Anthera Pharmaceuticals Successfully Completes Interim Biomarker Analysis of VISTA-16 Study and Third Safety Review of Varespladib Methyl

VISTA-16 Study to Continue Global Enrollment

HAYWARD, Calif., April 18, 2011 /PRNewswire/ -- Anthera Pharmaceuticals, Inc. (Nasdaq: ANTH), a biopharmaceutical company developing drugs to treat serious diseases associated with inflammation, today announced that enrollment in the Phase 3 VISTA-16 study of varespladib in Acute Coronary Syndromes (ACS) will continue based on the positive outcome of an interim biomarker analysis and review of available patient safety data.

An independent statistician completed an analysis of various biomarkers of cardiovascular risk and determined that treatment with once-daily varespladib met the pre-specified criteria for the study to proceed. The analysis required patients on varespladib to demonstrate pre-defined treatment effects versus placebo at relevant time points on a collection of biomarkers including: secretory phospholipase A2 (sPLA2), low density lipoprotein cholesterol (LDL-C), C-reactive protein (CRP), interleukin-6 (IL-6), and a composite responder endpoint defined as patients achieving LDL-C less than 70 mg/dL and CRP below 1.0 mg/L.

In parallel with the biomarker analysis, the VISTA-16 independent Data Safety and Monitoring Board (DSMB) completed a review of the available safety database including all reported adverse events and serious adverse events and recommended the continuation of the VISTA-16 clinical study without modification. This represents the third meeting of DSMB since the start of the study.

"We continue to believe that positive changes in patient biomarkers similar to changes seen in the FRANCIS Phase 2 clinical study will correlate to a reduction in major adverse cardiovascular events in patients treated with varespladib for 16 weeks," said Paul F. Truex, President and Chief Executive Officer of Anthera Pharmaceuticals. "We are hopeful this approach will eventually prove that rapid and safe reduction of inflammation following an acute coronary syndrome will translate into better treatment options for this high-risk patient population."

"VISTA-16 represents an innovative approach based on years of extensive study of the negative effects of inflammation in patients with ACS", commented Stephen J. Nicholls, M.D., Ph.D., Cardiovascular Director of C5 Research at the Cleveland Clinic and Chairman of the VISTA-16 Executive Committee. "We are excited to be continuing our efforts to bring forward this promising therapeutic."

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. Enrollment in VISTA-16 will be stopped after a minimum of 385 primary endpoint events have occurred. High-risk patients are defined as patients who have risk factors that place them at a higher risk of experiencing a secondary coronary event. These risk factors include 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-prescribed dose of atorvastatin for 16 weeks — the period when patients have the highest risk of experiencing a secondary cardiovascular event. As per a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA), the primary endpoint of the VISTA-16 study will be a reduction in major adverse coronary events (MACE), which was defined by recent FDA draft guidance as cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or documented unstable angina with objective evidence of ischemia requiring hospitalization.

About Varespladib and sPLA2

Varespladib is a potent oral inhibitor of the pro-inflammatory 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 Phase 2 clinical study in ACS patients, treatment with varespladib improved independent markers of cardiovascular risk including CRP, IL-6, LDL-C and varespladib's target enzyme, sPLA2. Recent analysis of data from diabetic patients in the same Phase 2 study demonstrated treatment with varespladib was associated with early and statistically significant reductions in these prognostic inflammatory markers of cardiovascular risk. In February 2010, Anthera received an SPA from the U.S. FDA for the VISTA-16 Phase 3 study for the use of varespladib in treating high-risk ACS patients. The next substantial review of clinical safety and efficacy data will be conducted after 50 percent of the anticipated primary endpoints have occurred. At this review the DSMB will conduct the first prescribed statistical efficacy review of the primary endpoint of the VISTA-16 Study. This review is expected to take place in the second half of 2011.

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 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 (BAFF) which has been associated with a variety of B-Cell mediated autoimmune diseases, including systemic lupus erythematosus (lupus). For more information, please visit www.anthera.com.

About C5Research

C5Research, Cleveland Clinic Coordinating Center for Clinical Research, is an academic research organization (ARO), which provides clinical trial services to the pharmaceutical, biotechnology, and medical device industries. C5Research also supports NIH and Cleveland Clinic investigator-initiated clinical research and work with other AROs and contract research organizations to develop, implement, and successfully conduct clinical trials.

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 Annual Report on Form 10-K for the year ended December 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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