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WORLD-WIDE CLINICAL DRUG TRIAL BEGINS IN TUPELO

TUPELO, Miss.—Two local physicians recently enrolled the first participant in the world in a new study for cancers of the head and neck.

The clinical trial is for Multikine®, a mixture of biologically active, natural cytokines that simulate the body's healthy immune system response. Cytokines play a key role in regulating the body's immune system. Julian Hill, M.D., a physician at Hematology and Oncology Associates at BridgePoint, and Mont Berry, M.D., of Ear, Nose and Throat Physicians of North Mississippi, P.A., are conducting the study. Both physicians are on the medical staff at North Mississippi Medical Center.

Interleukin-2, one of the substances present in the Multikine, was discovered more than 30 years ago. It is produced by the immune system in response to trauma, malignancy and infection. It has anti-cancer properties and was originally tested by the National Cancer Institute in kidney cancer. "However, the doses necessary to fight kidney cancer were so high that it became toxic to the body," Dr. Hill said.

In cancers of the oral cavity, there has been some success using the standard of care, which includes surgery followed by radiation or a combination of radiation and chemotherapy. "In this study, the Multikine® is injected around the tumors, since they are easily accessible," Dr. Hill said. "Since it is injected around the tumor bed, the doses can be small enough that they are not toxic. Initial studies have shown a 12 percent improvement in the cure rate (as determined by Pathology)."

In this new trial, Multikine is being injected prior to the current standard of care therapy. Multikine will be administered around the tumor and in the area of the draining lymph nodes for five days a week, for three weeks, prior to beginning standard of care therapy.

North Mississippi Medical Center (Drs. Hill and Berry), is one of several centers in the United States participating in the study. Other participating clinical centers are located abroad in Canada, Europe, Taiwan, Israel and India. There are about 48 centers globally distributed and 880 participants will be enrolled in the trial.

If Multikine proves to be beneficial, the study will have established a new standard of care for newly diagnosed head and neck cancer patients, meaning that every newly diagnosed patient with advanced primary disease would be expected to receive Multikine, and reimbursement would be customary.

This study is also the first Phase III study in the world in which immunotherapy is given to patients before receiving conventional treatment. This is significant because conventional therapy weakens the immune system and Multikine works by activating the intact immune system before the ravages of conventional therapy.

Study participants will be followed three years. A central, multinational committee will monitor the data throughout the course of the study.

For more information, call (662) 844-9166.