

TAC improves disease free survival and overall survival over FAC in node positive early breast cancer patients, BCIRG 001: 55 months follow-up.

Martin M, Pienkowski T, Mackey J, Pawlicki M, Guastalla JP, Weaver C, Tomiak E, Al-Tweigeri T, Chap L, Juhos E, Guevin R, Howell A, Fornander T, Hainsworth J, Coleman R, Vinholes J, Modiano M, Pinter T, Hugh J, Nabholz JM, Loret C, Rupin M, Blitz S, Riva A, Vogel C. On behalf of the BCIRG 001 Investigators.

This study accrued 1,491 patients from June 1997 to June 1999. The 1st planned interim analysis with a median follow-up of 33 months and 289 events presented at ASCO 2002 (Abs.141) showed significant improvement in disease free survival (DFS) in favor of TAC. This is the 2nd interim analysis at a median follow-up of 55 months with 399 DFS events. A statistical boundary of 0.001 for DFS adjusted for nodal (N) status was defined for this analysis.

Intent-to-Treat Efficacy Analyses Prospectively Powered (n=1,491)

| DFS | Hazard Ratio TAC/FAC (95% CI) | P-value |
|--|--|----------------|
| Adjusted for N status (Primary endpoint) | 0.72 (0.59-0.88) | 0.0010 |
| 1-3 nodes (n=923) | 0.61 (0.46-0.82)* | 0.0009 |
| 4+ nodes (n=568) | 0.82 (0.63-1.08)* | 0.1629 |
| Hormone Receptor Positive† | 0.73 (0.57-0.94) | 0.0132 |
| Hormone Receptor Negative† | 0.66 (0.47-0.93) | 0.0163 |
| Overall Survival | | |
| Adjusted for N status | 0.70 (0.53-0.91) | 0.0080 |

*Ratio of Hazard Ratios: 1.34 (0.90-2.00), p= 0.1476, †: Centrally reviewed

For DFS, there were 172 events on TAC and 227 on FAC: 80% and 75% of pts on TAC were alive and disease-free at 4 and 5 years respectively, vs. 71% and 68% on FAC. For OS, there were 91 events on TAC and 130 on FAC: 89% and 87% of pts on TAC were alive at 4 and 5 years respectively, vs. 85% and 81% on FAC. HER2neu amplification was centrally reviewed. TAC/FAC DFS hazard ratio was 0.61 (0.42-0.90; p=0.0118) in HER2+ pts, and 0.76 (0.58-0.99; p=0.0380) in HER2- pts. There were no changes in the toxicity profile since the first interim analysis. Conclusion: TAC significantly improves DFS and overall survival over FAC and should be considered to be one of the most active adjuvant treatments in patients with node positive early breast cancer.