

**FOR IMMEDIATE RELEASE**

**AtheroGenics Reports Positive Final Results from CART-2 Clinical Trial of AGI-1067**

**AGI-1067 Achieves Statistically Significant Plaque Regression Versus Baseline**

**Conference Call and Webcast at 8:30 a.m. EST on November 22, 2004**

ATLANTA, GA – November 22, 2004 – AtheroGenics, Inc. (Nasdaq: AGIX), a pharmaceutical company focused on the treatment of chronic inflammatory diseases, today announced positive results from its Phase IIb CART-2 clinical trial of AGI-1067, the Company's novel anti-inflammatory agent that targets atherosclerosis. Data from the study were independently analyzed by the Montreal Heart Institute (MHI) under the direction of Jean-Claude Tardif, M.D., Principal Investigator of CART-2, and by the Cleveland Clinic Foundation (CCF) under the direction of Steven Nissen, M.D.

The primary endpoint of the trial was a change in coronary atherosclerosis, measured as total plaque volume after a 12-month treatment period compared to baseline values. Combined results of the final analysis from the two laboratories indicate that AGI-1067 reduced plaque volume by an average of 3.9 mm<sup>3</sup> (2.3%), which was statistically significant (p=0.0015). In the Standard of Care group, results indicate a minor reduction in plaque volume of 1.5 mm<sup>3</sup> (0.8%), which was not statistically significant (p=0.45). While the plaque regression observed in the AGI-1067 group exceeded that observed in the Standard of Care group numerically, the difference did not reach statistical significance (p=0.29), although a trend towards significance (p=0.12) was seen in the Montreal Heart analysis.

An important secondary endpoint from the trial, change in plaque volume in the most severely diseased 5 mm subsegment, showed statistically significant (p<0.0001) regression from baseline by an average of 1.8 mm<sup>3</sup> (4.8%). Overall adverse event rates were similar in the AGI-1067 and Standard of Care groups, and AGI-1067 was found to be generally well-tolerated.

“We are pleased with the results of the CART-2 study and believe these data provide good evidence that, in contrast to current therapies, AGI-1067 has the ability to regress plaque in coronary arteries when dosed over a 12-month period,” commented Rob Scott, M.D., Senior Vice President of Clinical Development and Regulatory Affairs and Chief Medical Officer at AtheroGenics. “We believe that AGI-1067 is showing its potential to be a leader in the next generation of oral cardiovascular therapeutics.”

The following is a table of the plaque volume changes for the AGI-1067 and Standard of Care groups, as reported by the Montreal Heart Institute and the Cleveland Clinic:

| <b><u>Change in Plaque Volume</u></b>                |                                        |                 |                                |                 |
|------------------------------------------------------|----------------------------------------|-----------------|--------------------------------|-----------------|
|                                                      | AGI-1067 groups (n=183)                |                 | AGI-1067 groups                |                 |
|                                                      | Standard of Care group (n=49)          |                 | Standard of Care group         |                 |
|                                                      | <b><u>Montreal Heart Institute</u></b> |                 | <b><u>Cleveland Clinic</u></b> |                 |
| <b><u>Primary Endpoint</u></b>                       | <b><u>mm<sup>3</sup></u></b>           | <b><u>%</u></b> | <b><u>mm<sup>3</sup></u></b>   | <b><u>%</u></b> |
| (n=187)                                              |                                        |                 |                                |                 |
| (n=50)                                               |                                        |                 |                                |                 |
| Total AGI-1067 groups<br>2.2%                        | -4.0 (p=0.002)                         | -2.4%           | -4.0 (p=0.0043)                | -               |
| Standard of Care group<br>1.3%                       | -0.4 (p= 0.85)                         | -0.2%           | -2.5 (p= 0.28)                 | -               |
| <b><u>Most Severely Diseased 5 mm Subsegment</u></b> |                                        |                 |                                |                 |
| Total AGI-1067 groups<br>5.1%                        | -2.0 (p<0.0001)                        | -5.2%           | -1.9 (p<0.0001)                | -               |
| Standard of Care group<br>2.7%                       | -1.1 (p= 0.09)                         | -2.8%           | -1.1 (p= 0.13)                 | -               |

Treatment with AGI-1067 also produced a statistically significant reduction in levels of myeloperoxidase (MPO), an inflammatory biomarker that correlates with future cardiovascular events. In particular, high levels of MPO have been linked to increased risk of heart attack.

