Anthera Enrolls First Patients in Pivotal Varespladib Phase 3 Clinical Study

HAYWARD, Calif., June 23, 2010 /PRNewswire via COMTEX News Network/ -- Anthera Pharmaceuticals, Inc. (Nasdaq: ANTH), a biopharmaceutical company developing drugs to treat serious diseases associated with inflammation and autoimmune disorders, today announced patient enrollment has commenced in the Company's pivotal VISTA-16 (**V**ascular **I**nflammation **S**uppression to **T**reat **A**cute Coronary Syndrome for **16** Weeks) Phase 3 clinical study of varespladib (A-002). High-risk patients are defined as those who have additional disease characteristics that increase their likelihood of experiencing another coronary event; these characteristics include a history of previous cardiovascular disease, age, diabetes, or metabolic syndrome.

"Current best practice to slow coronary artery disease (CAD) progression and reduce the risk of a subsequent cardiovascular event is directed at the treatment of individual cardiovascular risk factors such as high cholesterol or clotting. The VISTA-16 study with varespladib is designed to validate the hypothesis that reduction of inflammation, particularly following an ACS, leads to improved outcomes in patients with cardiovascular disease. The enrollment of patients in VISTA-16 is an important milestone for the development of varespladib," stated Colin Hislop, M.D., Anthera's Senior Vice President and Chief Medical Officer. "I am particularly pleased that we are enrolling patients in both the United States and Europe as part of our initial roll out of the study. We look forward to the first DSMB review after 1000 patients have been randomized and treated."

"We have made major advances in treating patients with heart disease in terms of lowering blood pressure and improving lipid profiles, but there remains a substantial risk of clinical events," said Stephen Nicholls, M.D., Ph.D., Cardiovascular Director, Cleveland Clinic Coordinating Center for Clinical Research (C5 Research), who is leading the study. "We are excited to be conducting a trial that examines inflammation, especially in terms of trying to develop a therapy that specifically reduces inflammation within the plaque."

VISTA-16 is a multinational, randomized, double-blind, placebo-controlled Phase 3 clinical study which will enroll up to 6,500 high-risk ACS patients in up to 15 countries at up to 500 centers. Enrollment in VISTA-16 will be stopped after a minimum of 395 primary endpoint events have occurred. High-risk patients are defined as having risk factors that place the patient at a higher risk of experiencing a secondary coronary event, such as previous cardiovascular disease, diabetes, or metabolic syndrome. Within 96 hours of experiencing primary ACS, patients are treated with varespladib or placebo once-daily in combination with a physician-controlled dose of atorvastatin for 16 weeks - the period of highest risk for patients to experience a secondary cardiovascular event. As per a Special Protocol Assessment agreement with the US FDA, the primary endpoint of the VISTA-16 study is a reduction in major adverse coronary events (MACE) defined by recent FDA draft guidance to include cardiovascular death, non-fatal myocardial infarction, non-fatal stroke or documented unstable angina with objective evidence of ischemia requiring hospitalization.

About Varespladib and sPLA2

Anthera Pharmaceuticals' varespladib is a potent and highly selective inhibitor of the proinflammatory enzyme secretory phospholipase A2 (sPLA2). Elevated levels of sPLA2 have been implicated in a variety of acute inflammatory conditions, including ACS and acute chest syndrome, as well as chronic diseases, such as stable coronary artery disease (CAD). In Anthera's FRANCIS clinical study in ACS patients, varespladib demonstrated marked improvements in independent markers of cardiovascular risk including C-reactive protein, IL-6, LDL-C and varespladib's target enzyme, sPLA2. Recent analysis of data from diabetic patients in Anthera's Phase 2 FRANCIS study demonstrated treatment with varespladib was associated with early and statistically significant reductions in these prognostic inflammatory markers of cardiovascular risk. In February, the Company received a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration (FDA) for the VISTA-16 Phase 3 study of varespladib in high-risk ACS patients.

About Anthera Pharmaceuticals

Anthera Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing products to treat serious diseases associated with inflammation, including cardiovascular and autoimmune diseases. Anthera has one Phase 3 clinical program, A-002, and two Phase 2 clinical programs, A-623 and A-001. A-002 and A-001 inhibit a novel enzyme target known as secretory phospholipase A2 (sPLA2). Elevated levels of sPLA2 have been implicated in a variety of acute inflammatory conditions, including acute coronary syndrome and acute chest syndrome, as well as chronic diseases such as stable coronary artery disease (CAD). Anthera's Phase 2 product candidate, A-623, targets elevated levels of B-lymphocyte stimulator (BLyS), which has been associated with a variety of B-cell mediated autoimmune diseases, including systemic lupus erythematosus, or lupus. For more information, please visit www.anthera.com.

Safe Harbor Statement

Any statements contained in this press release that refer to future events or other non-historical matters are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These include, but are not limited to, statements relating to the anticipated initiation of Anthera's clinical studies, anticipated duration and expected results of these studies, and the progression of Anthera's products through future stages of clinical development. These forward-looking statements are based on Anthera's expectations as of the date of this press release and are subject to certain risks and uncertainties that could cause actual results to differ materially as set forth in the Company's public filings with the Securities and Exchange Commission, including Anthera's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010. Anthera disclaims any intent or obligation to update any forward-looking statements, whether because of new information, future events or otherwise, except as required by applicable law.

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