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inhibition (Bcl2 family, NFKB, IKB) and hypoxia (PAI-1, VEGF, OPN, HIF-1) in tumor tissue and surrogate specimens.

CONCLUSIONS

The 11 month median survival achieved with the addition of PS-341 to Gem/Carbo in this phase II study is unprecedented in prior SWOG trials in advanced NSCLC, and does not appear to be explained by altered patient characteristics. The toxicity profile of this regimen is favorable. A phase III trial of Gem/Carbo ± Bortezomib in advanced stage NSCLC is under development. Supported by CA38926, CA32102. ▲

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RESULTS:

250 patients were randomized 1:1. Overall PSA response rates were: DN-101: 63%, Placebo 52% ($p = 0.07$). Overall 18% (DN-101: 20%, Placebo: 16%) of patients entered the intermittent chemotherapy. The median duration of the first chemotherapy holiday was 16 weeks (range 4-74+) (DN-101: 15 weeks, Placebo: 16 weeks). Upon resumption of treatment after the first holiday, 50% of patients responded with a $\geq 50\%$ reduction in serum PSA from their post-holiday baseline, 35% met criteria for stable PSA for at least 12 weeks, and 15% progressed on therapy.

CONCLUSIONS:

This is the first report of intermittent chemotherapy in AIPC prospectively tested in a large multi-institutional trial. This strategy results in a clinically meaningful duration of chemotherapy holidays and can be offered to a minority (18%) of patients. Upon re-treatment, most patients (85%) again respond or stabilize PSA values. ▲

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healing, and bowel perforation in each arm. Confirmed ITT ORR (TREE1 vs. TREE2 respectively) = FOLFOX 41% vs. 52%, bFOL 20% vs. 39%, CapeOx 27% vs. 46%. Median TTP (months) + 95% CI (TREE1 vs TREE2 respectively) = FOLFOX 8.7 (6.5, 9.8) vs. 9.9 (7.9, 11.7), bFOL 6.9 (4.2, 8.0) vs. 8.3 (6.6, 9.9), CapeOx 5.9 (5.1, 7.4) vs. 10.3 (8.6, 12.5). Probability of survival at 18 months (TREE1 vs. TREE2 respectively) = FOLFOX 53% vs. 63%, bFOL 50% vs. 63%, CapeOx 49% vs. 68%. As of January 9, 2006, 56 TREE1 pts (38%) and 122 TREE2 pts (57%) are alive.

CONCLUSIONS

These data demonstrate these three Ox/FP regimens to be tolerable and effective. Addition of bev to Ox/FP regimens improves response rate and TTP with acceptable tolerability, and no unexpected toxicity. ▲

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rate according to International Working Group MDS criteria was 17% (15/89) for DAC vs 0% for SC ($p < 0.001$). Responses occurred in all IPSS groups and were also seen in pts with 5q and 7 deletions. Response rate was 13% (2/16) in pts with 5q deletions and 21% (4/19) in pts with 7 deletions. In pts without 5q or 7 deletions, response rates were 16% (11/67) and 14% (9/64), respectively. Complete cytogenetic responses were observed in 35% (9/26) of DAC pts vs 10% (2/21) of SC pts ($p = 0.08$, Fisher's exact). Also, 1 pt receiving DAC had a minor cytogenetic response. 10/10 DAC pts with cytogenetic response had clinical benefit (6 CR, 2 PR, 1 hematologic improvement, and 1 with normalization of marrow blast count). The primary toxicity was myelosuppression.

CONCLUSION:

DAC induces a substantial rate of cytogenetic responses in pts with MDS, suggesting that the clinical improvements induced by this agent are related to elimination of the neoplastic clone rather than to pure differentiation effects. ▲

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fatigue (14% \geq grade 3), GI events (\geq grade 3 diarrhea, abdominal pain, and nausea/vomiting in 5%, 4%, and 3%, respectively), and peripheral neuropathies (7% \geq grade 3). Hematologic toxicities were minimal except for transient thrombocytopenia (10% \geq grade 3), as previously seen with Vc.

CONCLUSIONS

This study confirms the activity of Vc in relapsed/refractory MCL in a multicenter international setting and supports its rapid development as a new treatment for relapsed MCL. Vc is also being studied in the first-line setting in combination with standard chemotherapy. ▲

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at all follow-up encounters.

RESULTS:

To date, 32 patients are evaluated, median age 35 years, 81% CT-naïve. Prior to CT, 97% of patients reported no more than a little interference with functioning from nausea. Most patients reported no significant interference with functioning due to nausea on days 1-4 of cisplatin (73% reported none/a little bit) and days 5-9 (87% none/a little bit). PALO + DEX was well tolerated; treatment-related adverse events were mild-moderate headache (18.8%), constipation (6.3%), and abdominal pain (3.1%), none serious.

CONCLUSIONS:

Three doses of PALO + 5 doses of DEX over an 8-day period effectively prevented both emesis and significant nausea in the majority of patients with germ cell tumors receiving multiple-day cisplatin-based CT. This regimen appears to be an improvement over historical CINV control. ▲