FIRST SAFETY DATA FROM A RANDOMISED PHASE III (CIBOMA/2004-01/GEICAM 2003-11) TRIAL ASSESSING ADJUVANT CAPECITABINE MAINTENANCE THERAPY AFTER STANDARD CHEMOTHERAPY FOR TRIPLE-NEGATIVE EARLY BREAST CANCER

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BACKGROUND

- Patients with triple-negative breast cancer (TNBC) represent a high-risk group.
- Few standard (palliative) treatment options for this patient population are available.
- Capecitabine has proven efficacy in metastatic breast cancer; both as monotherapy and in combination with docetaxel.*
- In addition, capecitabine has a favourable safety profile characterised by minimal alopecia and myelosuppression.
- A large adjuvant trial programme is exploring the role of capecitabine in early breast cancer (Table 1).
- Preliminary data are promising, with interim efficacy data from the FinXX and ABCSG-24 trials.

OBJECTIVES

- To present interim safety data from CIBOMA/2004-01/GEICAM 2003-11, a multicentre, randomised trial assessing adjuvant capecitabine maintenance therapy after standard chemotherapy for triple-negative early breast cancer.
- Recruitment to the study is currently ongoing with accrual of 876 patients planned.

METHODS

Eligibility criteria
- Patients ≥18 years of age
- Operable node-positive (or node-negative with tumour diameter ≥1 cm).
- Centrally confirmed hormone receptor-negative, HER2-negative EBC.
- Operable node-positive (or node-negative with tumour diameter ≥1 cm).
- Baseline disease characteristics are also well balanced between the two treatment groups (Table 1).
- Apart from World Health Organization performance status (WHO PS) of 0 or 1, patients if possible PS 0.
- Adequate renal and hepatic function and performance status.

RESULTS

- 1,440 cycles of capecitabine were administered (median 8.0, range 0–8).
- 8 cycles.
- Median RDI of capecitabine was 90.0%.
- Five deaths occurred during the study: three in the capecitabine arm and two in the observation arm.

CONCLUSIONS

- CIBOMA/2004-01/GEICAM 2003-11 is the first prospective, adjuvant study to specifically target patients with TNBC in a large trial of capecitabine maintenance therapy.
- The safety profile of adjuvant capecitabine maintenance therapy is consistent with its known toxicity profile.
- More than 90% of patients are alive (64.7% at 5 years).
- Median survival is 57 months (95% CI 53–71).

REFERENCES