

FDA Approved Anti-HER2 Therapy for HER+ Cancer

Henry Hongrong Cai, MD* and Ayesha A Pandit, MD MS

Premier Research, 3800 Paramount Parkway, Morrisville, NC 27560, USA

MINI-REVIEW

According to US national Breast Cancer Foundation, 1 in 8 women in the United States will develop breast cancer in her lifetime. In 2020, an estimated 276,480 new cases of invasive breast cancer will be diagnosed in women in the U.S. as well as 48,530 new cases of non-invasive (in situ) breast cancer. 81% of breast cancer diagnoses in the United States are invasive. 20% of invasive breast cancers are found to have human epidermal growth factor receptor 2 (HER2) protein overexpression and/or HER2 gene amplification. HER2 was selected as target to develop monoclonal antibody therapy for HER2+ breast cancer and other HER2+ cancer.

In 1975, Georges Köhler, César Milstein, and Niels Kaj Jerne created monoclonal antibody (mAb) technique by using a mouse x mouse hybridoma. They shared the Nobel Prize in Medicine in 1984 for the discovery. Eight years later, in 1992 US FDA approved the first therapeutic mAb muromonab-CD3 (trade name Orthoclone OKT3) to reduce acute rejection in patients with organ transplants. Since then, genetic engineering technique was developed and used into preparation of humanized mAb. as of December 22, 2022, FDA has approved 151 therapeutic mAbs (not including two diagnostic mAb).

Among them total 58 of the mAbs are approved for treatment of cancer [1]. This mini review focuses briefly on the characteristics of total 12 anti-HER2 therapeutic antibodies approved by FDA for the treatment of breast cancer (Table) [2-13].

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*Corresponding Author

Henry Hongrong Cai, MD

Premier Research, 3800 Paramount Parkway,
Morrisville, NC 27560, USA,
Tel +1 252 230 6449

E-mail: henry.cai@premier-research.com;
drcai66@gmail.com

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Anti-HER2 Monoclonal Antibodies Approved By FDA

Approval on	MAH	Drug Name	Active Ingredients	Indication	Boxed Warning	Adverse Events
09/25/1998	GENEN TECH	HERCEPTIN	trastuzumab	Adjuvant Breast Cancer; Metastatic Breast Cancer; Metastatic Gastric Cancer	Cardiomyopathy; Infusion Reactions, Pulmonary Toxicity; Embryo-Fetal Toxicity	headache, diarrhea, nausea, and chills; congestive heart failure; neutropenia
06-08-2012	GENEN TECH	PERJETA	pertuzumab	metastatic breast cancer (MBC); Early Breast Cancer (EBC)	Left Ventricular Dysfunction; Embryo-fetal Toxicity	diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy
02/22/2013	GENEN TECH	KADCYLA	ado-trastuzumab emtansine (ADC Antibody Drug Conjugate, microtubule inhibitor)	metastatic breast cancer (MBC); Early Breast Cancer (EBC)	Hepatotoxicity, liver failure and death; reductions in left ventricular ejection fraction (LVEF)	fatigue, nausea, musculoskeletal pain, hemorrhage, thrombocytopenia, headache, increased transaminases, constipation and epistaxis
02/28/2019	GENEN TECH	HERCEPTIN HYLECTA	trastuzumab and hyaluronidase- oysk (Hyaluronidase increases absorption)	Adjuvant Breast Cancer; Metastatic Breast Cancer	Cardiomyopathy; Infusion Reactions, Pulmonary Toxicity; Embryo-Fetal Toxicity [Hypersensitivity and Administration-R elated Reactions (ARRs)]	fatigue, arthralgia, diarrhea, injection site reaction, upper respiratory tract infection, rash, myalgia, nausea, headache, edema, flushing, pyrexia, cough, and pain in extremity.
06/29/2020	GENEN TECH	PHESGO	Pertuzumab, trastuzumab, and hyaluronidase-zzxf	Early Breast Cancer (EBC); Metastatic Breast Cancer (MBC)	Cardiomyopathy; Embryo-fetal Toxicity; Pulmonary Toxicity:	diarrhea, alopecia, neutropenia, nausea, fatigue, rash, and peripheral neuropathy
12-01-2017	MYLAN GMBH	OGIVRI Biosimilar to HERCEPTIN	trastuzumab-dkst	Breast Cancer; gastric or gastroesophageal junction adenocarcinoma	Cardiomyopathy; Infusion Reactions, Pulmonary Toxicity; Embryo-Fetal Toxicity	fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash
12/14/2018	CELLTRION	HERZUMA Biosimilar to HERCEPTIN	trastuzumab-pkrb (modified Fc)	Adjuvant Breast Cancer; Metastatic Breast Cancer; Metastatic Gastric Cancer	Cardiomyopathy; Infusion Reactions, Pulmonary Toxicity; Embryo-Fetal Toxicity	fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash
01/18/2019	SAMSUNG BIOEPIS	ONTRUZANT Biosimilar to HERCEPTIN	trastuzumab-dttb	Breast Cancer; gastric or gastroesophageal junction adenocarcinoma	Cardiomyopathy; Infusion Reactions, Pulmonary Toxicity; Embryo-Fetal Toxicity	fever, chills, headache, infection, congestive heart failure,
03-11-2019	PFIZER	TRAZIMERA Biosimilar to HERCEPTIN	trastuzumab-qyyp	Adjuvant Breast Cancer; Metastatic Breast Cancer; Metastatic Gastric Cancer	Cardiomyopathy; Infusion Reactions, Pulmonary Toxicity; Embryo-Fetal Toxicity	fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash.
06/13/2019	AMGEN	KANJINTI Biosimilar to HERCEPTIN	trastuzumab-anns	Adjuvant Breast Cancer; Metastatic Breast Cancer; Metastatic Gastric Cancer	Cardiomyopathy; Infusion Reactions, Pulmonary Toxicity; Embryo-Fetal Toxicity	fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash.
12/20/2019	DAIICHI SANKYO	ENHERTU	fam-trastuzumab deruxtecan-nxki (ADC topoisomerase I inhibitor)	Metastatic Breast Cancer; Locally Advanced or Metastatic Gastric Cancer	Interstitial lung disease (ILD) and pneumonitis; Embryo-Fetal Toxicity	Neutropenia; Left Ventricular Dysfunction; fatigue, vomiting, alopecia, AST, ALT increased
12/16/2020	MACRO GENICS	MARGENZA	margetuximab-cmkb (modified Fc)	metastatic HER2+ breast cancer received >= prior anti- HER2 regimens	Left Ventricular Dysfunction; Embryo- Fetal Toxicity	fatigue/asthenia, nausea, diarrhea, vomiting, constipation, headache, pyrexia, alopecia, abdominal pain, peripheral neuropath

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