as on the issue of genetic predisposition and b) independent conduct of trials of aromatase inhibitors under the BIG umbrella.

S44 Review of Italian breast cancer study group (GROCTA) trials

F. Boccardo, A. Rubagotti, D. Amoroso. *On behalf of GROCTA, National Tumour Institute, Genoa, Italy*

The 1st GROCTA trial was aimed at comparing 5-yr TAM treatment to 10 CT cycles (6 CMF followed by 4 Epi-doxo monotherapy courses) in a group of 504 pre- postmenopausal, node +ve, ER +ve breast ca. pts. This study also included an arm combining TAM with CT, 10-yr results (15-yr results will be presented at the meeting) showed no difference between TAM and TAM plus CT, while both treatments were significantly superior to CT alone. Subgroup analysis according to menopausal status, no. of involved nodes, T size and T grade yielded comparable results. The results of this study prompted us to activate 2 further studies in ER +ve women. A confirmatory study (GROCTA 02) was performed in 244 pre- perimenopausal pts by comparing 5 yrs of TAM treatment (plus 2 yrs of GOS) to 6 CMF cycles. Again no difference has emerged so far between TAM and CMF at a m.f.u. time of 53 mos while CT appeared to be more toxic. Postmenopausal women were scheduled to receive 3 yrs of TAM treatment and then to be randomly allocated to further 2 yrs of TAM or to 2 yrs of low-dose AG (GROCTA 04B). This trial explored the possibility to circumvent TAM resistance with the sequential administration of an aromatase inhibitor. 659 pts have been entered since Sept. 92, 370 of whom have been randomized to TAM (n = 187) or AG (n = 183). Groups are well balanced with respect to age and major prognostic factors. Preliminary results (m.f.u. time = 36 mos) show no major difference in pts outcome, though AG was more toxic than TAM, confirming the feasibility of this approach. Therefore a new trial (ITA trial) with a similar design but employing a less toxic and possibly more potent aromatase inhibitor, i.e. anastrozole, in place of AG will be activated in 1998. The GROCTA 03 study investigated the potential superiority of alternating adjuvant CT over standard CMF. This study, which included 107 node +ve premenopausal women and was restricted to ER −ve pts, was prematurely closed because more pts allocated to the triple alternated CT appeared to have relapsed and died at the first interim analysis. Another innovative approach, i.e. the use of HD-CT, was explored by the GROCTA 06 trial which included 53 pts with 10+ nodes and an age of ≤55 yrs. These pts were scheduled to receive 3 standard CEF cycles

followed by one cycle of HD-CT (CYC, 5 g/m^2; VP-16, 1.5 g/m^2; CDDP, 150 mg/m^2) without any form of bone marrow rescue. This HD-CT program proved to be feasible without life-threatening side effects in most pts. However, it was not superior to CMF-based CT we had previously employed in a comparable group of pts in previous GROCTA trials. These findings prompted us to explore new HD-CT programs with the use of peripheral stem cell support and in addition the possible value of new drugs such as taxol and vinorelbine. New generation trials will explore also the value of new prognostic indicators such as tumour proliferative activity, which are prospectively used to allocate pts to different treatment options.

S46 Review on current trials of the German adjuvant breast cancer group (GABG)

M. Kaufmann. *GABG, Germany*

Objectives of currently active randomized trials of the GABG in women with primary breast cancer are:

(1) Risk orientated selection of patients by menopausal status, nodal involvement and hormonal receptor content
(2) Chemo-endocrine or endocrine-endocrine sequences in pre- and postmenopausal patients
(3) Chemo or endocrine therapy in premenopausal patients
(4) Reduction of local treatment (axillary surgery, radiotherapy)
(5) Dose-intensification in high risk patients
(6) Primary chemotherapy in operable breast cancer

The trial for an individual patient can be identified by the scheme as shown in the table below.

Table S46

Preoperative: <70 J., T-size >3 cm, N0–1, M0: primary chemotherapy: Doxorubicin + Docetaxel >70 J., T-size <3 cm, N 0, M0: GABG G: breast surgery +/− axillary dissection + TAM 5 yrs. *Postoperative:* (pT1–3, R0, M0, <70J.):

Status	Hormonal receptor	Nodal status			
		N 0	N 1–3	N 4–9	N 10+
Premenop.	R+	GABG A: Zol vs CMF × 3	ZEBRA (closed): Zol vs CMF × 6		GABG E: E_{120} vs. EC-CMF;
	R−	GABG B: CMF × 3 +/− Zol		GABG B*: EC × 4-CMF × 3 +/− Zol	Zander Trial;
Postmenop.	R+	T <1 cm, G 1–2 Lo Ro GBSG V: +/− Tam +/− RT		T >1 cm; N 0–9: ARNO-Trial Tam 2 yr. – Arimidex 3 yr. vs. Tam 5 yrs	IMA Trial;
	R−	GABG D: CMF × 3 +/− Tam		GABG D*: EC × 4-CMF × 3 +/− Tam	