**OP1 ADHERENCE TO 6-MONTH ORAL ALPHA LIPOIC ACID FOR PREVENTION OF PLATINUM-INDUCED POLYNEUROPATHY**

Y. Guo *, J.L. Palmer, A. Forman, L. Ho, S. Tummala, M. Fisch. University of Texas M.D. Anderson Cancer Center, Houston, TX, USA

**Background:** Peripheral neuropathy induced by platinum-containing chemotherapy causes pain, and frequently becomes a dose-limiting factor for cancer treatment. The neurotoxicity appears to be irreversible; therefore prevention of neuropathy is necessary. Our aim was to determine whether α-lipoic acid (ALA, thioctic acid) can prevent peripheral neuropathy for patients receiving platinum.

**Methods:** Adult patients were randomised to receive either 600 mg ALA or placebo three times a day for 24 weeks. Neuropathy was measured by the FACT/GOG-NTX score, and pain was measured by the brief pain inventory (BPI).

**Findings:** Of the 243 patients randomised, 96 completed treatment for 24 weeks. At baseline, the ALA (n = 122) and placebo (n = 121) groups were comparable for age (58 ± 11 and 60 ± 11 years; p = 0.26), gender (51% and 49% male; p = 0.85), prior platinum exposure (p > 0.99), FACT/GOG-NTX score, and BPI score. At 24 weeks, only 43 evaluable patients remained in the ALA group, and 53 evaluable patients in the placebo group. The drop-out rate was 65% for the ALA group and 56% for placebo (p = 0.17). Reasons for drop-out were: withdrew consent (57 of 147, 39%), refused to take medication or non-compliant (35 of 147, 24%), lost to follow-up (2 of 147, 3%), death (2 of 147, 1%), change of chemotherapy regimen (8 of 147, 5%), physician decision (8 of 147, 5%), adverse effects (4 of 147, 3%), or other (31 of 147, 21%).

**Interpretation:** Intensive schedules of oral agents may be particularly challenging in the symptom-prevention setting. Strategies to gauge the pre-enrolment risk of non-adherence, and to monitor adherence, are worthy of further exploration.

**Funding:** YG and MF are supported in part by the National Institutes of Health. The authors declared no conflicts of interest.

**FOOTNOTE:** doi:10.1016/j.ejcsup.2011.02.002

---

**OP2 NAB-PACLITAXEL IN THE TREATMENT OF ADVANCED PANCREATIC CANCER REFRACTORY TO GEMCITABINE – FINAL RESULTS OF A PHASE 2 TRIAL**

G. de Lima Lopes a,*, P. Hosein b, C. Gomez b, V. Pastorini b, J. Macintyre b, M. Easley b, I. Reis b, J. Merchan b, P. Bejarano b, C. Rocha-Lima b. a Johns Hopkins Singapore International Medical Centre, Republic of Singapore. b University of Miami, Miami, FL, USA

**Background:** There are few treatment options for patients with advanced pancreatic cancer who do not respond to gemcitabine. Expression of secreted protein acidic and rich in cysteine (SPARC) might be a predictive marker of activity for nanoparticle albumin-bound (Nab)-paclitaxel (Nab-P). We aimed to assess the feasibility and efficacy of Nab-P in gemcitabine-refractory individuals, and the use of SPARC as a predictive factor.

**Methods:** In this phase 2 trial, patients with advanced pancreatic cancer refractory to gemcitabine and with ECOG performance status (PS) 0–2, received Nab-P 100 mg/m2 on days 1, 8, and 15 of a 28-day cycle. The primary endpoint was 6-month overall survival (OS). Secondary endpoints were response rate (by RECIST criteria), progression-free survival (PFS), safety and toxicity profile, and SPARC expression.

**Findings:** 19 eligible patients accrued. The median age was 61 years, nine patients were male, 18 had stage IV disease, and 15 had a PS of 0–1. 6-month OS was 58% (95% CI 33–76%), median OS was 7.3 months (2.8–13.3), and median PFS was 1.6 months (1.5–3.4). One patient had a partial response (PR) and six had stable disease (SD; three of which lasted longer than 6 months). After two cycles, the median CA 19-9 level decreased by 52% in patients who had SD or PR, versus 18% in patients with PD. Non-haematological toxicities were generally mild, with grade 1 or 2 nausea in 63% of patients, anorexia in 47%, hypocalcaemia in 37%, and vomiting in 26%. Grade 3 or 4 neutropenia, neutropenic fever, and anaemia occurred in 32%, 11%, and 11% of patients, respectively. There were no cases of grade 3 or 4 neuropathy. SPARC expression did not correlate with clinical outcomes.

**Interpretation:** Nab-P is active in pancreatic cancer refractory to gemcitabine. A randomised phase 3 trial is ongoing to confirm the efficacy of Nab-P in pancreatic cancer, and the usefulness of SPARC as a predictor of its activity.

**Funding:** Abraxis Inc.

**FOOTNOTE:** All authors receive research funding from Abraxis Inc, manufacturer of Nab-P.

**FOOTNOTE:** doi:10.1016/j.ejcsup.2011.02.003

---

**FOOTNOTE:** doi:10.1016/S1359-6349(11)00002-4