



Contact: Dr. Mary Lechowicz  
Email: mlechow@emory.edu

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### **KAPOSI SARCOMA PILOT TRIAL: VALPROIC ACID: AMC STUDY # 038**

ROCKVILLE, MD, MAY 11, 2011: Results from a pilot study of the safety of valproic acid in patients with Kaposi sarcoma (KS) and the effect this drug has on human herpesvirus 8 (HHV-8, the viral cause of KS) were recently published. Accumulating evidence from basic science laboratories has suggested that valproic acid, a medication commonly used to treat bipolar disease and other conditions, could have efficacy in the treatment of KS by inducing HHV-8 from a “latent” or mostly inactive life phase to a “lytic” or cycle of the viral life where the virus might be more amenable to antiviral or anticancer therapies. This was a prospective, single arm, open-label study which means that all participants received valproic acid and that no one was treated with a placebo.

A total of 18 patients received valproic acid orally for 28 days, followed by a 2 week period where the medication was gradually reduced and then stopped. Four of the patients had a modest shrinkage of their KS lesions; the remaining 14 participants had stable or slowly progressive KS. In no instance did KS lesions grow rapidly while patients were receiving the study drug, and valproic acid did not cause an increase in HIV viral loads. The drug had no measurable effect on HHV-8 activity, and valproic acid was well-tolerated by all study participants. The AMC is confident that new strategies and treatments will emerge that will help all patients with Kaposi's sarcoma.

**Reference:** Lechowicz M, Dittmer DP, Lee JY, et al. Molecular and Clinical Assessment in the Treatment of AIDS Kaposi Sarcoma with Valproic Acid. *Clin Infect Dis* 2009;49:1946-49.

<http://www.ncbi.nlm.nih.gov/pubmed/19911999>

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AIDS Malignancy Consortium Trial # 038: A Pilot Trial of Valproic Acid in Patients with Kaposi's Sarcoma

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<http://www.AIDSCancer.org>