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# Roche Pharmaceuticals

## Pilot Study Opens the Door for Avastin Use in Curative Setting for Women With Breast Cancer

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San Antonio, Texas (ots/PRNewswire) - - Roche in Collaboration With Genentech Commit to Large Phase III Adjuvant Clinical Programme Set to Unlock Avastin's Potential in Early Breast Cancer

According to new phase II study data, Avastin (bevacizumab) can proceed to be tested after breast cancer surgery in combination with anthracycline containing regimens. These findings pave the way for Avastin's use as a curative treatment for women with this devastating disease. Data presented today at the San Antonio Breast Cancer Symposium (SABCS) from the E2104 study showed that standard anthracycline-based chemotherapy (doxorubicin) can be added to Avastin after surgical removal of the breast tumour, without a concerning increase in the incidence of cardiac adverse events typically associated with this form of chemotherapy.

These data support the commencement of phase III adjuvant breast cancer clinical programme which will include over 10,000 patients with early stage breast cancer. Avastin already offers women with late-stage (metastatic) breast cancer the chance to live twice as long without their disease progressing(1).

"The unique way Avastin works also lends itself for use in women with earlier stages of breast cancer" said Dr Kathy Miller of Indiana University School of Medicine, USA and principal investigator of the E2104 study. "We now know that Avastin use in combination with anthracyclines does not result in concerning rates of cardiac dysfunction in the adjuvant setting and armed with this evidence Avastin's impact can be fully validated in a large worldwide phase III clinical trial programme."

Data from the E2104 study have shown that cardiac dysfunction is not a major concern with the treatment combination of Avastin and doxorubicin. As presented in SABCS, two patients with symptomatic congestive heart failure were reported in each of the 2 Avastin-containing treatment arms which included more than 100 patients each. This is within the range expected to occur with the use of anthracycline based chemotherapy alone.

Following the completion of the accrual of Avastin adjuvant colon cancer trials and now confirmation of the safety of Avastin in the adjuvant breast cancer setting, the phase III adjuvant breast cancer programme is already recruiting patients. The large adjuvant programme consists of 2 trials in HER-2 negative breast cancer patients:

- The E5103 study is set to include 4,950 patients and will compare Avastin with the addition of an anthracycline-containing chemotherapy course versus anthracycline-containing chemotherapy alone.

- The BEATRICE study will investigate Avastin in combination with standard chemotherapies compared to chemotherapies alone in 2,530 planned patients who are not candidates for hormonal therapy.

In addition, Avastin is being investigated in HER-2 positive breast cancer patients post surgery via the BETH trial. This study will investigate the addition of Avastin to Herceptin (trastuzumab) in combination with established chemotherapy regimen.

Worldwide, breast cancer is the leading cause of cancer death in women under the age of 55. Each year there are more than one million diagnoses and more than 400,000 deaths from breast cancer(2).

### About E2104

E2104 is a phase II study designed to evaluate the safety and feasibility of incorporating Avastin into an anthracycline containing adjuvant therapy regimen. The study included 226 women with lymph node positive breast cancer who have had already undergone surgical removal (mastectomy) of the lesion and lymph node dissection. The study was sponsored by the National Cancer Institute (NCI), part of the US National Institutes of Health, and conducted by a network of researchers led by the Eastern Cooperative Oncology Group (ECOG). Patients were sequentially assigned to one of two treatment arms:

- Treatment arm A received dose-dense combination of doxorubicin and cyclophosphamide with Avastin, followed by paclitaxel and Avastin, followed by Avastin alone. Avastin was given every 2 weeks at a dose of 10 mg/kg for 1 year.

- Treatment arm B was only different to arm A in that Avastin was introduced after completion of doxorubicin therapy in conjunction with paclitaxel. As with arm A, patients remained on Avastin for 1 year after Avastin initiation.

The primary objective of the study was to determine the incidence of clinically apparent cardiac dysfunction in patients with lymph node positive breast cancer treated with bevacizumab and dose dense doxorubicin/cyclophosphamide followed by paclitaxel (ddAC>T). Patients were evaluated clinically and with serial assessments of left ventricular function over the course of their treatment and for six months following treatment.

#### Additional information

- Roche in Oncology: [http://www.roche.com/pages/downloads/company/pdf/mboncology05e\\_b.pdf](http://www.roche.com/pages/downloads/company/pdf/mboncology05e_b.pdf)
- Roche Health Kiosk, Cancer: [http://www.health-kiosk.ch/start\\_krebs](http://www.health-kiosk.ch/start_krebs)

#### References

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- (1) Miller KD, et al. E2100 Breast Cancer Res Treat 2005;94:S6 (Abstract 3)
- (2) Kamangar F, et al. J Clin Oncol 2006; 24(14): 2137-50.

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