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FDA expands approval of Gilenya to treat MS in pediatric patients

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The US Food and Drug Administration (FDA) has approved Gilenya (fingolimod) for the treatment of children and adolescents 10 to less than 18 years of age with relapsing forms of multiple sclerosis (RMS), making it the first disease-modifying therapy indicated for these patients.

This approval expands the age range for Swiss pharma giant Novartis' blockbuster drug Gilenya, which was previously approved for patients aged 18 years and older with RMS.

Gilenya was granted Breakthrough Therapy designation by the FDA in December of 2017 for this pediatric indication. In the first quarter of this year Gilenya generated sales of $821 million, a year-on-year rise of 8%.

"For the first time, we have an FDA-approved treatment specifically for children and adolescents with multiple sclerosis," said Billy Dunn, director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research.

While MS is mostly diagnosed in adults, children and adolescents with the chronic disease often experience more frequent relapses and brain lesions than adults with MS.

"Since revolutionizing the treatment of relapsing MS as the first oral disease-modifying therapy, Gilenya has become an important mainstay of treatment for adult patients," said Paul Hudson, chief executive of Novartis Pharmaceuticals.