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Expert discusses first and only drug approved for progressive multiple sclerosis

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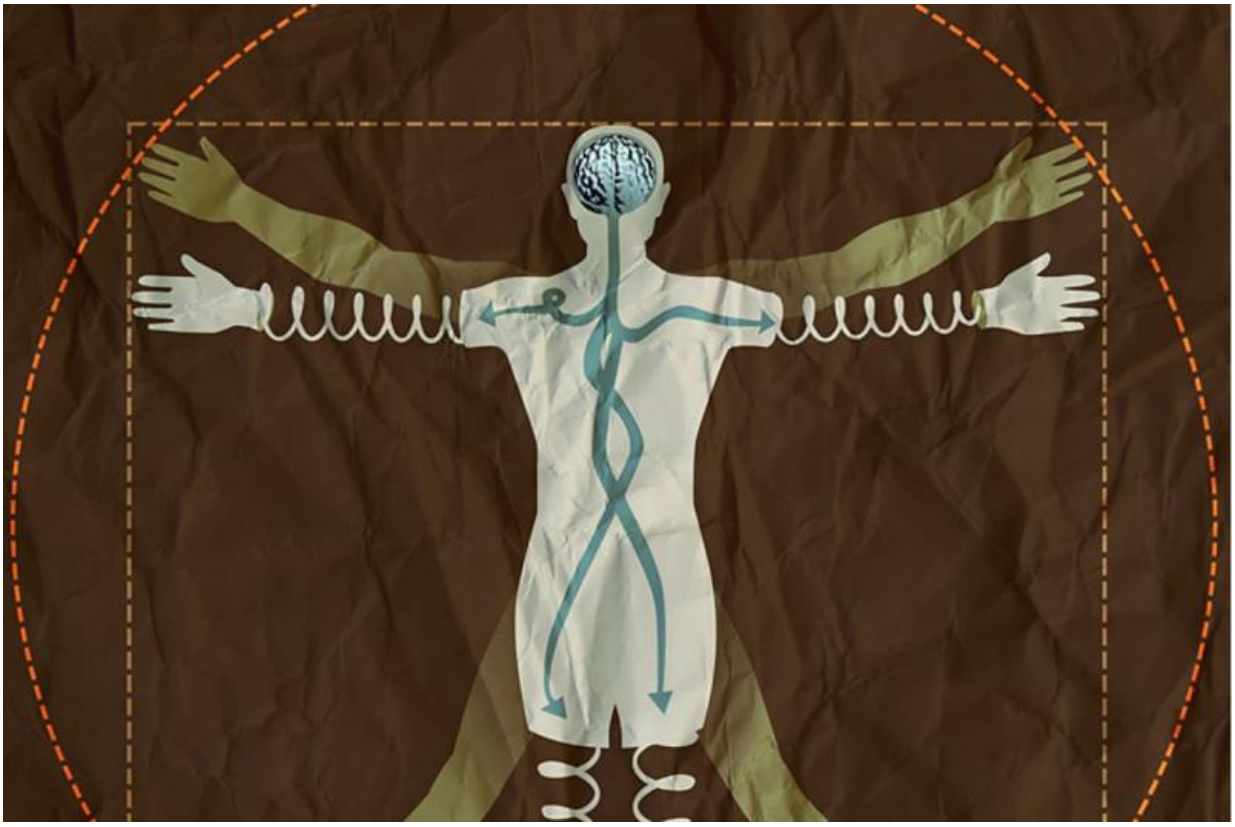

Dr. Matthew Tremblay, who specializes in the care of patients with multiple sclerosis at UConn Health, discusses a new drug just approved by the FDA. Credit: Stock Image

Neurologist Dr. Matthew Tremblay, who specializes in the care of patients with multiple sclerosis at UConn Health, discusses the first drug

just approved by the FDA for patients with difficult to treat primary progressive MS.

