FDA approves ozanimod for multiple sclerosis

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The U.S. Food and Drug Administration has approved ozanimod, an immune-modulating therapy invented at Scripps Research, for the treatment of adults with relapsing forms of multiple sclerosis. The drug is also in advanced clinical development for adults and children with moderate-to-severe ulcerative colitis and Crohn's disease.

In patient studies supporting ozanimod's New Drug Application, those who took the once-daily oral medicine experienced significantly less disease progression—including fewer relapses and preservation of the brain from atrophy—than those who received standard care, with very few side effects. The drug, licensed to Bristol Myers Squibb, will be sold under the trademarked name Zeposia.

"Today's FDA approval of ozanimod is a celebratory milestone for the multiple sclerosis community, which is in need of new, intelligent drug interventions to help patients control the progression of their disease," says Hugh Rosen, MD, Ph.D., who invented ozanimod along with fellow Scripps Research professor Edward Roberts, Ph.D., and their laboratory colleagues.

Nearly 1 million people in the United States are living with multiple sclerosis, according to the National MS Society, and approximately 85 percent of those patients are diagnosed with the relapsing forms of the disease that ozanimod is designed to treat.

In multiple sclerosis, the immune system mistakenly attacks myelin sheath, the protective layer that surrounds nerves in the brain. This disrupts the flow of information within the brain and between the brain and body, bringing about symptoms that can range from numbness and bladder issues to vision problems and muscle paralysis.

Ozanimod works by acting on certain types of immune cells called lymphocytes that are centrally involved in the autoimmune attack on myelin sheath. It binds to receptors on the cells' surface, keeping them from reaching the brain. As a result, the number of activated lymphocytes is decreased, diminishing the immune attack.

The fundamental discoveries that led to ozanimod were reported by Rosen, Roberts and their Scripps Research colleagues in a series of papers from 2002 to 2008. In 2009, Scripps Research licensed ozanimod to biotechnology startup Receptos, which Celgene purchased in 2015 for $7.2 billion. Celgene was acquired by Bristol Myers Squibb in 2019.

Ozanimod is also being studied as a treatment for forms of inflammatory bowel disease, with late-stage clinical trials underway for ulcerative colitis and Crohn's disease, for which it is a first-in-class treatment.

The ozanimod approval for multiple sclerosis is the latest in a string of FDA-approved drugs to originate from Scripps Research's laboratories, following on most recent approval of tafamidis for the rare but often fatal heart disease known ATTR-CM.

Scripps Research also invented drugs that have been brought to market to treat more than a dozen other high-need conditions including arthritis, lupus, respiratory distress syndrome, gastric cancer, metastatic non-small cell lung cancer, hemophilia, anthrax inhalation and neuroblastoma. Additional drugs are in development for more than 10 other conditions, ranging from osteoarthritis to Parkinson's disease, with several in clinical trials.

"There are hardly any other academic institutions in the world that have the multidisciplinary expertise to discover a new disease-modifying compound and generate clinical data in support of its development," Rosen says.

Additional molecules developed by Rosen and Roberts at Scripps Research are currently in phase 2 clinical trials for major depressive disease and anxiety, and in phase 1 studies for treatment of autism.

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