# In the news

## A VAST INCREDULITY?

In a major set-back for Genentech, Avastin (bevacizumab) has not been approved for treating breast cancer by the US Food and Drug Administration (FDA).

Avastin has already proved successful against colorectal cancer (for which it was approved in 2004) and lung cancer (approved in 2006). It has been used by an estimated 200,000 patients in the United States and last year generated $1.7 billion for Genentech. With many doctors prescribing Avastin 'off-label' to treat metastatic breast cancer, Genentech were hoping that the clinical trial data that saw the drug approved in Europe would be accepted by the FDA. "There is no other way to say it: this was a surprise," said biotech analyst Christopher Raymond. "Regulators are starting to tighten the screws a bit" (http://www.latimes.com, 6 December 2007).

The FDA's advisory committee voted 5–4 against approval, illustrating how divided opinion is. The issue at stake was whether Avastin increased lifespan rather than merely extending progression-free survival. The conclusion was that it did not — "You've not shown these patients are living better, and certainly they are not living longer," said Maha Hussain, the committee's chair (http://www.nytimes.com, 6 December 2007). Moreover, concern was raised about the toxic side effects, with several deaths being attributed to the drug itself.

However, some pointed to the difficulty in measuring survival after trials have finished. "Many of my patients after their first-line approach go through five, six, seven additional regimens," said Gary H. Lyman, who voted in favour of approval. "One has to wonder if the survival differences aren't being clouded" (http://www.nytimes.com, 6 December 2007).

Genentech suggested that it might now seek conditional approval for the drug, with survival data to follow later, but in the meantime its share price dipped sharply.

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