

Avastin dramatically improves response, survival in deadly recurrent glioblastomas

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The targeted therapy Avastin, alone and in combination with the chemotherapy drug CPT-11, significantly increased response rates, progression-free survival times and survival rates in patients with a deadly form of brain cancer that had recurred.

Patients with recurrent [glioblastoma](#) have a grim prognosis, and conventional treatments were typically limited to largely ineffective and highly toxic chemotherapies. Only about 5 percent of patients respond to further treatment - meaning their tumors shrink by 50 percent or more. And only 15 to 20 percent of patients make it to the six month mark before their disease progresses again. Survival is limited to six to seven months.

But a randomized Phase II study of Avastin alone and Avastin given with CPT-11 have improved those statistics, dramatically increasing response rates, progression-free survival times and overall survival. Early results from the study prompted the U.S. [Food and Drug Administration](#) to agree to an accelerated approval of Avastin in May 2009 for use in patients with recurrent glioblastomas, said Dr. Timothy Cloughesy, director of the Neuro-Oncology Program at UCLA's Jonsson Comprehensive Cancer Center and senior author of the study. The program allows provisional approval of medicines for cancer or other life-threatening diseases.

The study, conducted at 11 centers across the country, was published this week in the early online version of the *Journal of Clinical Oncology*.

"This is a huge breakthrough for us. In all the years we've been treating recurrent glioblastomas using conventional and investigational agents, we've never had anything like the responses we're seeing with Avastin," said Cloughesy, who also is a professor of neurology. "You just don't get these kinds of responses in this patient population. We're seeing dramatic improvements."

The two-armed study enrolled 167 patients with recurrent glioblastoma. One arm evaluated Avastin used as a single agent, the other Avastin given with CPT-11. An independent radiological facility was used to measure tumor responses, Cloughesy said.

In the Avastin only arm, 28.2 percent of patients responded to the treatment, meaning their tumors shrunk by 50 percent or more, a significant increase from the historic 5 percent response rates. Of the 80 patients, 42.6 percent surpassed the six month mark without their disease progressing, up from the historic 15 to 20 percent of patients. Survival was 9.2 months, a slight increase of the typical six to seven month survival time.

In the arm studying Avastin with CPT-11, 37.8 percent of patients responded to the treatment, while 50.3 percent surpassed the six month progression-free survival mark. Overall survival was 8.7 months, a little less than the Avastin only study.

Cloughesy believes the study shows the apparent power of Avastin when used alone in treating deadly brain cancers for which few effective treatments now exist.

"I think what this tells us is that the majority of the effects we're seeing are due to the Avastin," he said.

In addition, Avastin was well tolerated. While some serious side effects

were noted - brain hemorrhage, strokes and heart attacks - they were seen in a very small number of patients. Avastin also appeared to reduce brain swelling, allowing patients to significantly lower the steroid dose they had to take, eliminating a number of debilitating side effects.

"Because their brain swelling went down and they could lower their doses of steroids, some patients saw a marked improvement in function," Cloughesy said.

About 20,000 patients will be diagnosed with glioblastoma this year, of those 14,000 will die.

The last new systemic therapy for recurrent glioblastoma was approved in 1976. Until Avastin, all other experimental therapies tested in this type of cancer failed to meet the FDA guidelines for approval. It's vital that less toxic, more effective therapies are found to fight glioblastoma, Cloughesy said, both when it recurs and when it is first diagnosed. Studies are underway now to see if the study results can be validated in patients with newly diagnosed glioblastomas.

A significant study finding was that Avastin was nearly as effective alone as it was when given with [chemotherapy](#), but was much better tolerated. In consultation with their doctor, a patient facing less than a year to live might opt for [Avastin](#) alone to promote better quality of life and avoid the toxic side effects of chemotherapy.

Source: University of California - Los Angeles

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