FDA fast-tracks EMD Serono MS drug

Mass High Tech: The Journal of New England Technology

EMD Serono, which is developing an oral tablet for the treatment of Multiple Sclerosis, has received a priority review by the U.S. Food and Drug Administration. This means that the FDA will make a decision on approval of the drug target within six months, rather than the customary 10 months.

EMD Serono, based in Rockland, is an affiliate of German drug maker Merck KGaA,

“This is a critical milestone on the path to potential approval for short-course therapy with Cladribine Tablets, moving us one step closer to meeting an unmet need as an oral, disease-modifying drug available for relapsing MS,” said Fereydoun Firouz, president and CEO of EMD Serono, in a statement. “Our commitment to people living with MS is to transform the way they approach their therapy options, and priority review for short-course therapy with Cladribine Tablets means we are moving closer to delivering on this promise. We look forward to working with the FDA throughout the regulatory process.”

The company published the results of its Phase 3 study on the potential therapy in The New England Journal of Medicine in February. In May, it restarted its Stimuvax clinical program [1] for patients with non-small cell lung cancer.

Another oral tablet to treat MS, developed by Swiss drug maker Novartis, was given preliminary approval by an FDA advisory panel last month. A final decision on approval is expected by September. A final decision on the EMD Serono drug target would likely lag behind the Novartis decision .

SOURCE [2]

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