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FDA approval gives new hope to Multiple Sclerosis patients

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FDA approves Genzyme's AUBAGIO for Multiple Sclerosis

Singapore: Genzyme, a Sanofi company, received approval from the US FDA for AUBAGIO (teriflunomide) as a new once-daily, oral treatment indicated for patients with relapsing forms of multiple sclerosis (MS). AUBAGIO has shown significant efficacy across key measures of MS disease activity, including reducing relapses, slowing the progression of physical disability, and reducing the number of brain lesions as detected by MRI.

The ongoing AUBAGIO clinical development program, involving more than 5,000 patients in 36 countries, is amongst the largest of any MS therapy. Some patients in extension trials have been treated for up to 10 years. Interestingly, the AUBAGIO label includes a boxed warning citing the risk of hepatotoxicity and teratogenicity (based on animal data).

"We are very excited to introduce AUBAGIO as a new treatment option that can make a difference in the lives of people with multiple sclerosis," said Mr David Meeker, president and CEO, Genzyme. "The approval of our first MS therapy represents an important milestone for Genzyme and underscores our commitment to long-term leadership and partnership in the MS community."

"Many people living with MS struggle with the additional burden of injectable therapies administered daily to weekly," said Dr Aaron E Miller, medical director, Corinne Goldsmith Dickinson center for multiple sclerosis, Mount Sinai Medical Center. "The FDA's approval of AUBAGIO, a new oral treatment option, is an encouraging advancement for the MS community and may be a valuable treatment for people living with this often debilitating disease."

"We are greatly encouraged to see a new oral therapeutic option become available to people living with MS," said Dr Timothy Coetzee, chief research officer, National MS Society. "With collaborative research underway around the world, this is an extremely hopeful time for anyone who is diagnosed with MS."