

FDA approves Ogsiveo for desmoid tumors

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The U.S. Food and Drug Administration has approved SpringWorks Therapeutics Inc.'s Ogsiveo (nirogacestat) tablets for adult patients with progressing desmoid tumors who require systemic treatment.

The Fast Track and Breakthrough Therapy-designated approval was based on results from an international, multicenter trial in which 142 [adult patients](#) with progressing desmoid tumors not amenable to surgery

were randomly assigned to receive 150 mg of Ogsiveo or placebo orally twice a day.

Results from the trial showed clinically meaningful and statistically significant improvement in progression-free survival for Ogsiveo compared with placebo. There was also a statistically significant benefit seen for Ogsiveo in the objective response rate (41 versus 8 percent). Additional benefit was seen for patient-reported pain favoring the Ogsiveo arm.

"Desmoid tumors are rare tumors that can lead to severe pain and disability," Richard Pazdur, M.D., director of the FDA Oncology Center of Excellence, said in a statement. "Today's approval will offer the first approved treatment option for patients beyond surgery and radiation."

More information: [More Information](#)

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