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Herceptin Case Study

Herceptin: 25 years of progress in breast cancer treatment

In late 2006, Genentech's <u>Herceptin</u> was approved in the adjuvant (early-stage) setting for HER2-overexpressing breast cancer based on data that demonstrated the largest improvement in survival for women with breast cancer in 25 years. The story of Herceptin, which started 25 years ago, sheds light on the nature of the risks involved in cancer research, the time and resources required to make significant progress in cancer treatment, and Genentech's commitment to testing our cancer medicines in earlier stages of the disease.

In the early 1980s, Genentech researcher Axel Ullrich was the first to clone the human gene for epidermal growth factor receptor, a protein that helps trigger epithelial cell division. Further experiments by Ullrich pointed to the existence of a distantly related receptor, which was cloned in collaboration with current Chief Executive Officer Art Levinson and other scientists at Genentech. The structure of this newly found gene, which we named

HER2, was revealed to be closely related to a known cancer-causing gene in chickens, raising the possibility that this human counterpart could play a role in human cancer. Genentech scientists began working to develop antibodies to the HER2 protein, aiming to determine whether these antibodies might inhibit the growth of certain cancer cells.

While waiting for a flight at the Denver airport after a scientific conference, Ullrich met University of California, Los Angeles oncologist Dr. Dennis Slamon, who had been studying cancer and was dedicated to finding more effective treatments for the disease. They began talking about their research projects, and before long realized that they should combine efforts.

In 1987, Slamon, Ullrich, and colleagues published data in Science showing that approximately 25 percent of women with metastatic (advanced) breast cancer had tumors that overexpressed the HER2 protein and that this type of breast cancer (HER2-positive) was a very aggressive form of the disease, with greater likelihood of recurrence and decreased survival compared to HER2-negative breast cancer.

By 1990, Genentech scientists had humanized an antibody directed against the HER2 protein. This antibody, which would become Herceptin, was shown to inhibit the growth of human breast cancer cells that overexpress HER2. Slamon, along with other physicians, began testing Herceptin in the clinical setting.

Genentech conducted Phase I trials in 1991 and Phase II trials in 1993. In March 1997, the pivotal Phase III trials showed that Herceptin in combination with chemotherapy improved survival in this very difficult-to-treat patient population. As the first in a class of targeted biologic therapies designed to seek and destroy specific cancer cells, Herceptin represented a new direction in cancer treatment and is considered by many to be an important first step towards 'personalized medicine.'

Herceptin was approved by the FDA in 1998 in the metastatic breast cancer setting. Based on its effectiveness in the metastatic setting, Genentech began studies to determine if Herceptin might be effective when used as adjuvant therapy for women with earlier stages of breast cancer.

In May 2005, data from a joint interim analysis of more than 3,500 patients showed that the addition of Herceptin to standard adjuvant therapy reduced the risk of breast cancer recurrence by 52 percent in patients with HER2-positive breast cancer compared to those who received standard adjuvant therapy alone. The data represented a major milestone in breast cancer research and gave new hope to women with early-stage HER2-positive breast cancer. The trials suggested that Herceptin plus chemotherapy could potentially prevent or delay early-stage HER2-positive breast cancer from developing into metastatic disease or stop the disease from coming back. On November 16, 2006, the FDA approved Herceptin, administered weekly, in combination with chemotherapy for the adjuvant treatment of HER2-overexpressing, node-positive breast cancer.

Genentech's focus is on understanding the fundamental biology by which cancer grows, in the hopes of changing the way cancer is treated. We have proven with Herceptin that when you understand the biology of a target, monoclonal antibodies can be a precise, effective and well-tolerated way to hit the target specifically and to help patients. Genentech has worked on the HER pathway for 25 years, and Herceptin, Tarceva, and other projects in our pipeline demonstrate our success and leadership in fully exploiting this important cancer pathway to advance cancer treatment.

The Herceptin adjuvant approval also highlights a first step in a major initiative to study Genentech targeted therapies in earlier stages of disease where they have the potential to have the greatest impact on patient survival. Making progress in cancer treatment takes tremendous time, persistence, patience and resources, but we couldn't be more excited about the kind of patient benefit that may occur when we test a therapy on patients in the early-stage setting.

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