Lessons learned from the bevacizumab experience.

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Abstract

BACKGROUND: Bevacizumab is an important agent in the oncologic armamentarium, with activity in a broad spectrum of solid tumors. It has been approved in the management of metastatic colorectal cancer, non-small cell lung cancer, renal cancers, and recurrent glioblastoma multiforme.

METHODS: We reviewed the published literature and briefing documents of the US Food and Drug Administration that provided the data leading to approval or change in approval status.

RESULTS: Bevacizumab initially received accelerated approval for the treatment of advanced breast cancer. However, lack of confirmatory data from additional clinical trials resulted in the loss of that indication. Both the expected and unexpected toxicities reported from clinical trials using bevacizumab have helped us to understand the drug's mechanism of action and to identify who are most likely to benefit from this important agent.

CONCLUSIONS: The side effects of treatment may provide important information about drug mechanism and efficacy. Bevacizumab is clearly an important agent in oncology and is likely to become more significant once a clinical or pathological marker to predict its efficacy has been identified.


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