Response **I**n a**D**vanced br**E**ast cancer) is a global randomized double-blind placebo-controlled phase III study assessing the efficacy and safety of L-BLP25 in combination with hormonal treatment as first-line therapy for postmenopausal women with hormone receptor-positive, advanced BC. Here we present the design of the STRIDE study.

Methods: Eligible pts are postmenopausal women aged ⩾18 years with estrogen and/or progesterone receptor-positive, inoperable (by RECIST criteria) locally advanced, recurrent, or metastatic BC. They have HER2-negative disease and express ⩾1 of the following five HLA haplotypes: HLA-A2, -A3, -A11, -B7, or -B35. Accrual into the study is ongoing with a target of 909 pts to be recruited by approximately 180 sites in around 30 countries worldwide. In addition to receiving standard hormonal treatment (tamoxifen, anastrozole or letrozole), pts are randomized 2:1 to receive either 1000 μg L-BLP25 or placebo. Pts receive weekly subcutaneous vaccinations for 8 weeks, followed by maintenance vaccinations every 6 weeks until disease progression. Patients are stratified by disease stage, concomitant use of tamoxifen vs aromatase inhibitors, and exposure to prior adjuvant hormonal treatment. The primary endpoint is progression-free survival (PFS) time; secondary endpoints include overall survival time, objective tumor response, safety/tolerability, and quality of life. Exploratory biologic analyses are planned.

Results: The final analyses of PFS time and secondary efficacy endpoints will be conducted using data obtained when more than 586 progression-defining events have occurred in the study population.

Conclusions: The STRIDE study will investigate whether vaccination with L-BLP25 can extend PFS time in pts treated with hormonal therapy as first line therapy, who have inoperable, locally advanced, recurrent or metastatic BC.

Wednesday, 24 March 2010 18:15–19:15

POSTER SESSION

Targeting and profiling predictive and prognostic factors

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How the 70-gene tumour expression profile "MammaPrint" can assist in St Gallen 2009 treatment recommendations in 12 Italian hospitals

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Background: A microarray-based 70-gene tumor expression profile "MammaPrint" was established as a powerful predictor of disease outcome in breast cancer. The St Gallen 2009 recommendations include gene-expression signatures as an indicator for adjuvant therapy. Here we determined in a prospectively assessed Italian cohort how the 70-gene profile can assist in patient management.

Methods: MammaPrint was determined on 524 samples submitted in 2008 and 2009, from breast cancer patients (clinical T1−4N0−3M0) aged 26 to 98 years (median age 62 years). Fresh tumor samples were prospectively collected in 12 Italian hospitals by core needle biopsy or from a surgical specimen (study protocol MP 090). We assessed agreement between the treatment advice as recommended by the 2009 St Gallen Highlights and classification according to the 70-gene MammaPrint profile.

Results: According to the St Gallen 2009 treatment recommendations, 17 patients could forego any adjuvant treatment (<1cm, LN0, PVI 0). Of these patients, 9 (53%) were classified to be poor prognosis signature by MammaPrint. The 84 Her2+ patients would be recommended anti-HER2 treatment as well as adjuvant chemotherapy according to the 2009 recommendations. Of these patients, 11 (13%) were classified as good prognosis signature by MammaPrint. All 43 (ER−) patients who are recommended chemotherapy alone are classified as poor prognosis by MammaPrint. For the 380 ER+, HER2− patients, 9 would be recommended no adjuvant chemotherapy (Grade I and LN0 and 2 cm and ER >50%) and 199 would be recommended adjuvant chemotherapy being either Grade III, or ?4LN, or >5 cm, or ER < 50%. Of these 199 patients, 60 (30%) are classified as low risk by MammaPrint. The remaining 172 ER+, HER2− patients fall in the subgroup for which St Gallen 2009 states that they have characteristics that are not useful for decision making; MammaPrint classified 102 (59%) as poor prognosis and 70 (41%) as good prognosis. Clinical data collection for an additional 364 patients is pending.

Conclusion: Widespread use of the MammaPrint prognosis signature has been accomplished in Italian community hospitals. For the majority of patients (90%) the St Gallen Highlights 2009 either recommend or suggest considering treatment with cytotoxic adjuvant therapy for whom MammaPrint indicates a low risk of recurrence in 31% of cases, potentially sparing patients from adverse effects.

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Socioeconomic differences in breast cancer tumour size and relative survival in the Netherlands

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Background: Breast cancer is the most commonly diagnosed cancer among females in developed countries. Despite improvement in survival over the last years, socially deprived females with breast cancer seem to have a decreased survival; usually due to a higher stage of disease at diagnosis. Aim of this study was to assess differences in T-stage and survival according to socioeconomic status (SES) for females with breast cancer in the Netherlands.

Methods: All females diagnosed with breast cancer between 1995 and 2005 in the Netherlands were selected from the Netherlands Cancer Registry. Patients were linked to the database of the Netherlands Institute for Social Research which keeps record of the SES according to postal code. A multivariable logistic regression was used to assess factors associated with SES. Overall Survival (OS) and Relative Survival (RS) were calculated where RS was calculated as the ratio between the survival observed and the survival that would have been expected based on the corresponding general population.

Results: Overall, 127599 patients were included. There was an association between SES and T-stage at diagnosis ($p < 0.0001$) after adjusting for histology, grade, N-stage and M-stage. Both OS and RS were associated with SES, with a decreased survival for the patients with a lower SES. Overall, 5-year OS was 80% for the high SES group and 75% for the low SES group (HR 1.4 (95% CI 1.3−1.5; $p < 0.001$) and RS was 87% versus 83% (RER 1.3 (1.2−1.4; $p < 0.001$). The socioeconomic differences remained statistically significant ($p < 0.001$) after adjustment for age, years, grade, TNM stage and surgical treatment.

Conclusion: Socioeconomic differences in T-stage and survival were observed in the Netherlands. The higher T-stage at diagnosis of patients with a lower SES only partly explains the decreased survival for females with breast cancer. To improve the decreased survival further research is needed to identify reasons for these socioeconomic disparities.

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Molecular biomarkers to predict neoadjuvant chemotherapy response in breast cancer patients treated with weekly paclitaxel plus carboplatin

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Background: Previously, we have reported the weekly PCb (Paclitaxel + Carboplatin) regimen in neoadjuvant chemotherapy (NCT) for breast cancer had a pCR rate of 19.4% (SABCS 2009, abstract 1099). However, there is lack of reliable marker to predict the efficacy of PCb. To identify molecular biomarkers and built different models including various markers to predict the efficacy and to evaluate whether including candidate molecular markers can improve the predictive accuracy of model for predicting response of weekly PCb NCT.

Materials and Methods: Retrospectively analyzed patients treated with weekly PCb (Paclitaxel 80 mg/m^2 and Carboplatin AUC=2, given day1, day8 and day15 out of every 4 weeks) NCT, routine clinical and pathological markers as well as pCR status were collected. Hormonal Receptor (HR)