CANCER FACTS

National Cancer Institute • National Institutes of Health
Department of Health and Human Services

Herceptin® (Trastuzumab): Questions and Answers

1. What is Herceptin? How does it work?

Herceptin (trastuzumab) is a monoclonal antibody. It belongs to a group of drugs made in the laboratory that are designed to attack specific cancer cells. Herceptin is given intravenously (by injection into a blood vessel) to treat some breast cancers. Genentech, Inc., located in South San Francisco, manufactures Herceptin.

Herceptin targets cancer cells that "overexpress," or make too much of, a protein called HER–2 or *erb* B2, which is found on the surface of cancer cells. Herceptin slows or stops the growth of these cells. Herceptin is used only to treat cancers that overexpress the HER–2 protein.

Approximately 25 to 30 percent of breast cancers overexpress HER–2. These tumors tend to grow faster and are generally more likely to recur (come back) than tumors that do not overproduce HER–2.

The amount of HER–2 protein in the tumor is measured in the laboratory using a scale from 0 (negative) to 3+ (strongly positive). The result helps the doctor determine whether a patient might benefit from treatment with Herceptin. Patients whose tumors are strongly positive for HER–2 protein overexpression (a score of 3+ on the laboratory test) are more likely to benefit. There is no evidence of benefit in patients whose tumors do not overexpress HER–2 (a score of 0 or 1+ on the laboratory test).

2. How is Herceptin currently used in the treatment of cancer?

Herceptin is approved by the U.S. Food and Drug Administration (FDA) for the treatment of metastatic breast cancer (breast cancer that has spread to other parts of the body). Herceptin can be given by itself or along with chemotherapy.

Researchers continue to study Herceptin in clinical trials (research studies with people) (see questions 6 and 7). These studies can show whether new treatments are more or less effective than standard ones and how the side effects compare.

3. What are some of the common side effects of Herceptin?

Side effects that most commonly occur during the first treatment with Herceptin include fever and/or chills. Other possible side effects include pain, weakness, nausea, vomiting, diarrhea, headaches, difficulty breathing, and rashes. These side effects generally become less severe after the first treatment with Herceptin.

Patients who receive Herceptin along with chemotherapy may experience side effects that are different from those of patients who take Herceptin by itself. Patients should discuss any concerns about the side effects of treatment with their doctor. The doctor may be able to make suggestions for managing side effects.

4. Can Herceptin cause any serious side effects?

Herceptin can cause damage to the heart muscle that can lead to heart failure. Symptoms of heart failure include shortness of breath, difficulty breathing, a fast or irregular heartbeat, increased cough, and swelling of the feet or lower legs.

Herceptin can also affect the lungs, causing severe or life-threatening breathing problems that require immediate medical attention.

Herceptin may also cause allergic reactions that can be severe or life-threatening. These reactions can involve a drop in blood pressure, shortness of breath, rashes, and wheezing. These reactions may be more common in patients who already have breathing difficulties or lung disease.

Because of these potentially life-threatening side effects, patients are evaluated carefully for any heart or lung problems before starting treatment and are monitored closely during treatment. Patients who develop any problems during or after treatment should call the doctor immediately or go to the nearest emergency care facility.

5. How did scientists study the effectiveness of Herceptin before it was approved by the FDA?

The safety and effectiveness of Herceptin were studied in two clinical trials with women whose metastatic breast cancers produced excess amounts of HER–2. In one clinical trial, women received either Herceptin and chemotherapy or chemotherapy alone. The women who received Herceptin and chemotherapy had slower tumor growth, greater reduction in tumor size, and longer survival than the women who received chemotherapy alone. In another trial, women received Herceptin by itself. In 14 percent of these women, the tumor got smaller or disappeared. Scientists continue to study the safety and effectiveness of Herceptin in clinical trials (see questions 6 and 7).

6. Is Herceptin being studied to treat nonmetastatic breast cancer?

Yes. The National Cancer Institute (NCI) is sponsoring two large, multicenter phase III clinical trials of Herceptin as adjuvant therapy to treat node-positive breast cancer; this is breast cancer that has spread to the lymph nodes under the arm (regional lymph nodes), but not to other parts of the body. These trials will take place in hospitals and cancer centers around the country. Adjuvant therapy is treatment given in addition to the primary therapy to kill any cancer cells that may have spread, even if the spread cannot be detected by radiologic or laboratory tests.

- The National Surgical Adjuvant Breast and Bowel Project (NSABP) is comparing chemotherapy alone to chemotherapy plus Herceptin for patients with node-positive breast cancer. This trial will enroll 2,700 patients.

- The North Central Cancer Treatment Group (NCCTG) is leading an Intergroup study to compare three different treatments in patients with node-positive breast cancer. This trial will enroll 3,000 patients.

A third clinical trial comparing three different treatments in patients with node-positive breast cancer or patients with high-risk node-negative disease is being coordinated by the Jonsson Comprehensive Cancer Center at the University of California Los Angeles (UCLA) and the Breast Cancer International Research Group (BCIRG). High-risk node-negative patients include those who are under 35 years old or who have a tumor that is more than 2 centimeters (a little more than three-quarters of an inch) in diameter or a tumor that is estrogen- and/or progesterone-receptor negative (a tumor that does not depend on these hormones in order to grow). This trial will enroll 3,150 patients.

Patients who are interested in receiving Herceptin as adjuvant therapy for breast cancer should consider participating in a clinical trial. For more information about these and other clinical trials, patients and doctors may call the Cancer Information Service (CIS) (see below) or visit the NCI's Web site at http://cancer.gov on the Internet.

7. Is Herceptin under study for cancers other than breast cancer?

Yes. Herceptin is also being studied in clinical trials for other types of cancer, including osteosarcoma (a type of bone cancer) and cancers of the lung, pancreas, salivary gland, colon, prostate, endometrium (lining of the uterus), and bladder. Some patients with these types of cancer have tumors that overexpress the HER–2 protein. These patients will be possible candidates for clinical trials with Herceptin.

Researchers are exploring the use of Herceptin by itself and in combination with anticancer drugs. They are also investigating the use of Herceptin with other types of cancer treatment.

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Sources of National Cancer Institute Information

Cancer Information Service

Toll-free: 1–800–4–CANCER (1–800–422–6237)
TTY (for deaf and hard of hearing callers): 1–800–332–8615

NCI Online

Internet

Use http://cancer.gov to reach the NCI's Web site.

LiveHelp

Cancer Information Specialists offer online assistance through the *LiveHelp* link on the NCI's Web site.

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