



## Vical Completes Enrollment in Allovectin-7(r) Phase 3 Trial for Metastatic Melanoma

SAN DIEGO, Jan. 28, 2010 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today announced that the company has completed enrollment of the planned 375 subjects in its multinational Phase 3 trial of Allovectin-7<sup>®</sup> in patients with metastatic melanoma. Allovectin-7<sup>®</sup> is a novel gene-based immunotherapeutic with a unique mechanism of action that is fundamentally different from currently approved treatments, and has the potential to be the first new primary treatment approved for metastatic melanoma in nearly 20 years.

"We are pleased to complete enrollment in this pivotal Phase 3 Allovectin-7<sup>®</sup> trial," said Vijay Samant, Vical's President and Chief Executive Officer. "We focused our recruitment efforts in North America, major European countries, Israel and Brazil, paving the path toward approvals in these key melanoma markets. Through the Special Protocol Assessment (SPA) process with the FDA, we designed our trial to demonstrate the advantages of our approach and improve the probability of success in achieving our primary endpoint of overall response rate."

"Immunotherapy takes longer than chemotherapy to begin working," added Mr. Samant, "but responses typically last longer as well. We believe our primary trial endpoint -- comparing response rates after at least 6 months of treatment -- captures the long-term benefit of Allovectin-7<sup>®</sup> over chemotherapy. We designed our trial to include patients most likely to benefit from our treatment, and specifically excluded patients with brain or liver metastases, patients previously treated with chemotherapy, and patients with elevated LDH levels. Our trial allows physicians to keep treating patients through at least two treatment cycles -- long enough for our immunotherapy to start working."

Allovectin-7<sup>®</sup>'s safety profile is excellent -- with no drug-related serious adverse events reported to date in the Phase 3 trial. Three independent Safety Monitoring Board reviews revealed no safety concerns and support continuation of the current trial.

### The AIMM Trial

Vical is conducting the AIMM (Allovectin-7<sup>®</sup> Immunotherapeutic for Metastatic Melanoma) trial, a Phase 3 pivotal trial of the company's Allovectin-7<sup>®</sup> cancer immunotherapeutic as first-line therapy in approximately 375 patients with Stage III or IV recurrent metastatic melanoma in accordance with a SPA agreement completed with the U.S. Food and Drug Administration (FDA). Patients may have been previously treated with surgery, adjuvant therapy, and/or biotherapy, but cannot have been previously treated with chemotherapy. The patients were randomized on a 2:1 basis: approximately 250 patients for treatment with Allovectin-7<sup>®</sup> and approximately 125 for treatment with their physician's choice of either of two chemotherapy agents, dacarbazine or temozolomide. The primary endpoint is a comparison of overall response rates at 24 weeks or more after randomization. The study will also evaluate safety and tolerability as well as survival.

Under a previously announced collaborative agreement, AnGes MG, Inc., is funding the AIMM trial through a series of cash payments and equity investments. Vical has received the full \$22.6 million committed by AnGes. In exchange for funding the trial, AnGes received exclusive marketing rights in Japan and other key Asian countries, and Vical is obligated to pay AnGes tiered royalties based on defined sales levels in the United States, and fixed royalties on rest-of-world sales. AnGes is obligated to pay Vical royalties on product sales in the specified Asian countries, plus certain sales-based milestone payments if defined sales levels are achieved. Each company will be responsible for obtaining regulatory approvals in any countries where it plans to market Allovectin-7<sup>®</sup>.

### Allovectin-7<sup>®</sup>

Allovectin-7<sup>®</sup> is a plasmid/lipid formulation containing the DNA sequences encoding HLA-B7 and beta-2 microglobulin, which together form a Major Histocompatibility Complex Class I antigen. Injection of Allovectin-7<sup>®</sup> directly into tumors is designed to stimulate an immune response against both local and distant metastatic tumors.

Vical estimates that the worldwide market for Allovectin-7<sup>®</sup> as a treatment for metastatic melanoma could exceed \$500 million annually, and applications for other types of cancer could further expand its total use. Because the mechanism of action for Allovectin-7<sup>®</sup> is not melanoma-specific, it has the potential to be used in any solid tumors. AnGes' interest in Allovectin-7<sup>®</sup> is driven by evidence of its activity in previous Phase 1/2 U.S. trials in head and neck cancer, which is far more prevalent than melanoma in Asia. Vical has produced all clinical lots used in the development of Allovectin-7<sup>®</sup>, and the company's existing

cGMP manufacturing facility has the capacity to meet anticipated commercial needs for several years after initial product launch.

Allovectin-7<sup>®</sup> 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 if marketing approval is received from the FDA, in addition to certain tax benefits for qualifying expenses.

## Metastatic Melanoma

The American Cancer Society estimated that more than 68,700 new diagnoses of, and approximately 8,650 deaths from, melanoma would occur in 2009 in the United States. There are no consistently effective therapies for advanced cases of metastatic 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.

## About Vical

Vical researches and develops biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. Potential applications of the company's DNA delivery technology include DNA vaccines for infectious diseases or cancer, in which the expressed protein is an immunogen; cancer immunotherapeutics, in which the expressed protein is an immune system stimulant; and cardiovascular therapies, in which the expressed protein is an angiogenic growth factor. The company is developing certain infectious disease vaccines and cancer therapeutics internally. In addition, the company collaborates with major pharmaceutical companies and biotechnology companies that give it access to complementary technologies or greater resources. These strategic partnerships provide the company with mutually beneficial opportunities to expand its product pipeline and address significant unmet medical needs. Additional information on Vical is available at [www.vical.com](http://www.vical.com).

The Vical Incorporated logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=5768>

This press release contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include whether Vical or others will continue developing Allovectin-7<sup>®</sup>; whether Allovectin-7<sup>®</sup> will be approved as primary treatment for metastatic melanoma in the United States or any other countries; whether the AIMM trial will meet its primary endpoint or any other trial endpoints; whether Allovectin-7<sup>®</sup> will achieve a higher response rate than chemotherapy after 6 months or more; whether any patients will derive benefit from treatment with Allovectin-7<sup>®</sup>; whether treatment through two 8-week cycles will be sufficient for Allovectin-7<sup>®</sup> to start working in any patients; whether the safety profile of Allovectin-7<sup>®</sup> will continue through trial completion; whether Vical will receive any or all of the sales-based milestone payments and royalties from AnGes for sales in the specified Asian countries, which will depend on the efforts of AnGes; whether any sales will be generated outside the specified Asian countries, which will depend on the efforts of Vical and potentially additional partners; whether Allovectin-7<sup>®</sup> will generate revenues exceeding \$500 million annually for metastatic melanoma, if any; whether Allovectin-7<sup>®</sup> will be successfully developed and commercialized for head and neck cancer or other indications; whether the company's existing manufacturing facility will meet commercial needs for several years after initial product launch, if at all; whether Vical will derive market exclusivity for seven years, if at all, or any tax benefits from the Allovectin-7<sup>®</sup> orphan drug designation; whether any product candidates will be shown to be safe and effective in clinical trials; the timing, nature and cost of clinical trials; whether Vical or its collaborative partners will seek or gain approval to market any product candidates; whether Vical or its collaborative partners will succeed in marketing any product candidates; and additional risks set forth in the company's filings with the Securities and Exchange Commission. These forward-looking statements represent the company's judgment as of the date of this release. The company disclaims, however, any intent or obligation to update these forward-looking statements.

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