“I consider these final data encouraging, particularly considering the inherent limitations of the trial, which we originally designed to investigate restenosis,” said Dr. Tardif. “Given the regression signal in the AGI-1067 group, as well as the drug’s ability to reduce myeloperoxidase, a biomarker closely associated with major adverse cardiac events, I believe we have enhanced our chances of seeing positive results in the Phase III ARISE trial.”

### **About the CART-2 Study**

Patients in the CART-2 study were randomized to placebo plus Standard of Care, or to one of three treatment groups. Starting 14 days prior to a scheduled angioplasty procedure, the first treatment group received AGI-1067 for the full 14 days, the second group received placebo for the first 11 days and AGI-1067 for the last three days, and the third group received placebo for the full 14 days. Following the angioplasty, all three treatment groups continued receiving AGI-1067 for 12 consecutive months. The dose of

AGI-1067 used for all patients in the treatment groups was 280 mg, dosed orally once per day, plus Standard of Care. Plaque volume was measured at the time of angioplasty and again at the end of one year using intravascular ultrasound (IVUS). With IVUS, a catheter containing a tiny ultrasound probe is inserted into a non-instrumented coronary artery to directly image and measure the size of the atherosclerotic plaques. The results of the study reflect those of the evaluable patient population as independently adjudicated by the CCF because of the original design of CART-2 as a restenosis study.

### **About AGI-1067**

AGI-1067 is a novel oral compound that was designed to selectively block the inflammatory process in atherosclerosis. AGI-1067 blocks signaling pathways within the endothelial cells that make up the inner lining of blood vessels, which in turn inhibits the production of VCAM-1 and other molecules involved in the inflammatory process. VCAM-1 recruits inflammatory cells to the surface of the endothelial cell, initiating the chronic inflammatory reaction that ultimately results in atherosclerosis.

### **Webcast Information**

AtheroGenics will host a conference call today at 8:30 a.m. EST to discuss this announcement. To participate in the audio portion and have the opportunity to pose questions, dial 1-877-407-8289 (domestic) or +1-201-689-8341 (international). It is recommended that you plan to call in at least 15 minutes prior to start time. A link to the webcast of the audio portion of the call and the accompanying slide presentation will be available on the Investor Relations section of the Company's website, under the "Investor Calendar" tab, at <http://www.atherogenics.com>. A replay of the call will be available by phone for 30 days at 1-877-660-6853 (domestic) or +1-201-612-7415 (international); reference Account # 1628; Conference ID #125537.

The webcast will be available for 30 days on the AtheroGenics website.

### **About AtheroGenics**

AtheroGenics is focused on the discovery, development and commercialization of novel drugs for the treatment of chronic inflammatory diseases, including heart disease (atherosclerosis), rheumatoid arthritis and asthma. The Company has two drug development programs currently in the clinic. AtheroGenics' lead compound, AGI-1067, is being evaluated in the pivotal Phase III clinical trial called ARISE, as an oral therapy for the treatment of atherosclerosis. AGI-1096 is a novel, oral agent in Phase I that is being developed for the prevention of organ transplant rejection in collaboration with Fujisawa. AtheroGenics also has preclinical programs in rheumatoid arthritis and asthma using its novel vascular protectant™ technology. For more information about AtheroGenics, please visit [www.atherogenics.com](http://www.atherogenics.com).

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*statements. These risks include statements which address operating performance, events or developments that we expect or anticipate will occur in the future, such as projections about clinical trial results, our future results of operations or our financial condition, research, development and commercialization of our product candidates, anticipated trends in our business, and other risks that could cause actual results to differ materially. These risks are discussed in AtheroGenics' Securities and Exchange Commission filings, including but not limited to the risks discussed in AtheroGenics' Form 10-K for fiscal 2003 and our Quarterly Report on Form 10-Q for the second quarter of 2004.*

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