

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

TrialResults-center www.trialresultscenter.org

1 combination with CT

Trial	Treatments	Patients	Trials design and methods
sorafenib + capecitabine vs capecitabine alone			
RESILIENCE , 2013 <i>ongoing</i> n=NA follow-up:	-	advanced HER2-negative breast cancer	
sorafenib + gemcitabine or capecitabine vs gemcitabine or capecitabine alone			
Schwartzberg , 2013 [NCT00493636] n=NA follow-up:	sorafenib (400 mg, twice daily) versus placebo	patients with HER-2-negative advanced breast cancer that progressed during or after bevacizumab	Parallel groups double-blind

References

RESILIENCE, 2013:

Baselga J, Costa F, Gomez H, Hudis CA, Rapoport B, Roche H, Schwartzberg LS, Petrenciuc O, Shan M, Gradishar WJ, A phase 3 trial comparing capecitabine in combination with Sorafenib or placebo for treatment of locally advanced or metastatic HER2-Negative breast Cancer (the RESILIENCE study): study protocol for a randomized controlled trial. *Trials* 2013;14:228. [[23876062](#)] [10.1186/1745-6215-14-228](#)

Schwartzberg, 2013:

Schwartzberg LS, Tauer KW, Hermann RC, Makari-Judson G, Isaacs C, Beck JT, Kaklamani V, Stepanski EJ, Rugo HS, Wang W, Bell-McGuinn K, Kirshner JJ, Eisenberg P, Emanuelson R, Keaton M, Levine E, Medgyesy DC, Qamar R, Starr A, Ro SK, Lokker NA, Hudis CA, Sorafenib or placebo with either gemcitabine or capecitabine in patients with HER-2-negative advanced breast cancer that progressed during or after bevacizumab. *Clin Cancer Res* 2013;19:2745-54. [[23444220](#)] [10.1158/1078-0432.CCR-12-3177](#)

2 combination with CT (without taxanes)

Trial	Treatments	Patients	Trials design and methods
bevacizumab + capecitabine vs capecitabine			
AVF2119g (Miller) cape , 2005 n=232/230 follow-up:	capecitabine + bevacizumab 15 mg/kg iv every 3 weeks versus capecitabine (2,500 mg/m ² /d) twice daily on day 1 through 14 every 3 weeks	patients with metastatic breast cancer previously treated with an anthracycline and a taxane	Parallel groups open US

continued...

Trial	Treatments	Patients	Trials design and methods
RIBBON-I (Robert) on top capecitabine , 2009 n=NA follow-up:	Capecitabine + bevacizumab 15 mg/kg iv every 3 weeks versus capecitabine (Cape; 2,000 mg/m(2) for 14 days),	irst-line treatment of human epidermal growth factor receptor 2-negative, locally recurrent or metastatic breast cancer	double-blind
bevacizumav + CT vs CT alone			
RIBBON-2 (Brufsky) , 2009 n=NA follow-up:	addition of BV to chemotherapies used as second-line treatment for MBC versus chemo+placebo	second-line treatment of human epidermal growth factor receptor 2-negative metastatic breast cancer	Parallel groups open 19 countries
bevacizumab + methotrexate vs methotrexate			
Burstein , 2005 n=NA follow-up:	-	-	

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RIBBON-2 (Brufsky), 2009:

Brufsky A, Rivera RR, Hurvitz SA, et al: Progression-free survival (PFS) in patient subgroups in RIBBON-2, a phase III trial of chemotherapy (chemo) plus or minus bevacizumab (BV) for secondline treatment of HER2-negative, locally recurrent or metastatic breast cancer (MBC) J Clin Oncol 28: 119s, 2010 (abstr 1021)

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3 combination with ET

Trial	Treatments	Patients	Trials design and methods
bevacizumab + endocrine therapy vs endocrine therapy			
LEA n=NA follow-up:	bevacizumab + letrozole/fulvestrant versus letrozole or fulvestrant	first-line therapy in postmenopausal patients with human epidermal growth factor receptor 2 (HER2) -negative and hormone receptor-positive advanced breast cancer	
cediranib + fulvestrant vs fulvestrant			
Hyams [NCT00454805] n=NA follow-up:	-	-	
enzastaurin + fulvestrant vs Fulvestrant			
De Jong n=NA	-	-	
Letrozole plus bevacizumab vs letrozole			
Dickler (CALGB 40503 , 2015 n=NA	-	-	

References

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4 combination with taxanes

Trial	Treatments	Patients	Trials design and methods
bevacizumab + docetaxel vs docetaxel			
AVADO (Miles) 7.5mg , 2010 n=248/241 follow-up:	bevacizumab 7.5mg/kg every 3 weeks plus docetaxel versus placebo plus docetaxel	first-line treatment of HER2-negative metastatic breast cancer	double-blind
AVADO (Miles) 15mg , 2009 n=NA follow-up:	-	first-line treatment of HER2-negative metastatic breast cancer	
bevacizumab + paclitaxel vs paclitaxel			
Martin bevacizumab , 2011 n=NA follow-up:	bevacizumab 10 mg/kg intravenously on days 1 and 15 of each 28-day cycle versus control	patients with HER2-negative locally recurrent or metastatic breast cancer	open design
motesanib + paclitaxel vs paclitaxel			
Martin (motesanib) , 2011 [NCT00356681] n=91/94 follow-up:	motesanib 125 mg orally once per da versus placebo	patients with untreated HER2-negative metastatic breast cancer	double-blind
sorafenib + paclitaxel vs paclitaxel alone			
Gradishar , 2013 n=NA follow-up:	paclitaxel (90mg/m ²), weekly, intravenously, 3 weeks on/1 week off) plus sorafenib (400mg, orally, twice daily) versus paclitaxel (90mg/m ²), weekly, intravenously, 3 weeks on/1 week off)	first-line therapy in patients with HER2-negative advanced breast cancer	Parallel groups double-blind
bevacizumab + taxanes vs taxanes			
E2100 (Miller) , 2007 [NCT00028990] n=368/354 follow-up:	paclitaxel + bevacizumab 10 mg/kg iv every 2 weeks versus paclitaxel 90 mg per square meter of body-surface area on days 1, 8, and 15 every 4 weeks	patients with metastatic breast cancer not previously treated	Parallel groups open
RIBBON-I (Robert) on top Tax or anthra , 2009 n=NA follow-up:	Taxanes or anthracyclines + bevacizumab 15 mg/kg iv every 3 weeks versus taxane (Tax) -based (nab-paclitaxel 260 mg/m ²), docetaxel 75 or 100 mg/m ²), or anthracycline (Anthra) -based (doxorubicin or epirubicin combinations [doxorubicin/cyclophosphamide, epirubicin/cyclophosphamide, fluorouracil/epirubicin/cyclophosphamide, o	irst-line treatment of human epidermal growth factor receptor 2-negative, locally recurrent or metastatic breast cancer	

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5 About TrialResults-center.org

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