

Clinical trials of HER2 inhibitors for advanced breast cancer (metastatic) in all type of patients

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1 margetuximab

Trial	Treatments	Patients	Trials design and methods
margetuximab vs trastuzumab + chemotherapy			
SOPHIA <i>ongoing</i> [NCT02492711] n=NA follow-up:	Margetuximab Plus Chemotherapy versus Trastuzumab Plus Chemotherapy	patients with advanced HER2+ breast cancer who have received prior treatment with trastuzumab, pertuzumab, and ado-trastuzumab emtansine in the neoadjuvant, adjuvant, or metastatic setting, and who have received at least one, and no more than two, lines of therapy in the metastatic setting	

References

SOPHIA, :

2 pertuzumab

Trial	Treatments	Patients	Trials design and methods
pertuzumab + trastuzumab + aromatase inhibitor vs trastuzumab + aromatase inhibitor			
MO27775 <i>ongoing</i> [NCT01491737] n=NA follow-up:	-	patients with HER2-positive and hormone receptor-positive advanced breast cancer	open label
pertuzumab + trastuzumab + capecitabine vs trastuzumab + capecitabine			
IPHEREXA <i>ongoing</i> [NCT01026142] n=NA follow-up:	-	patients with HER2-positive metastatic breast can	
pertuzumab + trastuzumab + docetaxel vs trastuzumab + docetaxel			
neoSphere (Group B) , 2012 [NCT00545688] n=107/107 follow-up:	pertuzumab and trastuzumab plus docetaxel versus trastuzumab plus docetaxel	women with locally advanced, inflammatory, or early HER2-positive breast cancer	

continued...

Trial	Treatments	Patients	Trials design and methods
CLEOPATRA , 2012 [NCT00567190] n=406/402 follow-up:	pertuzumab plus trastuzumab plus docetaxel versus placebo plus trastuzumab plus docetaxel	patients with HER2-positive metastatic breast cancer	Parallel groups double-blind

References

MO27775, 0:

PHEREXA, 0:

neoSphere (Group B), 2012:

Gianni L, Pienkowski T, Im YH, Roman L, Tseng LM, Liu MC, Lluch A, Staroslawska E, de la Haba-Rodriguez J, Im SA, Pedrini JL, Poirier B, Morandi P, Semiglazov V, Srimuninnimit V, Bianchi G, Szado T, Ratnayake J, Ross G, Valagussa P Efficacy and safety of neoadjuvant pertuzumab and trastuzumab in women with locally advanced, inflammatory, or early HER2-positive breast cancer (NeoSphere): a randomised multicentre, open-label, phase 2 trial. *Lancet Oncol* 2012;13:25-32 [[22153890](#)] [10.1016/S1470-2045\(11\)70336-9](#)

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CLEOPATRA, 2012:

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Swain SM, Baselga J, Kim SB, Ro J, Semiglazov V, Campone M, Ciruelos E, Ferrero JM, Schneeweiss A, Heeson S, Clark E, Ross G, Benyunes MC, Corts J Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer. *N Engl J Med* 2015;372:724-34 [[25693012](#)]

3 trastuzumab

Trial	Treatments	Patients	Trials design and methods
trastuzumab + anastrozole vs anastrozole alone			
TAnDEM (Kaufman) , 2009 n=NA follow-up:	anastrozole (1 mg/d orally) with trastuzumab (4 mg/kg intravenous infusion on day 1, then 2 mg/kg every week) until progression versus anastrozole	postmenopausal women with human epidermal growth factor receptor 2-positive, hormone receptor-positive metastatic breast cancer	
trastuzumab + capecitabine vs capecitabine alone			
von Minckwitz , 2009 n=NA follow-up:	trastuzumab + capecitabine versus capecitabine alone	Patients with HER-2-positive breast cancer that progresses during treatment with trastuzumab	
trastuzumab + docetaxel vs docetaxel alone			

continued...

Trial	Treatments	Patients	Trials design and methods
Marty , 2005 [M77001] n=NA follow-up:	-	patients with human epidermal growth factor receptor 2-positive metastatic breast cancer administered as first-line treatment	
trastuzumab + lapatinib vs lapatinib alone			
Blackwell , 2010 n=NA follow-up:	lapatinib + trastuzumab versus lapatinib alone	women with ErbB2-positive, trastuzumab-refractory metastatic breast cancer	
trastuzumab + letrozole vs letrozole alone			
Huober , 2012 n=NA follow-up:	letrozole plus trastuzumab versus letrozole alone	patients with HER2-positive, hormone-receptor-positive metastatic breast cancer	
trastuzumab + paclitaxel vs paclitaxel alone			
Gasparini , 2006 n=NA follow-up:	trastuzumab + weekly paclitaxel versus weekly paclitaxel	patients with advanced breast cancer overexpressing HER-2.	
trastuzumab + standard chemotherapy vs standard chemotherapy alone			
Slamon , 2001 n=NA follow-up:	standard chemotherapy plus trastuzumab versus standard chemotherapy alone	women with metastatic breast cancer that overexpressed HER2	

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References

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4 trastuzumab emtansine

Trial	Treatments	Patients	Trials design and methods
trastuzumab emtansine vs lapatinib plus capecitabine			
EMILIA , 2012 [NCT00829166] n=496/495 follow-up:	Trastuzumab emtansine versus lapatinib plus capecitabine	patients with HER2-positive advanced breast cancer, who had previously been treated with trastuzumab and a taxane	Parallel groups

continued...

Trial	Treatments	Patients	Trials design and methods
trastuzumab emtansine vs usual care			
TH3RESA , 2014 [NCT01419197] n=404/198 follow-up:	trastuzumab emtansine versus physician's choice	patients with progressive HER2-positive advanced breast cancer who had received two or more HER2-directed regimens in the advanced setting	Parallel groups open-label

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TH3RESA, 2014:

Krop IE, Kim SB, Gonzalez-Martn A, LoRusso PM, Ferrero JM, Smitt M, Yu R, Leung AC, Wildiers H Trastuzumab emtansine versus treatment of physician's choice for pretreated HER2-positive advanced breast cancer (TH3RESA): a randomised, open-label, phase 3 trial. Lancet Oncol 2014 Jun;15:689-99 [24793816] 10.1016/S1470-2045(14)70178-0

Entry terms: ado-trastuzumab emtansine, trastuzumab-DM1, trastuzumab-DM1 conjugate, T-DM1 cpd, trastuzumab emtansine, huN901-DM1, Kadcyla

5 About TrialResults-center.org

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