Study Title

Pilot Study of AuroLase® therapy for the treatment of canine and feline solid tumors.

Department of Small Animal Clinical Sciences
Virginia – Maryland Regional College of Veterinary Medicine

You are invited participate in a research study for anti-cancer chemotherapy in dogs and cats. This study is being conducted by Dr. Nikolaos G. Dervisis, an oncology specialist at the Virginia – Maryland Regional College of Veterinary Medicine. We ask that you read this form and ask any questions you may have before agreeing to be in the study. You will have the opportunity to ask any additional questions you have before signing. You may decline to participate without any fear of negative consequences for obtaining any services at our institution.

PURPOSE

Modern cancer therapies utilize strategies that aim to eradicate the tumor while balancing out an acceptable preservation of form and function and quality of life. The currently accepted treatment modalities for dog and cat solid tumors include surgery, radiotherapy, chemotherapy, or any combination of the three.

We are investigating a gold nanoparticle-based, ablative technique (AuroLase®) that offers significant promise in its potential to provide local tumor kill precision while limiting normal tissue toxicity. This approach has the potential to directly benefit animals with naturally occurring cancer, as well as benefit indirectly human cancer patients, through advancement of our knowledge on cancer therapy.

CRITERIA FOR SELECTION

You were selected as a possible participant because your pet has been diagnosed with a solid tumor and may be a potential candidate for treatment with AuroLase® therapy, an experimental treatment modality.

Your animal may qualify for this study if:
1. Your dog is larger than 20 lbs (9 kg) or your cat is larger than 6.6 lbs (3 kg) of body weight.
2. Your pet has no other serious, life-threatening illness (heart, liver, or renal failure).
3. Your pet has received no chemotherapy in the past 3 weeks, or radiation in the past 6 months.
4. Your pet's renal and liver function is considered adequate based on a complete blood count and serum chemistry profile.
5. Your pet does not have significant metastatic disease that would reduce the prognosis to less than 1 month, if untreated.

**PROCEDURES**

If you agree to participate in this study we will perform the following procedures:

**Pretreatment evaluation**

Before beginning treatment your pet will undergo the following:

1. **Complete physical exam**
2. **Lab work:** We will obtain blood samples from your pet for a complete blood count and chemistry profile. Four to six mls (about 1 teaspoon) of blood will be collected from a vein in your pet’s neck, which is the easiest access point. We will also collect 5 mls of urine, either through cystocentesis or free catch. These are the standard methods for obtaining blood at the Veterinary teaching Hospital. This will be performed before your pet’s treatment.
3. **Staging:** We will obtain chest radiographs (3 views) and perform an abdominal ultrasound to evaluate for potential metastatic spread of the disease. If we discover any significant findings during the abdominal ultrasound, fine needle aspiration and cytology of the lesions will be attempted, as is the routine procedure in our clinic.
4. **Biopsy of the tumor:** A tumor biopsy may be obtained under general anesthesia, following strict aseptic technique, for definitive diagnosis.

**Treatment**

AuroLase® Therapy consists of two procedures:

1) **Infusion of AuroShell® Particles**
2) **Laser treatment of the targeted tumor.**

*These two procedures will be separated by 24 hours.*

**AutoShell® particle infusion** will be carried out in a fashion analogous to chemotherapy administration: a pouch or pouches of nanoparticles will be infused into a peripheral vein. The infusion will progress in two distinct stages: 1) an initial monitoring stage for the first 5 minutes to confirm particle tolerance, and 2) a main stage to complete the infusion. We expect the infusion to last for about 30min.

**The Laser therapy procedure** will be carried out with surgical asepsis and under general anesthesia. The Laser dose will be delivered either continuously or as a 75% duty factor pulses for 3 minutes at the tumor site.

Standard anti-inflammatory and pain medications will be provided to be used at home as needed.

**FOLLOW-UP**

Your pet will need to return to the Veterinary Teaching Hospital 3, 6, 12, 18, and 24 weeks after the treatment, as part of the follow up after the AuroLase® treatment. At each recheck visit, your pet will have a physical exam, and additional diagnostics if indicated. We ask that you keep the clinical oncology service and investigators informed on the status of your pet’s health.
**Risks**

Some of the procedures performed in this study are routine clinical procedures. **The AuroLase® therapy is experimental and not part of the standard treatment.** Side effects that may be seen in your pet during this study may include but are not limited to fever, tumor inflammation, tumor-site discomfort, systemic inflammation, risk for severe infection, and death.

Although unexpected, there could be problems with the diagnostic procedures (lab-work, staging, biopsy). These problems can be due to inflammation or infection and may result in bruising at the collection site. Additionally, all animals going under general anesthesia are in risk of adverse effects that may result even in death. We will try to minimize all these risks by taking extensive steps to prevent contamination of the biopsy site, and monitor continuously the vital functions of your pet when under general anesthesia and during the recovery period.

**Benefits**

We are trying to develop a new, more effective and safe therapy against cancer. In addition the study will cover completely the initial lab-work (CBC, chemistry, urinalysis), cost of the biopsy, the cost of the AuroLase treatment, and the cost of the scheduled follow-up visits.

**Compensation**

Once informed consent is obtained, the study will cover the expenses for the initial lab-work (CBC, chemistry, urinalysis), tumor biopsy and histopathology, the AuroLase treatment, and the scheduled follow-up visits. In addition, the study will provide a financial incentive of $50.00 for every scheduled follow-up appointment is completed on time. The compensation will be in the form of a credit to your hospital account. This compensation will only partially cover the cost all diagnostic procedures required for the diagnosis and treatment of the disease.

You are responsible for any other clinical fees associated with medical complications of the AuroLase therapy or other medical problems.

**Participation in this study is voluntary**

You will not be penalized in any way if you elect not to participate in the study. You can withdraw from the study at anytime.

**Confidentiality**

The specific information collected about you and your animal will remain confidential. However, overall findings of the study will be published to benefit other animals and researchers, without revealing the identity of the owner or the animals.

Please do not hesitate to contact the investigators or research coordinator if you have any questions.

**Investigator:** Nikolaos G. Dervisis, DVM, PhD, DACVIM (Oncology) – Phone: 540-231-4621

**Clinical Trials Coordinator:** Mindy Quigley – Phone: 540-231-1363

**Institutional Animal Care and Use Committee:** 540-231-0959
I understand the above information and agree to participate in this study.
I agree to allow my pet to participate in this study including all procedures described:

YES ☐  NO ☐

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Client Signature                   Date

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Attending Veterinarian or Technician        Date