Medical Xpress

MS patients cheer FDA OK of new drug

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Patients facing limited options for treating their relapsing multiple sclerosis are celebrating the FDA's approval of a new aggressive drug treatment. The ruling reverses the agency's decision a year ago that the drug was not yet ready.

"Isn't it wonderful?" said Linda Kostelac, 64, of Belleville, Ill., who wrote letters to newspapers urging readers to sign an online petition after the initial thumbs-down of the drug Lemtrada. "It is a true Christmas present."

Kostelac has a son, 38, with MS. The ruling comes in time for Kostelac's son, but the year without it has been devastating for Kristen Canter, 37, a mother of two who lives near Cape Girardeau, Mo. Earlier this year, despite doing well, Canter had to stop using a medication because she was at higher risk of getting a dangerous brain infection the longer she took it. She was hoping to switch to Lemtrada but had to opt for another drug.

Canter deteriorated and now needs a walker or scooter to get around, and she can barely move her right arm. She had to quit her job as the director of development at the Southeast Missouri Food Bank and can't play outside with her sons, ages 3 and 6. Everything - from getting ready in the morning to attending school activities - is difficult.

"I just try and not think about it, because it gets me furious - that I could've maintained where I was instead of declining so much, that I could still be working and having a much more active life, going out with

my friends and doing more stuff with my kids," Canter said. "It is extremely frustrating, but I am excited it's been approved now, and I'm ready to move forward."

The U.S. Food and Drug Administrationinitially rejectedthe drug, despite dramatic improvements in study subjects, because of concerns over how rigorous the studies were and the potential forserious side effects. In June, the FDA allowed drug manufacturer Genzyme to resubmit its application with additional analysis of research data and information addressing the concerns.

Doctors, patients and advocates wrote letters to the FDA and gathered nearly 10,000 signatures on petitions, arguing that some patients are willing to face risks for a better quality of life. Lemtrada is generally reserved for patients who have not responded well to two or more other treatments.

"We are pleased that the voices of the MS community have been recognized, and that people with relapsing MS will have access to a new, needed treatment option," said Dr. Timothy Coetzee, chief of advocacy at theNational MS Society.

Multiple sclerosis is disabling disease in which the immune system attacks the central nervous system. Unpredictable symptoms range from numbness and tingling to blindness and paralysis. About 2.3 million people worldwide have MS, including 400,000 in the U.S.

Damage from multiple sclerosis varies by patient, and patients also respond differently to medication.

"Many of our patients are not responding to our current therapies," said Dr. Barry Singer, director of theMS Center for Innovations in Careat Missouri Baptist Hospital. He was involved in clinical studies of the drug

and advocated for the FDA to change its mind. "Based on our experience as investigators," Singer said, "we saw the tremendous impact that Lemtrada has on the lives of those living with MS."

A study of nearly 1,400 patients with progressive forms of the disease showed that those taking Lemtrada had nearly 50 percent fewer new attacks than those taking the current best medication. New brain lesions also significantly reduced. The drug has been approved in more than 40 countriesincluding Canada, Australia and European nations.

"Today's approval is the culmination of more than a decade of work by Genzyme to develop Lemtrada," CEO David Meeker said after the drug was approved last month. "Lemtrada demonstrated superior efficacy over Rebif on annualized relapse rates in the two studies which were the basis for approval. A comprehensive risk evaluation and mitigation strategy will be instituted in order to help detect and manage the serious risks identified with treatment."

The drug must include a warning about the risk of serious, sometimes fatal autoimmune conditions as well as serious life-threatening infusion reactions. The warning also notes Lemtrada may increase the risk of malignancies, including thyroid cancer and melanoma. The drug will be distributed through a restricted program to ensure that it is given only by certified health-care facilities and that patients are followed closely.

Harold Johnson, 44, of Swansea, Ill., was aware of the risks when he agreed six years ago to participate in studies of Lemtrada. The drug - which is given intravenously once a year over five days the first year and three days the next - changed his life.

"I rolled the dice on myself because I had to. I had to do something," Johnson said. "I wanted to live life, the rest of it I had left, with some quality in there."

The medication he was injecting three times a week made him feel like a zombie. His vision got worse, and he would choke when eating or drinking. He would shake and sometimes needed a cane or walker. His brain scans showed dozens of active lesions.

Today, his lesions are inactive. Johnson can ride his bike, play in the park with his dog, build robots in his basement and work full time as a computer technician at Southwestern Illinois College. He even got married. "I never thought I would see something this effective in my lifetime," he said.

Canter is on a list with others who plan to get their first Lemtrada infusion late next month at Missouri Baptist once the certification is in place. Canter is not sure if it will help her regain some of what she lost. She just wants to do whatever she can to be there for her children.

"All you want is hope, and this gives me hope," she said. "The way the past nine months have been, it scares me to think what is going to happen nine months from now if I don't try this. That's what scares me more than anything."

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