HERCEPTIN® (Trastuzumab) is a recombinant DNA-derived humanized monoclonal antibody that selectively binds with high affinity in a cell-based assay (Kd = 5 nM) to the extracellular domain of the human epidermal growth factor receptor (HER2, also known as c-erbB-2, ERBB2, or ErbB-2) protein. The HER2 protein overexpression.

In vitro, HERCEPTIN® binds with high affinity in a cell-based assay (Kd = 5 nM) to the extracellular domain of the human epidermal growth factor receptor (HER2, also known as c-erbB-2, ERBB2, or ErbB-2) protein.

HERCEPTIN® binds to the HER2 extracellular domain with a dissociation constant of approximately 5 nM. This affinity is sufficient to achieve clinical benefits in HER2-overexpressing tumors.

HERCEPTIN® is a humanized, anti-HER2 monoclonal antibody, which provides neutralization of HER2 signaling.

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For patients with known or suspected human epidermal growth factor receptor 2 (HER2) positive metastatic breast cancer, HERCEPTIN® (trastuzumab) was shown in women with HER2-overexpressing breast cancer (34% of all women in the trial) receiving HERCEPTIN plus chemotherapy to live a median of 6.4 months longer than those receiving chemotherapy alone.

HERCEPTIN® (trastuzumab) is a recombinant, humanized, monoclonal antibody directed against the extracellular domain of the human epidermal growth factor receptor 2 (HER2) protein. HER2 is a member of the family of epidermal growth factor receptors. HER2 is a transmembrane glycoprotein which is expressed on the cell surface of many normal and malignant cell types. HER2 is overexpressed in a subset of breast cancers and the overexpression of HER2 correlates with decreased time to disease recurrence, increased risk of distant metastasis, and decreased overall survival.

INDICATIONS AND USAGE

For patients with known or suspected human epidermal growth factor receptor 2 (HER2) positive metastatic breast cancer, HERCEPTIN® (trastuzumab) in combination with chemotherapy significantly prolongs survival. HERCEPTIN® (trastuzumab) in combination with chemotherapy is indicated for the treatment of:

1. Women with metastatic breast cancer for whom an optimal medical therapy including surgery and radiation has failed, and who have received prior chemotherapy. HERCEPTIN® (trastuzumab) should be continued in patients who respond to the initial loading dose if the initial loading dose was well tolerated. HERCEPTIN® (trastuzumab) may be administered as a single agent or in combination with chemotherapy. HERCEPTIN® (trastuzumab) should not be administered to patients who are allergic to HERCEPTIN® (trastuzumab).

2. Women with metastatic breast cancer who have previously received chemotherapy and HERCEPTIN® (trastuzumab) is an option in this setting following progression on prior chemotherapy.

3. Women with HER2-positive early (non-metastatic) breast cancer and node-positive disease for whom adjuvant therapy is indicated. HERCEPTIN® (trastuzumab) may be given for up to 1 year in patients who respond to the initial loading dose if the initial loading dose was well tolerated. HERCEPTIN® (trastuzumab) may also be given with chemotherapy as a single agent. HERCEPTIN® (trastuzumab) should not be administered to patients who are allergic to HERCEPTIN® (trastuzumab).

4. Women with HER2-positive early (non-metastatic) breast cancer who have not received prior chemotherapy and HERCEPTIN® (trastuzumab) as a single agent or in combination with chemotherapy for up to 1 year in patients who respond to the initial loading dose if the initial loading dose was well tolerated. HERCEPTIN® (trastuzumab) should not be administered to patients who are allergic to HERCEPTIN® (trastuzumab).

5. Women with HER2-positive early (non-metastatic) breast cancer or HER2-positive locally advanced breast cancer who have not received prior chemotherapy. HERCEPTIN® (trastuzumab) may be administered as adjuvant therapy for up to 1 year in patients who respond to the initial loading dose if the initial loading dose was well tolerated. HERCEPTIN® (trastuzumab) should not be administered to patients who are allergic to HERCEPTIN® (trastuzumab).

6. Men with HER2-positive metastatic breast cancer for whom an optimal medical therapy including surgery and radiation has failed, and who have received prior chemotherapy. HERCEPTIN® (trastuzumab) should be continued in patients who respond to the initial loading dose if the initial loading dose was well tolerated. HERCEPTIN® (trastuzumab) may be administered as a single agent or in combination with chemotherapy. HERCEPTIN® (trastuzumab) should not be administered to patients who are allergic to HERCEPTIN® (trastuzumab).

HISTORY

HERCEPTIN® (trastuzumab) was developed by Genentech, Inc. in collaboration with Eli Lilly and Company. Herceptin was approved by the U.S. Food and Drug Administration on November 20, 1998.