Immunolight Therapy for Canine Cancer

Clinical Trial: Client Information

We greatly appreciate your interest in our clinical trial evaluating the benefit of Immunolight Therapy for the management of various cancers in dogs. Your pet's radiation oncology clinician will explain the disease characteristics of type of cancer, as well as the available treatment options. This handout will provide information regarding the clinical trial and explain your responsibilities, patient procedures, and associated risks, should you agree to have your pet participate.

Immunolight Therapy involves the use of ***psoralen***, a naturally-occurring compound found in broccoli and figs, as well as ***phosphors***, tiny particles that absorb energy from X-rays to emit UV light in and around cells. For decades, psoralen has been used to treat skin disorders, cancer and autoimmune disease. Immunolight Therapy converts penetrating forms of energy, such as low-dose radiation therapy, into energies that are capable of activating the drug inside the body. This activation generates light inside the tumor to induce an immune response against cancer–akin to a related technology (photopheresis) that has been successfully used to treat people with lymphoma of the skin. Immunolight Therapy has shown great promise in laboratory models of human breast cancer. Its short term safety has been documented in dogs; in that safety study, Immunolight Therapy also showed great promise as treatment for some kinds of cancer.

With the support of the Immunolight team, doctors in the department of Radiation Oncology at North Carolina State University's College of Veterinary Medicine are working with researchers at Duke University's School of Medicine to develop Immunolight Therapy as a treatment option for dogs with various tumors. The goal of this therapy is to provide an alternative treatment for cancer; the hallmark of Immunolight Therapy be a non-invasive, immune-based treatment that does not involve the introduction of cytotoxic agents used in conventional chemotherapy, thus eliminating the potentially life altering side effects of current therapies.

We hypothesize that Immunolight Therapy, given in up to 15 treatment session spanning 3 weeks, will be effective at generating an immune response that is beneficial for dogs with various forms of cancer.

Requirements, Incentives and Risks

Eligibility:

- Dogs with tumors that measure no more than 8 cm in greatest dimension, and which are amenable to Immunolight Therapy, will be considered for this study.
- Participating dogs must be otherwise healthy at the time of diagnosis as characterized by a physical examination and routine lab work (complete blood count, serum chemistry panel and urinalysis).
- Dogs may not have received prior immune-based cancer treatment.
- Dogs may not have received other treatments for their tumor, including steroids, chemotherapy, radiation, intralesional, or homeopathic therapies within 3 weeks of treatment with Immunolight Therapy and without documented progression of their cancer since that treatment.
- Dogs must have a predicted survival of at least 6 weeks without cancer therapy.
- Dogs may not have any disease precluding general anesthesia on 15 days over a 3 week period.
- Dogs may not have any disease necessitating use of chronic anti-inflammatory or immunosuppressive drug therapy, or history of autoimmune disease.

Procedure:

Diagnostics/Staging

Your dog must receive the following diagnostic and staging tests within the 14 days preceding initiation of Immunolight therapy to confirm eligibility of enrollment:

- Complete medical history and physical examination by a participating NC State clinician, including measurements of affected lymph nodes.
- Blood work (complete blood count and serum biochemical profile)
- Urinalysis
- Chest X-rays

Once completed, you will then schedule appointments to have your dog treated with Immunolight Therapy.

Once enrolled in the study, small samples of tumor and/or lymph nodes will be obtained just before starting Immunolight Therapy, and 3 weeks after finishing.

Immunolight Therapy

You must agree to abide by this treatment schedule:

- Immunolight Therapy will be administered on 5 consecutive days during weeks 1, 2 and 3.
- Each Immunolight Therapy session will require your dog to undergo a brief general anesthesia.
    - Treatment will consist of injection of commercially- produced pharmaceutical grade psoralen and a novel phosphor into the tumor. The injected area will then be exposed to a low dose of radiation therapy. If the tumor completely disappears before the end of 15 treatments, we will stop early, and just monitor.

Is there a placebo group?

No.

