

## **LIGHT SCIENCES ONCOLOGY RECEIVES SPECIAL PROTOCOL ASSESSMENT FOR PIVOTAL PHASE III TRIAL OF LITX™ THERAPY IN METASTATIC COLORECTAL CANCER**

### *Second SPA Agreement Advances the Company's Development Agenda*

Seattle, WA (January 30, 2007) – Light Sciences Oncology today announced that it has reached an agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for a Phase III clinical trial comparing use of its Light Infusion Therapy™ (Litx™) with a standard treatment for metastatic colorectal cancer in the liver (MCRC). The SPA for MCRC follows an August 2005 SPA for a Phase III trial of Litx in hepatocellular carcinoma (HCC).

The SPA signifies an agreement between the FDA and the company on the scientific and regulatory requirements for a Phase III clinical trial. “The SPA for MCRC is a significant step forward in our goal to make even the most advanced cancer a treatable chronic disease,” says Llew Keltner, M.D., Ph.D., President and CEO of Light Sciences Oncology. “We now have two SPA agreements in place with the FDA guiding our pivotal trials: for hepatocellular carcinoma and now for metastatic colorectal cancer. Both agreements mean the company and FDA agree on the design of the Phase III trials to support efficacy claims in new drug application (NDA) submissions.”

Litx uses light-emitting diodes (LEDs) to activate the photoreactive drug LS11 (talaporfin sodium). Each molecule of light-activated LS11 causes the production of many singlet oxygen molecules that kill target tissues with minimal side effects through “programmed cell death,” or apoptosis, and vascular closure.

The pivotal Phase III trial, the final trial required before Litx can be submitted for marketing approval, is designed to demonstrate the Litx system's safety and efficacy. In a two-armed controlled randomized study expected to involve approximately 450 colorectal cancer patients with liver metastases, the trial will compare the Litx system plus standard chemotherapy to chemotherapy alone. Treatment efficacy will be measured with progression-free survival (PFS), as well as overall survival. LSO is conducting the trial globally to expedite patient recruitment and trial completion.

Despite decades of research targeting solid tumors, those cancers continue to confound the best efforts at treatment. The worldwide incidence of colorectal cancer is approximately one million cases per year. The National Cancer Institute reports that approximately 50% of patients diagnosed with colorectal cancer will suffer from advanced disease that has metastasized to other parts of the body, most commonly to the liver. Current cancer treatments—surgery, radiation therapy, chemotherapy, and other local ablative therapies—have significant shortcomings, such as severe toxicity, limited efficacy, tumor re-growth and resistance, high set-up and usage costs, complicated administration, and poor patient quality-of-life. Litx is designed to address all of those disadvantages.

Litx may avoid the serious toxicities associated with traditional treatments. It attacks tumors from the inside-out, rather than outside-in, the method used in many standard treatments. It kills all tumor cells in a prescribed “kill zone” around the LED array, rather than only the minority of cells undergoing rapid division. The Litx treatment may also close tumor blood supply vessels, which would result in starving remaining cancer cells of oxygen and nutrients. Multiple light sources and multiple treatments are feasible and can be tailored based on the size, shape and location of the target tumor.

LSO’s light-delivery unit drives a tiny array of LEDs at the end of a very narrow, flexible catheter-like device. Administering physicians insert the LED array into a tumor with a biopsy-like procedure requiring only a local anesthetic followed by intravenous injection of LS11. Emitting red light at a discrete frequency, intensity, and time period, the device activates LS11 in the “kill zone.” Unlike laser-based light-activated therapies, Litx does not require expensive equipment.

#### ABOUT LIGHT SCIENCES ONCOLOGY

Light Sciences Oncology, Inc. (LSO) is a privately owned company developing new treatments in oncology using its Light Infusion Technology (Litx) to enhance the safety and efficacy of cancer therapy compared to current standard regimens. In addition to Phase III clinical trials of Litx in hepatocellular carcinoma and metastatic colorectal cancer, the company is conducting a Phase II trial in glioma. In December 2006 LSO purchased the assets of its former parent company Light Sciences LLC (LSLLC), securing all Litx intellectual property and widening its scope of potential therapeutic applications to include benign neoplasms such as vascular disease and benign prostatic hyperplasia (BPH). LSO has positioned itself for growth as a fully integrated development company with a strong portfolio of intellectual property, an advantageous technology platform, innovative products in development, and an exceptionally talented team.

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