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### **STUDIES HIGHLIGHT GLOBAL RISKS OF VASCULAR DISEASE, PROBE CREATIVE NEW TREATMENTS**

**ATLANTA, GA (March 12, 2006)** — Patients with a build-up of plaque in arteries in the heart, brain and leg face a high risk of major cardiovascular complications. Researchers worldwide are responding to that threat by gathering comprehensive data and developing innovative new therapies, according to studies presented today at the American College of Cardiology's 55th Annual Scientific Session in Atlanta, Ga. ACC.06 is the premier cardiovascular medical meeting, bringing together more than 30,000 cardiologists to further breakthroughs in cardiovascular medicine.

"These new studies help us not only to understand the scope of the problem, but also to evaluate the effectiveness of new therapies for atherosclerotic disease, wherever it occurs in the body," said George A. Beller, M.D., F.A.C.C., University of Virginia Health Center.

#### Homocysteine Lowering in Stable Chronic Vascular Disease: The Heart Outcomes Prevention Evaluation (HOPE)-2 Trial

High blood levels of the amino acid homocysteine have been linked to an increased risk of cardiovascular disease. Treatment with folic acid, vitamin B<sub>6</sub>, and vitamin B<sub>12</sub> can reduce homocysteine levels by 25 percent to 30 percent, but the clinical benefits of vitamin supplements have been uncertain. The HOPE-2 study has taken steps to determine whether reducing homocysteine levels also reduces the long-term risk of heart attack, stroke or death.

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"The idea is very attractive, because homocysteine levels can be easily reduced in most people with inexpensive therapy," said Eva M. Lonn, M.D., M.S.c., F.A.C.C., a professor of medicine and cardiology at McMaster University, Hamilton, Ontario, Canada. "This is the largest trial worldwide completed to date to measure clinical events associated with a reduction of homocysteine levels following treatment with folate and other B vitamins."

Homocysteine is a normal byproduct of the breakdown of methionine, an essential amino acid. Folic acid, vitamin B<sub>6</sub>, and vitamin B<sub>12</sub> are involved in several steps of the complex homocysteine metabolic pathway, ultimately enhancing homocysteine breakdown and excretion.

The HOPE-2 trial involved an international team of researchers from 145 medical centers in 13 countries in North America, South America, and Europe. Investigators enrolled 5,522 patients with established cardiovascular disease or diabetes, randomly assigning them to daily vitamin intake with folic acid, 2.5 mg; vitamin B<sub>6</sub>, 50 mg; and vitamin B<sub>12</sub>, 1 mg, or placebo. After two years of vitamin supplements, homocysteine levels were reduced by about 25 percent.

Dr. Lonn will report on the clinical results of a follow-up averaging five years at a Late Breaking Clinical Trial session on Monday, March 13, at 2 p.m.

One-Year Cardiovascular Event Rates in a Global Contemporary Registry of Over 68,000 Outpatients with Atherothrombosis: The Reduction of Atherothrombosis for Continued Health (REACH) Registry Results

Patients with atherothrombosis—a condition in which atherosclerosis is complicated by a propensity to form blood clots— have a surprisingly high risk of death or major cardiovascular illness, even in stable form, according to data from a large international registry. Within a year, one in eight patients will die, will have a heart attack or stroke, or will be hospitalized for a complication of clogged arteries. The risk is even greater for patients with widespread vascular disease.

"I find these event rates to be high, given that we are dealing with a stable outpatient population treated with contemporary therapy," said Philippe Gabriel Steg, M.D., a professor of cardiology at Université Paris-7 and director of the coronary care unit at Hôpital Bichat-Claude Bernard, Assistance Publique-Hôpitaux de Paris, France.

This study was specifically designed to determine the "real-world" risk of a major adverse cardiovascular event (MACE) in patients with either established atherothrombotic disease or a

high risk for the condition. Drawing from a wide geographic area—44 countries in all—Dr. Steg and his colleagues recruited 68,000 patients with a history of coronary artery disease (CAD), cerebrovascular disease (CVD), or peripheral vascular disease (PVD), or at least three risk factors for atherothrombosis, including diabetes, uncontrolled high blood pressure, uncontrolled high blood cholesterol levels, cigarette smoking and advanced age. Participants were enrolled in the Reduction of Atherothrombosis for Continued Health (REACH) registry and will be followed-up for four years.

At one-year follow-up, investigators observed an overall MACE rate of 13 percent. However, patients with peripheral arterial disease—clogged arteries in the legs or abdominal organs—were at substantially higher risk, experiencing a one-year MACE rate of 22 percent. In addition, there was a stepwise increase in risk in those with widespread vascular disease. In patients with atherothrombotic disease in one location only, the MACE rate was 13 percent, whereas in those with atherothrombotic disease in three locations, the MACE risk climbed to 28 percent.

"It is critical that we stop viewing atherothrombosis as a cardiac, neurologic, or vascular disease and, instead, view it as a global disease," Dr. Steg said.

Dr. Steg will present the full one-year REACH registry results at a Late Breaking Clinical Trials session on Sunday, March 12, at 10:52 p.m.

#### Safety and Efficacy of Bone Marrow Mobilization With Granulocyte-macrophage Colony Stimulating Factor in Patients With Intermittent Claudication

A build-up of atherosclerotic plaque in the arteries of the legs can restrict blood flow and even make walking painful, a condition known as intermittent claudication. If the disease is widespread, it may be impossible to treat with conventional approaches, such as angioplasty or vascular surgery. Researchers in Atlanta, GA, are investigating a creative solution—injections of a type of growth factor that stimulates the body to develop new blood vessels. Early evidence suggests the approach is safe and significantly improves exercise capacity.

"This is a promising first step," said Arshed A. Quyyumi, M.D., F.A.C.C., a professor of medicine at Emory University School of Medicine. "It should stimulate further investigation into the use of growth factors as a viable therapy in patients with no other options."

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Dr. Quyyumi and his colleagues randomly assigned 45 patients with intermittent claudication to either placebo or one of three doses of granulocyte-macrophage colony stimulating factor (GM-CSF), which stimulates the bone marrow to produce endothelial progenitor cells (EPCs), which in turn play a key role in the formation of new blood vessels. The three-times-daily treatment continued for two weeks, a slow approach intended to maximize exposure of the leg tissues to the EPCs.

At three-month follow-up, patients treated with GM-CSF were able to exercise nearly a minute longer than at baseline, a statistically significant improvement. Pain-free exercise times were also significantly longer. By comparison, exercise times did not change significantly in the control group.

Dr. Quyyumi will present the full study results at a Late Breaking Clinical Trial session on Sunday, March 12, at 3 p.m.

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The American College of Cardiology ([www.acc.org](http://www.acc.org)) represents the majority of board certified cardiovascular physicians in the United States. Its mission is to advocate for quality cardiovascular care through education, research, promotion, development and application of standards and guidelines- and to influence health care policy. ACC.06 and the ACC inaugural i2 Summit, the first-ever meeting for interventional cardiologists, will bring together more than 30,000 cardiologists and cardiovascular specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.