**Title:** A Phase 1 Study of M032, a Genetically Engineered HSV-1 Expressing IL-12, in Canine Patients with Malignant Glial Brain Tumors

**Investigators:**
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**Study description:**
This multi-center study sponsored by the National Institute of Health investigates a novel immunotherapeutic approach for dogs with malignant brain tumors. The immunotherapy, which is an oncolytic virus, can replicate in glioma tumor cells and destroy them without affecting healthy cells in the brain. The virus will also cause tumor cells to secrete an immunity-stimulating protein (IL-12) before they die, which promotes an immune response against surviving tumor cells and thus increases the antitumor effect of the therapy. In addition, the IL-12 will interfere with production of new tumor blood vessels and thus starve the tumor of necessary nutrients. This same oncolytic virus is being used in a current FDA approved human brain tumor clinical trial at the University of Alabama.

Dogs diagnosed with a brain tumor using MRI images acquired at UGA or a referral practice and suggestive to be a glioma based on published characteristics will be eligible for the study.

**Inclusion criteria**
- Dogs between 1 and 10 years of age
- Dogs must be systemically well based on minimum database, history and physical examination
- Dogs must be judged to be only mildly neurologically affected by in-house neurologists based on (a) mentation level (b) normal cranial nerve function other than that associated with vision (c) absence of moderate or severe paresis (d) absence of moderate or severe ataxia (e) absence of compulsive demented behavior
- Dogs must be stable in terms of underlying seizure frequency, if any

All dogs will undergo a screening appointment which will include detailed history review, physical and neurologic examination, and routine labwork. Dogs meeting initial screening criteria will undergo anesthesia for surgery to remove as much of the brain tumor as possible, followed by implantation of a small catheter for delivery of post-surgical immunotherapy treatment. Immediately following surgery and within the same anesthesia event, dogs will undergo an abbreviated MRI to assess catheter placement and measurement of remaining tumor volume. If tumor histopathology confirms diagnosis of a glioma, dogs will receive a single infusion of immunotherapy approximately 24 hours postsurgery. Dogs will be monitored in the ICU for a minimum of two days following immunotherapy and will be discharged when it is clinically appropriate. Recheck examinations will be required at 14 days and also at 1, 3, 6, 9, and 12 months after surgery for repeat exam and labwork. Repeat MRI examinations will occur at the 1, 3, and 6-month rechecks.
If dogs appear to be deteriorating prematurely the owners may elect to pursue radiation therapy at their expense.

The surgery and implantation procedure, post-surgery MRI, post-operative hospitalization, and repeat MRI examinations and associated rechecks will be paid for by study funds as will any adverse events related to this course of treatment. The client will be responsible for costs of the initial referral exam and diagnostics leading to brain tumor diagnosis. Owners will also be responsible for costs of alternative treatments, such as radiation therapy.

**Duration of study:**
This study is currently OPEN. Study participation is 12 months duration following enrollment.

**Potential benefits to veterinary medicine:**
Results of this study may show that this novel immunotherapeutic approach for dogs with malignant brain tumors is efficacious and safe, and may lead to increased survival times, offering a viable alternative to surgery alone and/or radiation therapy.