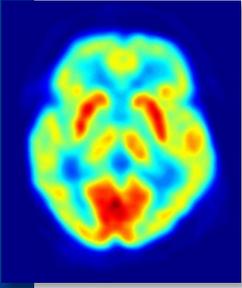
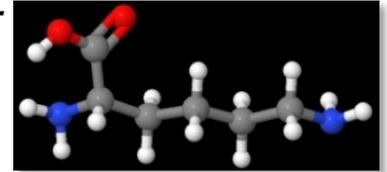


# Systemic Buffers as Inhibitors of Cancer Metastasis



*This technology is a method of preventing cancer metastasis using systemic, non-toxic buffers. Our studies show that our orally available systemic buffers significantly reduce the incidence of metastases in mouse models of human prostate and breast cancers. Prostate and breast are the most common cancer types in men and women and are the second leading causes of cancer related death in men and women. Our buffers may be developed into a preventative for controlling metastases from prostate, breast, and potentially other cancers in humans.*



## COMMERCIAL OPPORTUNITY

- 240,000 men a year are diagnosed with prostate cancer, and 20-30% will progress to metastatic disease despite therapy. 230,000 women a year are diagnosed with invasive breast cancer, and up to 50% of these women will progress to metastatic disease.
- The buffer will be targeted to men and women with locally advanced disease to prevent progression to metastatic disease, potentially in combination with current therapies. Currently there are approximately 55,000 men with non-metastatic castration-resistant prostate cancer and approximately 57,500 women with locally advanced breast cancer.
- The buffer could avoid expensive treatments for metastatic disease including Xtandi (Astellas) that costs \$90,000/year for metastatic castration-resistant prostate cancer, Sipuleucel-T (marketed as Provenge by Dendreon) that costs \$93,000/treatment regimen for metastatic castration-resistant prostate cancer, Faslodex (AstraZeneca) that costs \$10,000/year for metastatic breast cancer, and Herceptin (Roche) that costs \$54,000/year for metastatic breast cancer.
- Our buffers are orally available and non-toxic, which is a significant advantage over the current treatment options that cause serious side effects (such as anemia, neuropathy, osteoporosis, and/or seizures), and offer a unique and innovative approach to preventing deadly metastases.

## TECHNOLOGY

Our data demonstrate that a non-toxic systemic buffer, free-base lysine, added to drinking water, significantly reduces experimental metastasis in mice with prostate or breast cancer, compared to a control group given tap water only ( $p < 0.04$ ). Further study of experimentally induced metastases in mice showed a statistically significant increase in survival in lysine-treated mice ( $p < 0.05$ ). Studies have confirmed that the efficacy of lysine buffer is due to its buffering capacity, not metabolism of the amino acid. Ingestion of our buffers increase the buffering capacity of the blood, due to excess bicarbonate (a by-product from parietal cells) entering the bloodstream, that in turn inhibits low pH-dependent metastatic pathways. Our pending IP protection would cover non-toxic, non-volatile buffers used to inhibit metastasis through intratumoral extracellular pH, including the IEPA buffer.

## PUBLICATION/PATENT

- Hashim et al. (2011) *Clin Exp Metastasis*. 28(8): 841–849; Hashim et al. (2011) *J Cancer Sci Ther*; S1; Ribiero et al. (2012) *J Nutr Food Sci*, S2; Bailey et al. 2013 AACR Annual Meeting.
- US non-provisional patent application filed on 5/24/12 for Drs. Gillies, Morse, Silva, Hashim, Gatenby, and Martinez

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## LICENSING OPPORTUNITY



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