Follow-up:
You must agree to abide by this follow-up schedule:

- Recheck appointments must be scheduled at NC State for 3 & 6 weeks, and 3 & 6 months after finishing treatment. Bloodwork and/or chest X-rays may be obtained at these visits.
- Additional information may be collected by periodic phone calls to you/your veterinarian.

Risks:
Immunolight Therapy should be well-tolerated by your dog. However, possible side effects associated with treatment may include transient redness, irritation and/or infection of the tumor and/or nearby normal tissues, and changes in bloodwork (most commonly, transient and mild increases in liver values); these side effects should be self-limiting and easily managed with medications. If your dog does get bad side effects, you may notice swelling, ulceration, bleeding or pain. These types of side effects may necessitate more intense treatment, but are still likely to heal within a few weeks. While NC State veterinarians will be overseeing your pet's anesthesia, there are certain risks associated with anesthesia, the worst of which includes death.

Permission to use images:
Clients must agree to allow NC State to take and use photographs of their dog to aid with radiation therapy planning with Duke University collaborators. Additionally, images or recordings may be used for nonprofit educational purposes.

Owner responsibilities:

- You will be required to bring your dog to the NC State Veterinary Hospital for several visits (outlined above). Treatments can be performed on an outpatient basis. The study covers the cost of initial testing, treatment, follow-up and hospitalization needed for these procedures.
- You will be expected to keep all aforementioned follow-up appointments
- You must agree to post-mortem examination (autopsy) for your pet when he/she dies.

Incentives:

- NC State will pay for baseline staging tests, including physical examination, lab work (CBC, chemistry, and urinalysis) and chest X-rays.
    - *A value of over $400, without the support of this clinical trial.*
- We will also cover the cost of all Immunolight therapy sessions, including anesthesia, intratumoral injections of psoralen/phosphor solution, pharmacy compounding fee, hospitalization (as outlined above), labwork, and radiation therapy.
    - *A value of about $4,500, without the support of this clinical trial.*
- We will also cover the cost of the recheck examinations and all associated tests, 3 &6 weeks, and 3 & 6 months after treatment.
    - *A value of up to $900, without the support of this clinical trial.*
- The study will pay for treatment of unexpected complications directly associated with Immunolight therapy. Care for side effects must be provided at NC State, under the guidance of a radiation oncologist.
- The study will provide a study completion incentive of $200, if your pet receives Immunolight Therapy and completes all required follow-up.

Questions:
Please do not hesitate to contact your Radiation Oncology clinician if you are at all uncertain about any aspects of your pet's enrollment, treatment, risks, obligations, or incentives involved with this study.

Client Consent

By enrolling my pet in the aforementioned study, I agree to the following:

1. My dog has cancer; the specific type is called _____.
2. My dog will be treated by a group of veterinarians specializing in cancer treatment and radiation oncology.
3. The purpose of this study is to evaluate the effect of Immunolight Therapy on various cancers.
4. My dog will undergo general anesthesia up to 17 times, for treatment planning, Immunolight Therapy, follow-up. Each treatment involves injection of the investigational product (psoralen/phosphor solution) into the tumor, and radiation therapy to that site.
5. A small tumor biopsy will be performed while under anesthesia during the treatment planning visit, and the follow-up visit 3 weeks after treatment. This biopsy may include a small (2-3 mm) skin incision; it should cause minimal discomfort, but we may provide you with an E-collar and a few days worth of medication to manage any discomfort that is present or expected.
6. General anesthesia, surgery and Immunolight Therapy is generally well-tolerated, but is associated with certain risks including death.
7. I give my permission to publish data obtained in this study for the benefit of the scientific community. I understand that my pet will not be identified individually.
8. The attending clinician may withdraw my pet from the study if the patient is adversely affected or unfit to continue.

As a result of my discussion with Dr._____, and after reading the above, I voluntarily consent to the assignment of my pet into this clinical study. I consent to participate in this study and will follow the instructions of the veterinarians in charge as it pertains to therapy and follow up procedures.

Signed:_____ Date: _____
(Owner or authorized agent of the owner)

Witness: _____ Date: _____