

Randomized comparison of neoadjuvant docetaxel (D), epirubicin (E) and pegfilgrastim (P) (+ trastuzumab [T] in HER2+ patients [pts]) with and without capecitabine (C) for operable breast cancer (BC): Results of a planned safety analysis of ABCSG24.

Sub-category:

Adjuvant Therapy

Category:

Breast Cancer - Local-Regional and Adjuvant Therapy

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Abstract Disclosures

Abstract:

Background: ABCSG-24 is assessing the effect of adding C to DE and adding T to DE or DEC on pCR rate. Pts with operable BC (any T stage except T4d, N+/-, M0) scheduled for pre-operative chemotherapy six 3-weekly cycles of D 75 mg/m², d1 + E 75 mg/m² d1 + P 6 mg d2, ± C 1,000 mg/m² bid d1-14. After protocol amendment, HER2+ pts were also randomized to adjuvant ± neoadjuvant T. 04 to Nov 06, 262 pts were enrolled, including 29 HER2+ pts. 145 are evaluable (DE: 74 pts, 400 cycles; DEC: 71 pts, 344 cycles). The table shows grade 3/4 adverse events (AEs) in >2% of pts in either arm. Febrile neutropenia, serious AEs occurred in 22% vs 20% of pts in DE vs DEC, respectively. Fewer pts in the DE than in the DEC arm had dose reduction (0.5% vs 6.6% of cycles), withdrew consent (4% vs 13%) or were withdrawn by the investigator (17%). Reasons for withdrawal by investigator were: HFS, stomatitis, mucositis, diarrhea, vomiting, fatigue, asthenia, docetaxel hypersensitivity, and asymptomatic liver enzyme elevation. No serious toxicity has occurred with T. **Conclusions:** Despite infrequent grade 3/4 AEs in both arms, more pts in the DEC than in the DE arm were withdrawn, by either patient's or investigator's choice. Since May 06, no DEC pts have withdrawn consent due to improved pt education and symptom management. This finding reinforces the need for close monitoring and management of AEs. The addition of C to DE presents no safety concerns. Efficacy results are due

Grade 3/4 Adverse Events in >2% of Pts

	DE (n=74)	DEC (n=71)		
	G3	G4	G3	G4
Neutropenia	11%	11%	10%	10%
Thrombocytopenia	0%	0%	3%	0%

Infection	3%	1%	3%	0%
Diarrhea	4%	3%	3%	0%
Nausea	1%	0%	3%	0%
Hand-Foot Syndrome	0%	0%	4%	0%
Pain	3%	1%	1%	0%

► **Associated Presentation(s):**

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1. Tamoxifen, hot flashes, and breast cancer recurrence: Support for pharmacogenetics.

Meeting: [2007 ASCO Annual Meeting](#) Abstract No: 500 First Author: J. Mortimer
Category: Breast Cancer - Local-Regional and Adjuvant Therapy - Adjuvant Therapy

2. Tamoxifen-induced hot flashes are associated with estrogen receptor polymorphisms.

Meeting: [2007 ASCO Annual Meeting](#) Abstract No: 501 First Author: V. Stearns
Category: Breast Cancer - Local-Regional and Adjuvant Therapy - Adjuvant Therapy

3. Could treatment with tamoxifen be superior to aromatase inhibitors in early-stage breast cancer after pharmacogenomic testing? A modeling analysis.

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► **Abstracts by G. G. Steger:**

1. Brain metastasis-free survival in patients with HER2-positive metastatic breast cancer.

Meeting: [2011 Breast Cancer Symposium](#) Abstract No: 41 First Author: A. Berghoff
Category: Detection, Screening, and Imaging - Predictive and Prognostic Factors

2. Effect of change of body mass index (BMI) during therapy on the efficacy of endocrine therapy in premenopausal patients with breast cancer: An analysis of the ABCSG-12 trial.

Meeting: [2011 ASCO Annual Meeting](#) Abstract No: 514 First Author: G. Pfeiler
Category: Breast Cancer - HER2/ER - ER+

3. Impact of HER2-targeted therapy on overall survival (OS) in patients (pts) with HER2-positive (HER2+) metastatic breast cancer (MBC).

Meeting: [2011 ASCO Annual Meeting](#) Abstract No: 572 First Author: A. Berghoff
Category: Breast Cancer - HER2/ER - HER2+

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► **Presentations by G. G. Steger:**

1. Pathologic complete response (pCR) in patient subgroups: An analysis of ABCSG-24, a phase III, randomized study of anthracycline- and taxane-based neoadjuvant therapy with or without capecitabine in early breast cancer (EBC).

Meeting: [2010 ASCO Annual Meeting](#)

Presenter: [Guenther G. Steger](#)

Session: [Breast Cancer - Local-Regional and Adjuvant Therapy](#) (Poster Discussion Session)

2. 6 vs. 3 Cycles of epirubicin/docetaxel + G-CSF in operable breast cancer: Results of ABCSG 14.

Meeting: [2004 ASCO Annual Meeting](#)

Presenter: [Guenther G. Steger, MD](#)

Session: [Breast Cancer I](#) (Poster Discussion Session)

3. Fulvestrant beyond the second hormonal treatment line in metastatic breast cancer

Meeting: [2003 ASCO Annual Meeting](#)

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