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TUMOR BIOLOGY

An open-label trial of SMK treatment of advanced metastatic cancer.

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Abstract

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Background: SMK is a novel therapy that creates alteration in defenses to oxidative stress and increases free radical availability to the cancer cell. SMK is designed to penetrate the living cancer cells and introduce multiple mechanisms to kill the cell. Inducing transfer of electrons in the cancer cells allow catalyzed external free radicals to react and stress the cell. SMK is a combination of low dose agents used for non-cancer treatment. **Methods:** IRB approved study for metastatic cancer. No additional chemotherapy allowed. First 30 subjects meeting criteria were consented. SMK given orally and SQ, 5 days/wk, 6 weeks (1 cycle). Eligible subjects had cycles 2 and 3. **Results:** Average age 57.5 (30-81); 70% female; 30% Male. 90% Caucasian, 3.3% each- Asian, Hispanic, Native American. Cancer type: 43% breast, 20% lung, 10% pancreatic, 6.6% each: bile duct and prostate with bone metastasis, 3.3% each: colon, tongue, appendix and thyroid. 100% Breast cancer subjects had metastasis: 15% each: bone, lung, bone/lymph 8% each: lung, lymph, bone/brain/lung, bone/brain/spine, bone/liver, bone/brain, liver/bones/lymph. 10% treated for 1 cycle, 90% 2 -3 cycles. 13.3% maintained same ECOG rating. 76.6% had 1 pt, 6.6% had 2 pt, and 3.3% had 3 pt improvement. 13.3% had 1 pt decrease, 23.3% maintained the same, 63.3% had 1-3 pt improvement in health on EORTC (1-7) rating. 13.3% had a 1 pt decrease, 20% maintained the same, 66.7% had 1-4 pt improvement in quality of life on EORTC (1-7) rating. 56.6% gained 1-13lbs. 16.6% same weight, 26.6% lost 1-4 lbs. 73.3% had 1-8 pt. pain reduction (scale 1-10). 19.9% had minimal or moderate pain and maintained. 6.6% had minimal pain and had a 1 pt increase. 46.6% were on pain medication. 43% no longer needed pain medication after study. 100% Health and quality of life significantly improved: 16.6% show no uptake on a PT scan; 16.6% have significant reduction in quantity and/or size of the tumor; 26.8% have reduction in quantity/size of the tumor; 40% have a stable disease; 90% -Alive, median survival 257 days to date. 10% died, median survival 163 days.Total median survival 247 days (from first day of treatment). 100% had hyperpigmentation. No SMK related adverse events reported. **Conclusions:** SMK is a very promising treatment for metastatic cancer.

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