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Pathway to Herceptin Success

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1908

Paul Ehrlich, MD, wins the Nobel Prize for his idea that antibodies could be used like magic bullets to treat disease.

1975

Georges Köhler, PhD, and César Milstein, PhD, uncover the technique for producing monoclonal antibodies. The pair win the Nobel Prize in physiology or medicine in 1984.

1985

HER2 gene discovered.

1987

Dennis Slamon, MD, PhD, and his colleagues publish data showing the link between HER2 overexpression and an aggressive type of breast cancer that affects 20 to 25 percent of the 213,000 women diagnosed with breast cancer each year.

1990

Genentech scientists humanize an antibody directed at HER2 that comes to be known as Herceptin.

Early 1990s

Phase I and II trials conducted.

1997

Phase III trials for Herceptin completed. Results show that Herceptin in combination with chemotherapy slows the progression of cancer and increases tumor shrinkage in metastatic disease.

Early 1998

Development begins for a diagnostic kit to screen breast cancer patients for HER2 overexpression.

May 1998

Genentech submits application for FDA approval of Herceptin.

December 2000

Phase III trials initiated to evaluate Herceptin in the adjuvant setting for breast cancer.

March 2001

Data from a phase III trial is published in *The New England Journal of Medicine* that shows a 25 percent increase in survival rate for women with HER2-positive metastatic breast cancer who receive Herceptin and chemotherapy compared with chemotherapy alone.

2002

FDA approves use of FISH (fluorescent in situ hybridization) gene amplification test for HER2 gene.

2005

Data from three large trials of Herceptin used in the adjuvant setting, presented at the annual meeting of the American Society of Clinical Oncology, show the drug reduces the risk of recurrence by 50 percent in HER2-positive breast cancer patients.

February 2006

Genentech submits application to the FDA for approval of Herceptin with chemotherapy in early-stage HER2-positive breast cancer in the adjuvant setting.