

# Clinical trials of HER2 inhibitors for advanced breast cancer (metastatic) in HER2 positive patients

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## 1 margetuximab

Trial	Treatments	Patients	Trials design and methods
<b>margetuximab vs trastuzumab + chemotherapy</b>			
<b>SOPHIA</b> <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
<b>pertuzumab + trastuzumab + aromatase inhibitor vs trastuzumab + aromatase inhibitor</b>			
<b>MO27775</b> <i>ongoing</i> [NCT01491737] n=NA follow-up:	-	patients with HER2-positive and hormone receptor-positive advanced breast cancer	open label
<b>pertuzumab + trastuzumab + capecitabine vs trastuzumab + capecitabine</b>			
<b>PHEREXA</b> <i>ongoing</i> [NCT01026142] n=NA follow-up:	-	patients with HER2-positive metastatic breast can	
<b>pertuzumab + trastuzumab + chemotherapy vs trastuzumab + chemotherapy</b>			
<b>APHINITY (BIG 04-11)</b> <i>ongoing</i> [NCT01358877] n=NA follow-up:	-	HER2-positive nonmetastatic breast cancer	

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Trial	Treatments	Patients	Trials design and methods
<b>pertuzumab + trastuzumab + docetaxel vs trastuzumab + docetaxel</b>			
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	
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:

APHINITY (BIG 04-11), :

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
<b>trastuzumab + anastrozole vs anastrozole alone</b>			
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	
<b>trastuzumab + capecitabine vs capecitabine alone</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
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	
<b>trastuzumab + docetaxel vs docetaxel alone</b>			
Marty , 2005 [M77001] n=NA follow-up:	-	patients with human epidermal growth factor receptor 2-positive metastatic breast cancer administered as first-line treatment	
<b>trastuzumab + lapatinib vs lapatinib alone</b>			
Blackwell , 2010 n=NA follow-up:	lapatinib + trastuzumab versus lapatinib alone	women with ErbB2-positive, trastuzumab-refractory metastatic breast cancer	
<b>trastuzumab + letrozole vs letrozole alone</b>			
Huober , 2012 n=NA follow-up:	letrozole plus trastuzumab versus letrozole alone	patients with HER2-positive, hormone-receptor-positive metastatic breast cancer	
<b>trastuzumab + paclitaxel vs paclitaxel alone</b>			
Gasparini , 2006 n=NA follow-up:	trastuzumab + weekly paclitaxel versus weekly paclitaxel	patients with advanced breast cancer overexpressing HER-2.	
<b>trastuzumab + standard chemotherapy vs standard chemotherapy alone</b>			
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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### TAnDEM (Kaufman), 2009:

Kaufman, B Trastuzumab plus anastrozole versus anastrozole alone for the treatment of postmenopausal women with human epidermal growth factor receptor 2-positive, hormone receptor-positive metastatic breast cancer: results from the randomized phase III TAnDEM study. *J. Clin. Oncol.* 2009;27:5529-37 [[19786670](#)] [10.1200/JCO.2008.20.6847](#)

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von Minckwitz, G Trastuzumab beyond progression in human epidermal growth factor receptor 2-positive advanced breast cancer: a german breast group 26/breast international group 03-05 study. *J. Clin. Oncol.* 2009;27:1999-2006 [[19289619](#)] [10.1200/JCO.2008.19.6618](#)

von Minckwitz G, Zielinski C, Maarteense E, Vogel P, Schmidt M, Eidtmann H, et al. Capecitabine vs capecitabine+trastuzumab in patients with HER2-positive metastatic breast cancer progressing during trastuzumab treatment: The TBP phase III study (GBG 26/BIG 3-05) [Abstract 1025]. *American Society of Clinical Oncology.* 2008.

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### Huober, 2012:

Huober, J Higher efficacy of letrozole in combination with trastuzumab compared to letrozole monotherapy as first-line treatment in patients with HER2-positive, hormone-receptor-positive metastatic breast cancer - results of the eLEcTRA trial. *Breast* 2012;21:27-33 [21862331] [10.1016/j.breast.2011.07.006](#)

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## 4 trastuzumab emtansine

Trial	Treatments	Patients	Trials design and methods
<b>trastuzumab emtansine vs lapatinib plus capecitabine</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>EMILIA , 2012</b> [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
<b>trastuzumab emtansine vs usual care</b>			
<b>TH3RESA , 2014</b> [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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Entry terms: ado-trastuzumab emtansine, trastuzumab-DM1, trastuzumab-DM1 conjugate, T-DM1 cpd, trastuzumab emtansine, huN901-DM1, Kadcyła

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## 5 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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