Conclusion: Our study supports the prognostic impact of immunohistochemical detected cathepsin D expression in the epithelial component of breast cancer.

83 POSTER

A phase II study of a potent and selective aromatase inhibitor, anastrozole (ZD-1033), in Japanese postmenopausal women with advanced/recurrent breast cancer

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Purpose: This trial was conducted using two dose levels of 'Arimidex' (anastrozole) (0.5 mg or 1 mg once-daily), the aim being to determine the dose of anastrozole (ZD 1033) to be used in randomised comparative trials involving Japanese women.

Methods: The trial design was randomised, open-label, parallel-group. Patients were required to be postmenopausal with advanced/recurrent breast cancer. The primary endpoints were objective response and tolerability, with secondary endpoints including oestradiol (E2) measurements, and cortisol and aldosterone assessments.

Results: 73 postmenopausal patients entered the trial, 36 patients in the 0.5 mg group and 34 patients in the 1 mg group were eligible. Response rates (CR/PR) were 27.8% in the 0.5 mg group and 38.2% in the 1 mg group (n.s). Plasma E2 was significantly reduced from baseline with both doses of anastrozole (82% suppression with 0.5 mg and 81% with 1 mg being the maxium seen over the 12 week assessment period). There was no evidence of an effect upon adrenal steroidogenesis. Both doses of anastrozole were well tolerated (no toxicity's >grade 2), with no significant differences between the groups.

Conclusion: Based on the objective response data and oestradiol measurements, and since increased toxicity was not observed with the higher dose, anastrozole 1 mg was selected for further study in randomised comparative studies.

'Arimidex' is a trademark, property of Zeneca Limited

84 POSTER

The increasing of effect after discontinuation of the treatment with Taxotere in patients with breast cancer

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Purpose: 39 patients with morphologically proven advanced breast cancer were treated with taxotere. Taxotere was administered in dose 100 mg/m^2 every 3 weeks. As a premedication we used medrol instead dexametason.

Methods: 33 pts have received previously chemotherapy: neoadjuvant – 5 pts (2 – FAC, 3 – CMF), adjuvant – 23 pts (16 – CMF, 7 pts with anthracyclines), chemotherapy for advanced breast cancer had 18 pts (17 pts with anthracyclines, 1 pt – CMF).

Results: The results of treatment were the following: overall response was 20/39 (51.3%), CR – 3/39 (7.7%), PR – 17/39 (43.6%), SD – 7/39 (17.9%), PD – 12/39 (30.8%). 35% of pts achieved response after 3 cycles, and 100% – after 6 cycles.

Median survival overall group is 19.7 mo. One year survival is 82% of pts. The increasing of effect, that we observed in 6 pts after the stop of the treatment during follow up: in all 6 pts – after 3 mo, in 2 pts – after 6 mo. 1 pt achieved CR 3 mo later after treatment break. The duration of response was: PR from 9 to 25 mo, CR – 5 mo.

Conclusion: Taxotere is appears to be one of the most effective cytostatic agent against advanced breast cancer, and the effect can be increase after stop treatment. We consider the mechanism of this effect should be explain.

85 POSTER

Intratumoral focused chemotherapy with cisplatin/epinephrine injectable gel for palliative treatment of metastatic breast cancer

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Purpose: In a phase III study we are evaluating the safety and efficacy of intratumoral chemotherapy with cisplatin/epinephrine injectable gel (CDDP/epi gel) for local treatment of solid tumors of various histologies. The delivery system provides high tumor drug concentrations for extended periods.

Methods: Two identical, open-label studies enrolled patients with solid tumors who had failed previous therapy. CDDP/epi injectable gel was administered intratumorally (2 mg CDDP/cm^3 tumor) weekly for 6 weeks, or until objective complete response of all target tumors. Patients were then followed for 4 weeks. Evaluations included palliation or prevention of tumor-related symptoms for the most troublesome tumor (MTT), tumor response for the MTT and responses of all treated tumors (tumor response: ≥50% tumor volume decrease sustained ≥28 days), and adverse events.

Results: 30 patients with metastatic breast cancer represented the largest group of cancers treated in the ongoing study with 94 evaluable tumors (1–7 tumors/patient) treated to date. Total patient cumulative dose of 1 to 215 mg CDDP (median 27.4 mg) was administered in 1–6 intratumoral injections of CDDP/epi gel. Preliminary results show 6 of 30 (20%) patients had response of the MTT, and 11 of 30 (37%) patients had response of one or more tumors. Overall, 19/94 (20%) of all treated tumors had objective tumor responses. Treatment goals reflected the desire to improve function or disease management (wound care, pain control, tumor invasion). Ten of 30 patients (33%) attained the physician-selected primary treatment goal. Treatment with CDDP/epi gel was generally well-tolerated. Common toxicities (e.g., vomiting and nausea) of intravenous cisplatin were less frequent and easily managed with CDDP/epi gel.

Conclusion: Local tumor control with CDDP/epi gel provides a new therapeutic tool for management of solid tumors as a single modality and holds promise for use in combination with standard therapies.

86 POSTER

EORTC-IDBBC (Investigational Drug Branch for Breast Cancer): Seven years of active European collaboration

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IDBBC is a subgroup of the EORTC-Breast Group. The goals and a summary of the trials run till 1995 have been published recently (EJC 33: 1173, 1997). The following table summarizes the ongoing studies. More data from these studies will be presented at the conference.

Drugs	No. of pts Expected/entered	Comments
Doxo vs Doxo + CPA + Taxol	260/165	In collaboration with EORTC-ECSG (phase III).
Caelyx	32/14	6 week schedule (phase I–II). Accrual at 70 mg/m^2 is ongoing.
Docetaxel + Amifostine	21/18	Feasible. Toxicity of Docetaxel is less than expected!
Liarozole	116/110	Antitumor activity was seen. Significant GI and skin toxicity observed.
Exemestane vs Tamoxifen	100/39	First-line therapy (phase II).
Epirubicin (bolus) + CPA (bolus) + 5 FU (CI)	25/0 (feasibility)	Locally advanced disease. Escalating doses of Epirubicin.
Gemcitabine + 5 FU (CI)	15/0 (feasibility)	2nd or 3rd line therapy.

In parallel, the role of the MUGA scan in monitoring cardiac function, the pharmacokinetics of Docetaxel (± Amifostine) and Caelyx and the effects of Exemestane on the lipid profile and coagulation tests are under investigation.

87 POSTER

Topical use of Miltex® in patients with breast cancer's cutaneous manifestations

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Purpose: In patients with breast cancer's cutaneous manifestations first-line treatment includs local mamagement (surgical and/or radiotherapeutical). Also hormonal therapy and chemotherapy may be useful under certain clinical conditions. If traditional therapy is ineffective or impossible new