Q. What is multiple sclerosis?

A. Multiple sclerosis is believed to be an autoimmune disease that results in damaging inflammation of the brain and spinal cord. The damage occurs to a material known as myelin, which coats the axons [projections of nerve cells], allowing signals to conduct rapidly from one part of the nervous system to another.

Q. What are the symptoms of MS and the different types?

A. The most common form of MS, referred to as relapsing-remitting MS, is characterized by episodes or attacks with new neurologic symptoms caused by active inflammation in an area of the brain or spinal cord. The inflammation eventually subsides, allowing spontaneous recovery from symptoms after a period of weeks. Common symptoms of an MS relapse or attack include new numbness, tingling, or weakness in an area of the body, painful loss of vision, vertigo, double vision, and sometimes other less common symptoms. Other chronic symptoms that patients with MS experience can include fatigue, difficulty controlling bladder function, trouble with walking, and/or changes in sleep patterns and mood. A less common type of MS, affecting 10-15 percent of patients, is referred to as primary progressive MS. Unlike relapsing forms of MS, primary progressive MS patients develop chronic symptoms of MS – often gradual weakness and difficulty walking – without experiencing a relapse or attack. The difference between the two forms of MS, and specifically the mechanisms underlying disability progression, are not well understood.

Q. What can you tell us about the newly FDA-approved drug Ocrevus?

A. Ocrevus is a fully humanized monoclonal antibody against the CD20 marker on the surface of most B-cells, a type of lymphocyte responsible for producing antibodies against various pathogens and stimulating T-cells to attack similar pathogens. A similar medication was developed many years ago, called rituximab, which has proven to be successful for treatment of B-cell lymphomas and numerous autoimmune diseases, as well as MS. However, rituximab was only studied in a smaller phase 2 study in both relapsing and progressive MS nearly 10 years ago. Because of the smaller clinical trial, the medication was not considered by the FDA for the treatment of MS. Ocrelizumab was specifically tested in large-scale phase 3 trials for both forms of MS, with excellent efficacy. It will now be the first and only medication approved for the treatment of primary progressive MS.

Q. How does the drug work?

A. Ocrevus works by eliminating most of the B-cells in the body, without removing the stem cells needed to replenish the next generation of B-cells or the antibody-producing plasma cells necessary to maintain immunity from prior vaccinations and infections.

Q. What have studies shown about its effectiveness to help MS patients?

A. The OPERA I and OPERA II clinical trials demonstrated that Ocrevus is superior to an existing MS medication, Interferon beta-1a, for reducing MS relapses, MRI evidence of inflammation (referred to as gadolinium enhancement), and delaying physical disability related to MS. Also, the ORATORIO trial demonstrated that Ocrevus decreased

disability progression in patients with primary progressive MS when evaluated at both three-month and six-month intervals, as compared to a placebo. The study also found that patients on Ocrevus were less likely to have reduced walking speed compared to the pre-treatment measurements.

Q. Who is a candidate for the new drug?

A. Ocrevus was proven effective at treating both types of MS in the clinical trials published earlier this year in the New England Journal of Medicine. It is the first treatment to be approved by the FDA for patients with primary progressive MS. However, it is worth noting that the benefit in primary progressive MS may be appreciated mostly in a subset of patients who had evidence of inflammation on MRI studies and were younger in age.

Q. How does this drug change the care paradigm for current and new MS patients?

A. Ocrevus will change the care paradigm in a few ways. First, it will be the only FDA-approved medication for the treatment of primary progressive MS, for which there was previously no proven therapy to prevent disability progression. Second, Ocrevus is an infused medication that would only need to be administered twice a year. Lastly, safety can often be a barrier with MS medications, owing to the fact that they suppress the immune system. Ocrevus demonstrated similar safety to a medication that has been used for well over a decade. MS specialists will likely also draw on the experience with the medications predecessor, rituximab, to infer risks of serious infections.

Provided by University of Connecticut