), as a new systemic treatment offering important benefits to the ALS patient community. Radicava is expected to be available to patients and their doctors as early as August 2017, but actual availability may be up to three months after this date. Prior to its FDA approval, ALS Worldwide responded only to specific patient inquiries for individual compassionate usage of Edaravone, funded in whole or in part by patients and families themselves. The organization's role included sourcing and importing the medication, confirming its authenticity and safety, continuous monitoring of usage, and helping develop local medical oversight, administration of Edaravone, and correlation of patient usage and results. ALS Worldwide has provided similar services for other trial medications, under the supervision of our medical and scientific advisors, as part of the organization's ongoing effort to support the ALS patient community.

If interested in Edaravone, ALS Worldwide recommends taking the following actions:

1. Make an informed decision about the usage of Radicava by learning what is involved in [procuring a PICC line or Port-A-Cath](#).
2. Notify your local pharmacy that you wish to be informed as soon as Radicava becomes available.
3. Contact your insurance company concerning coverage for Radicava.
4. Discuss installation of the PICC line or Port-A-Cath with your local physician.

Read more about FDA's approval of Edaravone (Radicava), and access the approval news release from FDA as well as Mitsubishi Tanabe's news release on the estimated infusion cost of Edaravone by visiting the [ALS Worldwide website](#).

ALS Worldwide began in 2002 and has continued as a not-for-profit organization since 2008. Today, the organization strives to help people with ALS live better and longer lives by providing compassionate care and counseling, assistance in managing ALS symptoms, greater access to beneficial medications, information about medical devices and communication systems, caregiver support, and guidance on healthcare topics and resources.

ABOUT ALS WORLDWIDE

ALS Worldwide is the only nonprofit global health organization that provides FREE guidance, care, and support to people living with ALS via videoconference, email, social media, phone, and in-person visits in more than 125 countries. We strive to help people live better and longer with ALS. Until there's a cure, there's ALS Worldwide. Visit www.alsworldwide.org.

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