Allovectin-7(R) Achieves Median Survival of Nearly 19 Months in Phase 2 Melanoma Trial


The Phase 2 trial was a single-arm, open-label study in which 127 chemo-refractory or chemo-intolerant patients subjects were treated with high-dose Allovectin-7®. The median age of patients enrolled in the study was 60, and patients as old as 98 were treated with Allovectin-7®, yet there were no treatment-related Grade 3 or Grade 4 adverse events, and no withdrawals from the trial for tolerability. The overall response rate for the 127 patients receiving the high-dose treatment was 11.8%, with 4 complete responders and 11 partial responders. The median duration of response was 13.8 months, ranging from a minimum of 6 months to a maximum of 66 months and still ongoing. Median survival was 18.8 months. These data compare favorably against historical controls from other studies in metastatic melanoma.

Findings from the Phase 2 trial were incorporated into the design of a Phase 3 pivotal trial through a Special Protocol Assessment agreement with the U.S. Food and Drug Administration (FDA):

- The Phase 3 trial sought patients likely to have functional immune systems.
  - Vical's Phase 3 trial was among the first for metastatic melanoma to exclude patients with elevated levels of lactate dehydrogenase (LDH), a key biomarker predictive of prognosis.
  - The trial excluded patients previously treated with chemotherapy.

- The Phase 3 trial sought patients healthy enough to remain on study for at least two 8-week treatment cycles, the median time to response in the Phase 2 study.
  - The trial excluded patients with metastases to the brain or liver.
  - Response Evaluation Criteria In Solid Tumors (RECIST) standards were modified for the Phase 3 protocol to allow treatment continuation through two cycles at the physician's discretion, even if patients develop new melanoma lesions within defined limits.

- Vical's Phase 3 trial was designed to capture the long-term benefits of immunotherapy compared with chemotherapy.
  - The primary endpoint compares overall response rates at 24 weeks or more after randomization.
  - The study will also evaluate survival as well as safety and tolerability.

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 approximately 390 chemo-naive patients randomized on a 2:1 basis: approximately 260 for treatment with Allovectin-7® and approximately 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.

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, and applications for other types of cancer could further expand its total use.

Because the mechanism of action for Allovectin-7® is not melanoma-specific, it has the potential to be used in other types of solid tumors. AnGes MG, Inc., has licensed rights to commercialize Allovectin-7® in specified Asian countries, and is primarily interested in developing Allovectin-7® as a treatment for head and neck cancer, which presents a significant unmet medical need in Asia. Allovectin-7® is still available for licensing in North America, Europe and other regions.

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. Forward-looking statements include whether Vical or others will continue developing Allovectin-7®; whether Allovectin-7® will be approved as primary treatment for metastatic melanoma in the United States or any other countries; whether the Phase 3 trial will meet its primary endpoint or any other trial endpoints; whether Allovectin-7® will achieve a higher response rate than chemotherapy after 24 weeks or more; whether any patients will derive benefit from treatment with Allovectin-7®; whether the safety profile of Allovectin-7® will continue through trial completion; 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 other solid tumor indications; whether AnGes will develop or commercialize Allovectin-7® in Asia for head and neck cancer or any other indication; 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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