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TCF/CF pts); neutropenia was more frequent with TCF while anemia was less. With TCF/CF, 60-day all-cause mortality was 7%/9%. The TCF benefit/risk ratio tended to be less in pts  $\geq 65$  years.

**Conclusions:** Docetaxel is the first drug with a proven survival benefit in MGC. Tolerance of TCF and CF was limited in this sick patient population. Docetaxel combined with CF and appropriate risk management represents a new option for MGC. ●

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with a median follow-up time of 4.3 years (51 months). Intent to treat (ITT) analysis showed at least equivalence in terms of DFS between the treatment arms with a strong trend towards superior DFS for X vs. 5-FU/LV (HR = 0.87 [95% CI, 0.75-1.00],  $p = 0.0525$ ). Relapse-free survival (RFS) was significantly superior for X vs. 5-FU/LV (ITT: HR = 0.86 [95% CI, 0.74-0.996],  $p = 0.044$ ). These findings were confirmed in a multivariate analysis of DFS. X caused significantly ( $p < 0.001$ ) less all-grade diarrhea, nausea/vomiting, stomatitis, alopecia, and neutropenia, and less grade 3/4 neutropenia, stomatitis and neutropenic fever/sepsis than 5-FU/LV. Non-life-threatening hand-foot syndrome and hyperbilirubinemia were the only events reported more commonly with X than 5-FU/LV ( $p < 0.001$ ).

**Conclusion:** These updated findings with longer follow-up confirm the previously reported findings that X is at least equivalent to 5-FU/LV in terms of DFS. The superior efficacy of X over 5-FU/LV in metastatic disease (response rate) has translated into superior efficacy in the adjuvant setting (RFS). These findings provide a very clear rationale for replacing 5-FU/LV with X in the adjuvant treatment of colon cancer. ●

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dose; 6 pts started with amifostine 500 mg but required a dose reduction due to AEs, and 5/6 pts decreased their dose more than once.

**Conclusions:** SC amifostine was well tolerated by pts diagnosed with head and neck carcinoma in this prospective safety study, with a low incidence of severe (grade 3/4) targeted toxicities. ●

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mos LS BMD. Upfront ZA group shows a mean increase of 2.02% while the delayed group shows a mean decrease of 2.61%, resulting in a significant difference of 4.63% between groups ( $p < 0.001$ ). 347 of 602 pts (175 upfront/172 delayed) are evaluable for 12 mos TH BMD. Upfront ZA group shows a mean increase of 1.40% while the delayed group shows a mean decrease of 2.10%, resulting in a significant difference of 3.50% between groups ( $p < 0.001$ ). Serum markers of bone turnover (N-Telopeptide, Bone-Specific Alkaline Phosphatase) were collected and analyzed

on a subset of 226 pts at 3 month intervals for 1 yr. The results showed significant suppression of both markers over 12 mos in favor of upfront vs delayed ZA group. ZA was safe and well tolerated. Updated 12 mos BMD data on all pts will be presented at the meeting.

**Conclusions:** Upfront ZA prevents CTIBL in PMW with early BCa receiving adjuvant Let at 12 mos. ZA in combination with Let in this setting offers the potential to combine the anti-cancer efficacy of Let with the bone protective effect of ZA. ●

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prior chemotherapy for metastatic disease. All responses at 3 months were confirmed with a second CT scan at six months.

**Results:** 32 patients were accrued. The majority had visceral metastases (72%). Twenty tumors were either HER2 3+ and/or FISH+, the rest were either 2+ to 3+ or 2+. 30 were ER+ and 2 ER-, PgR+. Twenty-six had received prior tamoxifen the remaining six were endocrine-therapy naïve. Of 27 patients evaluable for response at the time of this report, there were 2 CR, 5 PR, 7 SD (at 24 weeks) and 13 PD giving an objective RR of 25% and clinical benefit rate (response or stable disease) of 52%. Median duration of response was 73 weeks (range 47 to 180+). The median overall TTP was 32 weeks (range 6 to 180+ weeks). Of the

remaining 5 patients, 2 have been followed for less than 24 weeks, 1 came off study early for toxicity and 2 withdrew consent before response could be assessed. 7 patients are still on therapy. The toxicities were mainly grade 1 to 2. The only serious complication was cardiomyopathy in a patient with prior doxorubicin and left chest wall irradiation.

**Conclusions:** TRAS with LET was well-tolerated and active with durable responses in about 1 in 4 patients. However, despite dual targeting, early progression occurred in 1 in 2 patients suggesting TRAS and AI have common resistance pathways. A final update and a central HER2 FISH analysis will be presented at the meeting. ●

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**Results:** 170 pts received either DAC ( $n = 89$ ) (3-hr infusion; 15 mg/m<sup>2</sup>/hr q 8 hrs for 3 days q 6 wks) plus SC or SC alone ( $n = 81$ ). Both groups were comparable for baseline characteristics. Response rate according to International Working Group (IWG) MDS criteria following a blinded, centralized bone marrow review, was 17% for DAC (9%, CR; 8%, PR) vs 0% for SC ( $p < 0.001$ ). Responses occurred in all IPSS groups. Responses were durable, lasting a median of 9 months. DAC responders vs all nonresponders had a median of 491 vs 274 AML-free days until death, a median of 657 vs 384 days of survival, and remained or became RBC/platelet transfusion independent during response. 7 of 15 pts

(47%) with CR or PR had a major cytogenetic response and 1 a minor cytogenetic response. Median TTAML/D in all pts was 340 days for DAC vs 219 days for SC ( $p = 0.043$  Wilcoxon, 0.160 Log-rank). Using a Cox proportional hazards model, the probability of progression to AML or death was 1.72-fold greater for SC than DAC ( $p = 0.017$ ). Quality-of-life evaluations showed DAC to be superior for global health status, physical functioning, fatigue, and dyspnea. As expected, the primary toxicity was myelosuppression, with the major Grade 3-4 toxicity being febrile neutropenia.

**Conclusion:** DAC is a promising therapy for MDS, with predictable toxicity. ●