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FDA Approves New Breast Cancer Drug Herceptin

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FDA APPROVES NEW BREAST CANCER DRUG THAT IS FIRST TO SUCCESSFULLY ATTACK GENETIC ALTERATION

The breakthrough breast cancer drug Herceptin was approved late Friday by the U.S. Food and Drug Administration, the first in an expected wave of new therapies that will attempt to beat back cancer by attacking the disease at its genetic roots.

Development of Herceptin was a joint effort of UCLA's Jonsson Cancer Center and the biotechnology company Genentech, Inc., of South San Francisco.

"This proves the paradigm that if we understand what is broken in the malignant cell, we may be able to fix it," said Dr. Dennis Slamon, director of the Revlon/UCLA Women's Cancer Research Program and leader of the Jonsson Cancer Center team that did the initial research leading to production of Herceptin.

"Decades of basic research are beginning to pay off with the development of new treatments like Herceptin," said Judith C. Gasson, director of the Jonsson Cancer Center. "We at the Cancer Center are honored and proud to have played a role in its development."

Hailed as a significant medical breakthrough in May after worldwide trials led to positive results in women with metastatic breast cancer, Herceptin received worldwide media attention after outcomes were announced at the American Society of Clinical Oncology in Los Angeles.

Herceptin can be effective for breast cancer patients who have an overabundance in their tumor cells of a gene called HER-2/neu. About 30 percent of women with breast cancer - or about 60,000 cases a year - fall into that category.

Taken once a week intravenously for 30 to 60 minutes, Herceptin does not cause the serious side effects associated with traditional chemotherapy, such as hair loss, nausea, fatigue and a drop in blood counts. A few patients who used Herceptin and the chemotherapy drug Adriamycin experienced cardiac abnormalities, but in most cases those problems responded to medication and patients were able to continue taking the antibody, Slamon said.

Herceptin works by halting the out-of-control growth prompted by an overabundance of the HER-2/neu gene.

The HER-2/neu gene produces a specific protein found on a cell's surface that acts like an antenna, receiving signals to grow. An overabundance of the gene means wild growth, and that translates into an aggressive cancer that grows and spreads quickly. Herceptin binds to the protein "antenna," preventing the cells from receiving and/or transmitting a growth signal.

Slamon emphasized that Herceptin does not work for all patients who have an overabundance of the HER-2/neu gene. However, researchers at UCLA's Jonsson Cancer Center are "working in the lab right now to find out why Herceptin does not help all women who overexpress the HER-2/neu gene," Slamon said.

During clinical trials, experimental Herceptin treatments were given to women for whom the best available standard chemotherapy was judged to be either a combination of the drugs Adriamycin and Cytosin or the single drug Taxol.

When taken in combination with the drugs Adriamycin and Cytosin, Herceptin resulted in a significant response (a 50 percent or greater measurable breast cancer reduction) in 52 percent of patients, as opposed to similar results in just 43 percent of patients who took Adriamycin and Cytosin alone. Therefore, using Herceptin in combination with Adriamycin and Cytosin was more than 20 percent more effective than using Adriamycin and Cytosin alone.

Results were even more impressive among women who took Herceptin in combination with the drug Taxol. While significant response to Taxol alone was only 16 percent, 42 percent of women taking Taxol in combination with Herceptin had significant responses, representing an improvement of 162 percent.

Overall, the Herceptin/chemotherapy combinations caused a significant decrease in measurable breast cancer in 48 percent of patients, whereas only 32 percent experienced significant response with chemotherapy alone. In other words, patients using Herceptin in combination with chemotherapy had a 50 percent better response rate than patients using chemotherapy alone. Moreover, that better response rate was accompanied by a greater than 60 percent increase in duration of the response over what was found in women treated with the chemotherapy alone.

Results of the Herceptin trials were announced by Slamon in May at the American Association of Clinical Oncology after a 2½-year worldwide study.

Women who participated in the trial were "randomized" so that about half received Herceptin combined with the best available chemotherapy, while the other half received chemotherapy alone.

Bakersfield resident Virginia "Ginger" Empey took Herceptin alone during clinical trials because she already had undergone her lifetime limit of chemotherapy. The 54-year-old former nurse continues to receive the antibody weekly at UCLA's Jonsson Cancer Center. Sentenced to a painful death by her former doctors more than three years ago, little evidence can be found today of the aggressive breast cancer that had spread to her liver.

"This drug gave me my life back," said Empey, who has lived to dance at her daughter's wedding and become a first-time grandmother. "I truly believe that. I'm so glad other patients will now be able to get Herceptin."

Three golf ball-sized tumors detected in Empey's liver more than three years ago now show up only as specks on her CT scans.

"They're so small the doctors don't know if they're tiny little tumors or just scar tissue," she said.

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Because of widespread medical need, the FDA designated Herceptin for fast-track consideration, taking less than six months to consider and approve the new drug. Genentech has been manufacturing Herceptin in anticipation of FDA approval, and company officials expect to begin distributing the drug within the next several weeks.

Herceptin could have ramifications for other cancers as well, Slamon said. About 20 percent of women with ovarian cancer, for example, overexpress the HER-2/neu gene, and Slamon said Herceptin may prove effective for women with that disease. Other cancers mentioned as potential Herceptin targets include gastric, endometrial, salivary gland, pancreatic, prostate, colorectal and non-small cell lung cancer.

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For more information about UCLA's Jonsson Cancer Center, its people and resources, visit our site on the World Wide Web at <http://www.cancer.mednet.ucla.edu>.

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