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### Docetaxel (T) given concurrently with or sequentially to anthracycline-based (A) adjuvant therapy (adjRx) for patients (pts) with node-positive (N+) breast cancer (BrCa), in comparison with non-T adjRx: First results of the BIG 2-98 Trial at 5 years median follow-up (MFU).

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#### BACKGROUND:

The activity of T in metastatic BrCa mandated evaluation as adjRx. We compared the efficacy of T with, or after A, both followed by CMF (cyclophosphamide/methotrexate/ 5-flourouracil), versus non-T adjRx.

#### METHODS:

Random assignment trial in resected N+ pts, 18-70 yrs, stratified by: center, 1-3 vs >3 nodes and age <50 vs > 50. The treatment arms were (mg/m<sup>2</sup>, intravenously unless otherwise stated): Ia: A 75 q 3 weeks x 4 ◊ CMF x3 (oral C 100 day 1-14, F 600 + M 40 d 1+8; q 28 days). Arm Ib; AC 60/600 x 4 ◊ CMF x 3. Arm II: A75 x 3 ◊ T100 x3 ◊ CMF x3. Arm III: AT 50/75 x4 ◊ CMF x 3. Pts subsequently

received hormono-(receptor+), and radiotherapy per local guidelines. Randomization was in the ratio (1:1:2:2). The trial was designed to have 80% power to detect a 78% hazard ratio (HR) for relapse in II+III v I, with final analysis at 1215, and interim at 405 and 810 events. The primary comparison between the II+III and I would be done at a one-tailed significance level of 0.025. Secondary comparisons of II vs Ia and III vs Ib would be done using a closed testing procedure at a one-tailed significance level of 0.025. The 95% confidence limits of the HR of III v II would be calculated. Due to a low relapse rate, the plan was amended with main analysis after 810 events or 5 years MFU.

#### RESULTS:

2887 pts were enrolled (6/1998 - 6/2001). Characteristics were well-balanced, 46% had >3N+. Grade 3/4 toxicity occurred in 22.9, 24.7, 35.3 and 28.6 % of pts in Ia, Ib, II and III respectively. At 62.2 months MFU (3/2006), 732 pts (25%) had events. Planned event-free survival (EFS) comparisons were:

#### CONCLUSION:

In this study, the HR for T v non-T adjRx was of borderline significance. There were possibly important differences related to schedule, sequential but not concurrent appearing superior to non-T adjRx. Overall survival analysis will require longer follow-up. Translational studies are underway. ▲

#### COMPARISON BETWEEN ARMS

#### H R [95% C.I.]

#### P-VALUE

A-T+AT vs A+AC (II+III vs I)

0.86 [0.74 - 1.00]

.051

A-T vs A (II vs Ia)

0.79 [0.64 - 0.98]

.035

AT vs AC (III vs Ib)

0.93 [0.75 - 1.14]

.48

A-T vs AT (II vs III)

0.83 [0.69-1.00 ]

Not planned