A social media sensation has finally paid off. The U.S. Food and Drug Administration (FDA) has recently approved the first drug to combat amyotrophic lateral sclerosis, or ALS, in 22 years. The new drug, Radicava, has shown that it can slow progress of the physical conditions related to the disease by 33%.

The ice-bucket challenge was a social media phenomenon that started in the summer of 2014 to help raise awareness and funds for ALS, also known as Lou Gehrig's disease. With more than 17 million people participating in the challenge that involved dumping a bucket of ice water over a person's head, the ALS Foundation reported that the social media craze had raised over $115 million. The icy water had worked.

The new drug Radicava, or edaravone, was developed by Japanese Mitsubishi Tanabe Pharma. The drug trials found that while Radicava slowed the progression of the disease, it is not able to reverse the conditions of ALS. However, it can slow the progression a significant amount to give its patients more time. The drug has been used for two years with success in Japan. In an interesting twist to the plot, the FDA's approval was solely based on the data collected from the Japanese trials. The FDA even worked with the company to file for US approval, making it the first time the FDA has approved a drug outside the US.

“After learning about the use of edaravone to treat ALS in Japan, we rapidly engaged with the drug developer about filing a marketing application in the United States,” Eric Bastings, M.D., deputy director of the FDA’s Division of Neurology Products, said in a statement. “This is the first new treatment approved by the FDA for ALS in many years, and we are pleased that people with ALS will now have an additional option.”

The clinical trials conducted in Japan took place in a six-month span with 137 participants who were randomized to receive edaravone or a placebo. The researchers observed that around week 24, participants who were receiving edaravone showed a smaller decline in their level of daily functioning compared to those receiving a placebo.

ALS is a rare progressive, neurodegenerative disease, that attacks and kills the nerve cells that control voluntary muscles. The Centers of Disease Control and Prevention estimates that approximately 12,000-15,000 Americans have ALS. It is usually discovered in people between the ages of 55 and 75 years of age, and on average live from 2-5 years after symptoms develop.

The only national nonprofit, ALS Association, is thrilled with the FDA’s announcement for the new drug.

“We thank the FDA and MT Pharma for working together to expedite the approval of the first new ALS-specific treatment in decades,” said ALS Association President, Barbara Newhouse

in a statement. “We hope (the) announcement signals the beginning of a new chapter in the fight against this terrible disease.”

It is hoped that Radicava will be available on the US market in August 2017.

(additional source: CNN)

For more pharmaceutical information, see our pharmaceutical industry page.

(via WCVB Channel 5 Boston)
Share with friends and coworkers:

- Click to share on LinkedIn (Opens in new window)
- Click to share on Facebook (Opens in new window)
- Click to share on Twitter (Opens in new window)
- Click to share on WhatsApp (Opens in new window)
- Click to email a link to a friend (Opens in new window)