FDA approves Novartis brain tumour drug

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Swiss pharmaceutical company Novartis said Saturday that the US drug Food and Drug Administration had approved a drug for treating certain benign brain tumours which previously required surgery.

Everolimus, marketed as Afinitor, had been shown to be effective in reducing subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis, a genetic disorder affecting approximately 25,000 to 40,000 people, mainly children and adolescents, in the United States, it said.

Accelerated FDA approval was based on a study of 28 patients conducted by Cincinnati Children's Hospital Medical Center, in which nearly one-third of experienced a reduction of 50 percent or more in the size of their largest SEGA within six months, Novartis said.

The company said it was continuing to study the efficacy and clinical benefit of Afinitor in a wider trial, and had submitted marketing applications to the European Medicines Agency and the Swiss Agency for Therapeutic Products (Swissmedic).

If approved in the European Union for this indication, the treatment will be made available under the trade name Votubia, it said.

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