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

SAN DIEGO, June 16, 2010 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today announced that an independent Safety Monitoring Board (SMB) for the company’s Phase 3 trial of Allovectin-7® in patients with metastatic melanoma has completed the trial’s fourth scheduled safety analysis and recommended that the trial continue per the protocol.

The Phase 3 trial, initiated in January 2007, is evaluating Allovectin-7® as first-line therapy in patients with Stage III or IV recurrent metastatic melanoma. Vical completed enrollment in February 2010 of 390 chemo-naïve patients randomized on a 2:1 basis: 260 for treatment with Allovectin-7® and 130 for treatment with either dacarbazine or temozolomide. The company expects to complete patient follow-up and lock the Phase 3 clinical trial database in mid-2011.

Recently published results from a completed Phase 2 trial of Allovectin-7® in 127 patients with chemo-refractory or chemo-intolerant metastatic melanoma compare favorably against historical controls from other studies. Among the 15 responders (11.8%), 4 had complete responses and 11 had partial responses. The median duration of response was 13.8 months, with all responses lasting at least 6 months and the longest now at more than 7 years and still ongoing. The median survival for all patients was 18.8 months.

Allovectin-7® 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. Vical estimates that the worldwide market for Allovectin-7® as a treatment for metastatic melanoma could exceed $500 million annually. Because the mechanism of action for Allovectin-7® is not melanoma-specific, it has the potential to be successfully used in other types of solid tumors, which could further expand its total use.

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 if marketing approval is received from the FDA, in addition to certain tax benefits for qualifying expenses.

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®; whether Vical will complete patient follow-up and lock the Phase 3 clinical trial database in mid-2011, if at all; whether Allovectin-7® 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 Allovectin-7® will generate revenues exceeding $500 million annually for metastatic melanoma, if any; whether Allovectin-7® will be successfully developed and commercialized for use in other solid tumors; whether Vical will derive any market exclusivity or tax benefits from the Allovectin-7® orphan drug designation; 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.