Vical Initiates Pivotal Phase 3 Trial of Allovectin-7® as First-line Therapy for Metastatic Melanoma

Vical Incorporated announced the initiation of a Phase 3 pivotal trial of the company's Allovectin-7[®] cancer immunotherapeutic as first-line therapy in chemotherapy-naïve patients with recurrent Stage III or IV metastatic melanoma. The trial, known as AIMM (Allovectin-7[®] Immunotherapeutic for Metastatic Melanoma), will be conducted in accordance with a Special Protocol Assessment (SPA) completed with the U.S. Food and Drug Administration (FDA) at up to 50 clinical sites.

AnGes MG, Inc., will fund the clinical trial under a collaborative agreement with Vical. AnGes has the right to receive royalties based on defined sales levels in the United States, and fixed royalties on rest-of-the-world sales, including the European region. AnGes expects these royalties will become one of the major revenue.

"We are excited to begin the AIMM head-to-head superiority trial against first-line chemotherapy," said Robin M. Jackman, Senior Vice President of Business Operations at Vical. "There is a great need for new treatment options in metastatic melanoma, where no new first-line therapies have been approved in nearly 15 years. With a primary endpoint of durable response rate, we can complete the trial after scheduled follow-up for the last patient without having to wait for long-term survival data. We are working aggressively to enroll patients into this trial and advance this novel product toward commercialization in collaboration with AnGes."

Because of substantial unmet medical need, Allovectin-7® has been granted orphan drug designation for the treatment of invasive and metastatic melanoma by the FDA's Office of Orphan Products Development. Orphan drug designation provides U.S. marketing exclusivity for seven years upon marketing

approval by the FDA, in addition to certain tax benefits for qualifying expenses.

The AIMM trial calls for enrollment of approximately 375 patients with recurrent metastatic melanoma. Patients may have been previously treated with surgery, adjuvant therapy, and/or biotherapy, but cannot have been previously treated with chemotherapy. The patients will be randomized on a 2:1 basis: approximately 250 patients will be treated with Allovectin-7® and approximately 125 will be treated with their physician's choice of either of two chemotherapy agents, dacarbazine or temozolomide. The primary endpoint is a comparison of objective response rates at six months or more after randomization. The study will also evaluate safety and tolerability as well as survival.

About Allovectin-7®

Allovectin-7® is a plasmid/lipid complex containing the DNA sequences encoding HLA-B7 and β 2 microglobulin, which together form a Class I Major Histocompatibility Complex, or MHC-I antigen. Injection of Allovectin-7® directly into tumors is designed to stimulate an immune response against both local and distant metastatic tumors. Vical conducted a large Phase 2 trial evaluating Allovectin-7® immunotherapeutic as a single agent for patients with Stage III or IV metastatic melanoma. Based on advice from clinical experts and detailed guidance received from the FDA in an End-of-Phase 2 meeting, Vical successfully completed a SPA with the FDA for a Phase 3 trial of Allovectin-7® for certain patients with metastatic melanoma. The SPA specifies that the trial design and planned analyses address the study's objectives and the resulting study data could provide the primary basis to support a product license application.

About Metastatic Melanoma

The American Cancer Society estimated that approximately 62,000 new diagnoses of, and approximately 7,900 deaths from, melanoma would occur in 2006 in the United States. Currently, there are no consistently effective therapies for advanced cases of malignant melanoma where the cancer has spread to other parts of the body. The toxicity associated with FDA-approved treatments such as dacarbazine or interleukin-2 is often significant, resulting in serious or life-threatening side effects in many of the patients treated. Patients

with metastatic melanoma often are treated off-label with drugs such as temozolomide, which has been approved by the FDA for the treatment of certain types of brain cancer but not for the treatment of metastatic melanoma. Temozolomide is an orally-delivered pro-drug that converts in the body into the same active compound as dacarbazine.