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LATEST TECHNOLOGY DEVELOPMENTS

[A Busy Week for Multiple Sclerosis News](#)



It was good news for [Novartis](#) and bad news for [Merck KGaA](#) this week as regulators handed down their decisions on each company's multiple sclerosis (MS) drug candidate. On Wednesday, [Novartis'](#) Gilenya [became the first oral drug in the U.S.](#) approved to treat the chronic inflammatory disease. Gilenya is approved to reduce relapses and delay disability progression in MS patients.

[TheStreet.com reports](#) that Gilenya could be a game-changer, potentially racking up more than \$1 billion in peak sales. Current MS drugs, such as those made by [Biogen Idec](#), [Bayer](#), and [Teva Pharmaceuticals](#) are all administered by injection or infusion. Additionally, studies have shown Gilenya to be more effective than some current therapies at alleviating MS symptoms, and one study showed Gilenya to be more effective than [Biogen](#)'s Avonex at preventing relapses. [Biogen](#) also markets Tysabri, considered the most effective MS drug on the market, and is currently developing two other MS therapies.

The news wasn't as good for [Merck KGaA](#), as it was [announced](#) Friday that European regulators had rejected the German pharmaceutical company's MS drug cladribine. The European Medicines Agency did not believe that the benefits of the drug outweighed its risks. European authorities were concerned about a potential cancer risk and the drug's effect on the immune system. [Merck](#) believes that cladribine has the potential to generate \$1.5 billion in annual global sales and is considering an appeal of the decision. The FDA is expected to rule on cladribine in the fourth quarter of 2010. In recent months, [Merck](#) won approval for cladribine in Australia and Russia. [Merck](#) currently markets Rebif, an injectible MS drug.

Multiple sclerosis, widely believed to be an autoimmune disease, affects the central nervous system by damaging the protective sheath surrounding nerve fibers. While it is unknown exactly how many Americans have the disease, approximately 250,000 to 350,000 million people in the U.S. are believed to have MS, according to the [National Institute of Neurological Disorders and Stroke](#). MS is an unpredictable disease that

produces a broad range of symptoms, including muscle weakness, paralysis, difficulty with coordination and balance, impaired vision, numbness or tingling, speech impediments, cognitive impairments, and more. Symptoms vary from patient to patient. MS has no cure, and current treatment options are limited, creating a high demand for promising new MS therapies.

Market research firm [Reportlinker forecasts](#) that the total worldwide market for MS disease-modifying therapies will grow at an 8.1% compound annual growth rate (CAGR) from 2010 through 2015, with sales increasing from \$11.3 billion in 2010 to nearly \$16.7 billion by the end of 2015. Research into the disease is going strong, and new findings, such as the discovery that [adding the asthma drug albuterol to standard MS treatments appears to help patients' symptoms](#), or the discovery that [immune cells appear to play a major role in nerve damage associated with MS in animal models](#), could be useful in the development of future MS treatments.

Companies currently developing MS therapies include [RhinoCyte](#), which is focusing on adult stem cell therapy for MS; and [Opexa Therapeutics](#), which is developing a therapeutic vaccine. Other companies developing MS treatments include [Acorda Therapeutics](#), [Peptimmune](#), [MediciNova](#), [Active Biotech](#) (which has licensed its oral MS drug, laquinimod, to [Teva Pharmaceuticals](#)), and [Adeona Pharmaceuticals](#).