Brand Name: Herceptin
Generic: trastuzumab
Type: monoclonal antibody
Year Accepted/Phase: 1998

Mechanism:

Trastuzumab works by binding to the extracellular domain of the HER2 protein, preventing HER2 from sending growth signals and marking the cancer cells for destruction by the immune system.

Chemical Structure: N/A

Indication:

Herceptin is indicated for the treatment of HER2-positive metastatic breast cancer, early-stage HER2-positive breast cancer as adjuvant therapy, and HER2-positive advanced gastric or gastroesophageal junction cancer.

Clinical trials:

HERCEPTIN-Study 648 (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/11521723/
Purpose: Evaluate the efficacy and safety of trastuzumab in combination with chemotherapy versus chemotherapy alone in women with HER2-positive metastatic breast cancer.
Dates: Results published in 2001.
Results: The addition of trastuzumab to chemotherapy significantly improved overall survival and progression-free survival compared to chemotherapy alone. Patients receiving trastuzumab and chemotherapy had a median overall survival of 25.1 months versus 20.3 months for those on chemotherapy alone. These findings led to the FDA approval of Herceptin for metastatic breast cancer in September 1998.

BCIRG 006 Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/21991949/
Purpose: Compare the efficacy of different adjuvant chemotherapy regimens with and without trastuzumab in patients with HER2-positive early breast cancer.
Dates: Results published in 2005.
Results: The trial showed that adding trastuzumab to chemotherapy significantly improved disease-free survival and overall survival in patients with early-stage HER2-positive breast cancer. The risk of recurrence was reduced by approximately 50%. This led to the approval of trastuzumab for adjuvant treatment in early-stage HER2-positive breast cancer in November 2006.

HERA Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/16236737/
https://pubmed.ncbi.nlm.nih.gov/28215665/
Purpose: Evaluate the efficacy and safety of trastuzumab as an adjuvant therapy in patients with HER2-positive early breast cancer.
Dates: Initial results published in 2005; long-term follow-up results in subsequent years.
Results: The trial demonstrated that one year of trastuzumab treatment after adjuvant chemotherapy significantly improved disease-free survival and overall survival compared to observation alone. Long-term follow-up confirmed the sustained benefits of trastuzumab in reducing the risk of cancer recurrence.

ToGA Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/20728210/
Purpose: Assess the efficacy and safety of trastuzumab in combination with chemotherapy for the first-line treatment of HER2-positive advanced gastric or gastroesophageal junction cancer.
Dates: Results published in 2010.
Results: The addition of trastuzumab to chemotherapy significantly improved overall survival compared to chemotherapy alone, with a median overall survival of 13.8 months versus 11.1 months. These results led to the FDA approval of Herceptin for HER2-positive advanced gastric cancer in October 2010.