

Media Release

Embargo: Wednesday 23 September, 2009, 13.15 CET

Abstract: A randomized phase III study comparing epirubicin, docetaxel and capecitabine (EDC) to epirubicin and docetaxel (ED) as neoadjuvant treatment for early breast cancer. First results of ABCSG-24, a trial by the Austrian Breast and Colorectal Cancer Study Group (ABCCSG).

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Presentation: ORAL presentation, Wednesday 23 September 2009, 13.15–13.30 CET, joint 15th ECCO and 34th ESMO, Berlin, Germany.

Capecitabine added to standard treatment given before surgery helps to eradicate tumours in patients with early breast cancer

The Austrian Breast and Colorectal Cancer Study Group present data which highlight benefits of adding capecitabine to epirubicin and docetaxel in the neoadjuvant setting

Berlin, Germany 23 September, 2009 - Data from the ABCSG-24 study presented today at the joint 15th ECCO and 34th ESMO congress in Berlin, Germany, show that adding capecitabine (Xeloda[®]) to anthracycline- and taxane-containing regimens prior to surgery (neoadjuvant therapy) completely eradicated the tumour in 24% of women with HER2-positive or HER2-negative early breast cancer. This is an impressive finding since the proportion of women

achieving total tumour eradication with standard chemotherapy* for HER2-positive or HER2-negative early breast cancer is less than 20% (range 6–18%).¹

“These new data show that adding capecitabine to epirubicin and docetaxel neoadjuvant regimens when treating women with early breast cancer, results in increased efficacy compared to epirubicin and docetaxel alone. This new data could lead to improvements in treatment for women with early stages of the disease as the increased efficacy may result in prolonged overall survival,” said Professor Günther Steger, Division of Oncology, Department of Internal Medicine I, Medical University of Vienna, General Hospital Vienna, Vienna, Austria.

Despite recent advances, there is still an unmet need in the treatment and management of early breast cancer with relapse occurring in approximately 30–50% of patients, depending on individual risk factors, even after chemotherapy.² In addition to the ABCSG-24 study, several other studies of neoadjuvant combination regimens that included capecitabine have shown positive efficacy results.^{3,4,5,6,7,8,9} The therapeutic success in these studies was measured as complete pathological response (complete disappearance of tumour cells in the breast and in the lymph nodes), which is a strong predictor for long-term survival.^{1, 10}

Breast cancer is the second most common cancer in the world and the most common cancer among women.¹¹ There are 1.1 million new cases of female breast cancer each year worldwide.¹¹

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Notes to editors:

About the study

The primary aim of the study was to evaluate the efficacy of capecitabine added to epirubicin and docetaxel for six cycles (EDC) compared with six cycles of epirubicin and docetaxel (ED) in terms of the achievable rate of pathological complete responses (pCR) at the time of surgery in women with early breast cancer.

Between November 2004 and November 2008, 536 patients with biopsy-proven operable breast cancer who were scheduled to receive neoadjuvant treatment were recruited to the study:

* anthracycline plus cyclophosphamide or anthracycline plus a taxane

- Cancers were of any clinical T-stage (except T4d), with or without nodal involvement and without distant disease
- 236 patients enrolled for each group including a 5% drop out rate to give 510 eligible patients
- Patients were stratified according to known risk factors and randomised to receive either six cycles of EDC every 21 days (E: 75 mg/m² i.v. and D: 75 mg/m² i.v. on day 1, C: 2 x 1000 mg/m²/day for 14 days orally) or six cycles of ED (identical treatment regimen without C).

Results to date show:

- 24.0% pCR for the capecitabine containing treatment arm vs 16.0% pCR without capecitabine (p=0.02)
- Toxicity of ED is increased with the addition of capecitabine, but side effects of the EDC regimen are well managed (94% of patients completing all six cycles of EDC compared with 96% completing six cycles for ED alone)

ABCSG - A Global Player In Clinical Oncology

The Austrian Breast & Colorectal Cancer Study Group (ABCSG) is a cooperative institution that was set up to conduct controlled clinical trials in breast and colorectal cancer and to facilitate communication and the dissemination of knowledge among scientists and others dedicated to the cancer problem. Since its establishment in 1984, a total of more than 20.000 patients have been enrolled in ABCSG investigations. In certain patient risk groups, ABCSG is currently recruiting up to 30 per cent of all Austrian breast cancer patients to their clinical trials. The ultimate goal of the ABCSG is to enhance the standard of cancer treatment in this country and abroad by developing innovative approaches and testing increasingly more effective therapeutic strategies. For more information visit: www.abcsq.com

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