



Vical Licensee AnGes MG Reaches Agreement With FDA For Phase 3 Trial of Collategene (TM) Angiogenesis Product

SAN DIEGO, Jan. 12, 2010 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today announced that the company's licensee, AnGes MG, Inc., reported approval by the U.S. Food and Drug Administration (FDA) of the Special Protocol Assessment (SPA) agreement for a Phase 3 clinical trial of its Collategene(TM) angiogenesis product for patients with advanced peripheral arterial disease (PAD). The study will be multinational, randomized and placebo-controlled with a target population of 560 patients.

The Phase 3 trial will enroll no option as well as poor option patients with chronic and severe ischemia of the lower limb (Critical Limb Ischemia). No option patients are those unable to receive an endovascular intervention or surgical bypass procedure due to inflow, conduit or outflow reasons or due to a severe and irreversible co-morbidity where surgery is contraindicated. Poor option patients are those unable to receive an endovascular intervention and at high risk for bypass surgery due to their vascular anatomy or severe co-morbid disease. Inclusion of poor option patients will open the clinical trial to at least three to four times as many target patients compared to other trials within the industry which only include no option patients.

PAD is a major health problem caused mostly by atherosclerotic narrowing of lower limb arteries that significantly reduces the blood flow to the limbs. Early symptoms of PAD include transient pain in the legs upon walking, a condition called intermittent claudication, which is caused by ischemia. However, most patients with CLI develop ischemic rest pain and ischemic skin ulceration and gangrene without ever experiencing prior intermittent claudication. The prevalence of PAD is 3-10% increasing to 15-20% in subjects over 70 years old. The incidence of PAD and CLI is expected to rise in the United States due to an increase in obesity and diabetes. The U.S. healthcare burden associated with amputations is estimated to be greater than \$10 billion per year. The potential market for PAD therapies is estimated to be in excess of \$2 billion per year.

Collategene(TM) uses Vical's patented DNA technology to deliver a gene encoding hepatocyte growth factor (HGF), a human protein that causes growth of blood vessels when injected in areas of restricted blood flow. In March 2008, AnGes submitted a New Drug Application (NDA) for Collategene(TM) to the Japanese Ministry of Health, Labor and Welfare for treatment of CLI. The submission is under review. AnGes has designed the new Phase 3 trial to pursue approvals of Collategene(TM) in the United States, Canada, Europe, Latin America and other markets beyond Japan.

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 statements about the potential approval of Collategene(TM), the potential Phase 3 international trial of Collategene(TM), as well as Vical's focus, collaborative partners, and product candidates. Risks and uncertainties include whether Collategene(TM) will be approved in Japan; whether AnGes will succeed in marketing Collategene(TM) in Japan; whether AnGes will successfully negotiate with potential partner(s) to conduct the Phase 3 trial in the United States and Europe; whether AnGes or others will successfully expand into U.S. or other markets with Collategene(TM); whether any product candidates under development by Vical or its collaborative partners 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 other 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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