Vical's Allovectin-7(R) Phase 3 Trial Receives Positive Review From Safety Monitoring Board

SAN DIEGO, Dec. 28, 2009 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today announced that an independent Safety Monitoring Board (SMB) for the company's Phase 3 AIMM trial of Allovectin-7(R) in patients with metastatic melanoma has completed the trial's third scheduled safety analysis and recommended that the trial continue per the protocol. The trial is expected to complete enrollment of the planned 375 subjects in the next few weeks.

About the AIMM Trial

Vical is conducting the AIMM (Allovectin-7(R) Immunotherapeutic for Metastatic Melanoma) trial, a Phase 3 pivotal trial of the company's Allovectin-7(R) cancer immunotherapeutic as first-line therapy in approximately 375 chemotherapy-naive patients with Stage III or IV metastatic melanoma in accordance with a Special Protocol Assessment (SPA) agreement completed with the U.S. Food and Drug Administration (FDA). The SPA specifies the trial objectives and design, clinical endpoints, and planned analyses expected to be needed for product approval. The AIMM trial is currently enrolling patients at clinical sites in key centers worldwide.

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(R).

About Allovectin-7(R)

Allovectin-7(R) is a plasmid/lipid complex containing the DNA sequences encoding HLA-B7 and beta-2 microglobulin, which together form a Class I Major Histocompatibility Complex, or MHC-I antigen. Injection of Allovectin-7(R) 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(R) 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 designed the Phase 3 AIMM trial.

Allovectin-7(R) 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.

About 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. Currently, 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.

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, including: whether Vical or others will continue development of Allovectin-7(R); whether Vical will be able to recruit patients into the AIMM trial as planned, if at all; whether Vical will receive all of the clinical trial funding from AnGes under the collaborative agreement, which will depend on continued development of Allovectin-7(R) and certain other conditions; whether Vical will receive any or all of the sales-based milestone payments and royalties for sales in the specified Asian countries, which will depend on the efforts of AnGes in obtaining regulatory approval and commercializing Allovectin-7(R) in those countries; whether any sales will be generated outside the specified Asian countries, which will depend on the efforts of Vical and potentially additional partners in obtaining regulatory approvals and commercializing Allovectin-7(R) in those regions; whether Allovectin-7(R) or any other product candidates will be shown to be safe and effective; 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; whether defined sales levels will be achieved in any markets; 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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