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# Novartis brain cancer drug gets FDA nod

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**FDA okays Afinitor Disperz by Novartis for children with rare brain tumor**

**Singapore:** The US Food and Drug Administration has approved Afinitor Disperz (everolimus tablets for oral suspension) by Novartis, a new pediatric dosage form of the anti-cancer drug Afinitor (everolimus) used to treat a rare brain tumor called subependymal giant cell astrocytoma (SEGA). Afinitor Disperz is the first approved pediatric-specific dosage form developed for the treatment of a pediatric tumor.

Afinitor Disperz is recommended to treat patients of one year and older with tuberous sclerosis complex (TSC) who are diagnosed with SEGA that cannot be treated with surgery. Prior to approval of this new dosage form, Afinitor was recommended for use only in patients ages 3 years old and older. Afinitor was granted accelerated approval in 2010 to treat SEGA in patients with TSC.

"Appropriate pediatric dosage forms, such as Afinitor Disperz, help to ensure the safe and effective use of oncology drugs in children," said Dr Richard Pazdur, director of the Office of Hematology and Oncology Products at the FDA's Center for Drug

Evaluation and Research. "In addition, today's approval demonstrates the value of further studying a drug to better characterize its benefits and how it should be used in pediatric patients."

Afinitor Disperz is available in smaller dose increments than the adult dosage form. It also dissolves easily in a small volume of water, making it easy to administer to patients who are unable to swallow whole tablets.

Afinitor's manufacturer, Novartis, also provided updated safety and efficacy data from the single-arm study of 28 pediatric and adult patients used to support the drug's accelerated approval in 2010 for the treatment of SEGA in patients with TSC. The company also supplied new information from a more recent study of 117 pediatric and adult patients who were randomly assigned to take Afinitor or a placebo daily. Results showed 35 percent of patients treated with Afinitor experienced tumor shrinkage, compared with none who were treated with placebo.

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Afinitor Disperz should be used only in patients with TSC who require treatment for SEGA that cannot be surgically removed. The most common side effects observed in patients with SEGA were mouth ulcers and respiratory tract infections.

Afinitor and Afinitor Disperz remain under accelerated approval for the treatment of SEGA in patients with TSC. Studies are ongoing to further evaluate the long-term safety and effectiveness of Afinitor and Afinitor Disperz in pediatric and adult patients with SEGA. Afinitor Disperz is classified as an orphan drug because it is intended to treat a rare disease or condition. Afinitor Disperz's application was granted priority review, which FDA completed in six months.