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Genzyme multiple sclerosis drug gets TGA nod

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The TGA approval will enable health professionals to prescribe AUBAGIO 14 mg in Australia

Singapore: Australian therapeutic goods administration (TGA) has approved Aubagio (teriflunomide) 14 mg as a new once-daily, oral treatment indicated for patients with relapsing forms of multiple sclerosis (MS).

Aubagio is developed by Genzyme, a Sanofi company. The TGA approval will enable health professionals to prescribe Aubagio 14 mg in Australia, which is now the second country to gain marketing authorization for the treatment, following FDA approval in September.

"We are very pleased with the TGA approval of Aubagio that makes available a new option for healthcare professionals, and people living with MS in Australia who may benefit from this once-daily, oral treatment," said Dr Bill Sibold, head, multiple sclerosis, Genzyme. "The availability of Aubagio in the US and subsequent registration in Australia not only demonstrates our continued progress, it also reflects our commitment to deliver differentiated treatments and provide access for patients globally."

Aubagio is an immunomodulator with anti-inflammatory properties. Although the exact mechanism of action for Aubagio is not fully understood, it may result to a reduction in the number of activated lymphocytes in the central nervous system (CNS).

"We welcome the advent of a new oral treatment option for MS patients in Australia," said Professor Bill Carroll, chairman, MS Research Australia. "It is important for people with MS and their clinicians to have access to a range of well-tolerated and convenient therapies that may reduce the impact of the disease on their lives and suit their lifestyle."

Aubagio is marketed in the US and now Australia. Marketing applications for AUBAGIO are under review by the European Medicines Agency (EMA) and other regulatory authorities as well.