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I cover science and medicine, and believe this is biology's century.

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A Triumph In Breast Cancer -- And Another Expensive Drug

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When there was a bit of debate about whether the Food and Drug Administration should withdraw Avastin's accelerated approval in breast cancer, I and others observed that the real complaint should have been that the FDA did not grant accelerated approval of another Roche drug, known as T-DM1.

T-DM1 bound a tumor-killing drug, DM1, to Roche's blockbuster drug Herceptin, or, as its generically known, trastuzumab. While Avastin had failed to show much efficacy in large studies, T-DM1 looked incredibly promising. But the FDA, while deciding correctly to yank Avastin's breast cancer claim, also decided to wait until similar large trials had proved that T-DM1 was effective.

Now those studies are complete and today the drug has been approved (http://www.gene.com/media/press-releases/14347/2013-02-22/fda-approves-genentechs-kadcyla-ado-tras/), with the name Kadcyla. Like Roche's Herceptin, Kadcyla is only effective in patients whose tumors test positive for a molecular marker called HER2. In a clinical trial, it helped women survive 5.8 months longer than did other approved drugs: Roche's Xeloda or GlaxoSmithKline (http://www.forbes.com/companies/glaxosmithkline/)'s Tykerb. There were fewer side effects.

That's great for patients. But this is one case where they probably should have had access sooner. And then there's the matter of the drug's price: $94,000 a year for the average patient. Genentech will provide the drug free to those who can't pay.

Genentech licenses technology used in Kadcyla from Immunogen.

A note on the name: Given the fact that the FDA tries to avoid lookalike drug names, how do we explain how similar Kadcyla is to Kalydeco, the cystic fibrosis drug from Vertex Pharmaceuticals?

Below is a statement from Genentech spokesman Ed Lang:

> The monthly cost of Kadcyla in the United States (http://www.forbes.com/places/united-states/) is $9,800. The estimated cost of a course of Kadcyla is approximately $94,000. This is based on people taking Kadcyla for 9.6 months.
>
> When pricing Kadcyla, we considered a variety of factors including that cost of the combination of Tykerb and Xeloda (approximately $10,460 per month) which is the current standard treatment in this line of therapy and the comparator in the pivotal EMILIA study.
>
> In the EMILIA study, people receiving Kadcyla survived a median of 5.8 months longer compared to those taking Tykerb and Xeloda. Fewer people who received Kadcyla experienced Grade 3 or higher (severe) AEs than those who received Tykerb and Xeloda (43.1% vs 59.2%). No new safety signals were observed and AEs were consistent with those seen in previous studies.
>
> As part of this approval, Genentech will initiate patient assistance programs for people taking Kadcyla through Genentech Access Solutions. These programs help people who might not be able to afford this medicine. People who do not have health insurance, or who have reached the lifetime limit set by their insurance company, might qualify to receive Kadcyla free of charge.