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## **ANTHERA'S VARESPLADIB MEETS PRIMARY ENDPOINT IN PHASE 2 FRANCIS TRIAL FOR THE TREATMENT OF ACUTE CORONARY SYNDROME**

- Favorable results for secondary endpoints support outcomes benefit

**HAYWARD, CA – May 6, 2009** – Anthera Pharmaceuticals, Inc., a privately held biopharmaceutical company developing anti-inflammatory drugs, announced today that FRANCIS (Fewer Recurrent Acute coronary events with Near-term Cardiovascular Inflammation Suppression), a clinical trial designed to examine the impact of 500mg of varespladib when administered to patients within 96 hours of an Acute Coronary Syndrome (ACS) event, met its primary endpoint of a reduction in Low Density Lipoprotein Cholesterol (LDL-C). All patients in the FRANCIS trial received once daily doses of 80mg of Lipitor® (atorvastatin calcium), plus 500mg of varespladib or matching placebo. Varespladib is a potent and highly selective oral inhibitor of secretory phospholipase A<sub>2</sub> (sPLA<sub>2</sub>), an inflammatory enzyme implicated in ACS, vascular inflammation, atherosclerosis and adverse lipid profiles.

The pre-specified primary endpoint analysis was conducted when 500 patients reached at least eight weeks of treatment after an ACS event. In addition to meeting the primary endpoint, additional efficacy analyses at a variety of time points showed positive results for all clinically important secondary endpoints. The initial data review demonstrated:

- A statistically significant reduction in LDL-C at all prospectively defined time points and statistically significant reductions in total cholesterol and non-HDL cholesterol
- Varespladib's immediate and selective inhibition of sPLA<sub>2</sub> effectively suppressed inflammation following the index event and was further evidenced by a statistically significant reduction in C-reactive protein.
- A statistically significant greater proportion of patients treated with varespladib achieved LDL-C levels of 70mg/dL or less (a target established by the American Treatment Program III for high-risk patients) and maintained this lower level throughout the primary endpoint. The effect was more pronounced for patients achieving LDL-C below 50 mg/dL.

"Building on strong results from our first two clinical studies in stable cardiovascular patients, the FRANCIS study has validated the potential utility of aggressive varespladib treatment to improve outcomes in a high-risk patient population immediately following an ACS event," said Paul F. Truex, President and Chief Executive Officer of Anthera Pharmaceuticals, Inc. "In addition to meeting the primary and several secondary endpoints, clinical data from the FRANCIS study has met and/or exceeded our expectations and we hope to present the entire data set including biomarkers, safety, and secondary clinical endpoints (MACE) at an upcoming scientific conference."

"We are extremely excited by these data," said Colin Hislop, M.D., Senior Vice President Clinical Development at Anthera. "The favorable treatment effect of varespladib is consistent with our Phase 3 development plan and provides a robust data set to support substantial clinical benefit for this novel, first in class therapy."

With approximately 1000 patient exposures to date in three cardiovascular studies, varespladib has been generally well tolerated.

### **About the FRANCIS trial**

The FRANCIS trial is based upon direct feedback from Food and Drug Administration via the Special Protocol Assessment process. FRANCIS was designed to assess the impact of oral varespladib on known biological markers of cardiovascular risk. It enrolled 625 patients who will be treated for a minimum of six months. The study is being conducted at sites in Europe. FRANCIS is designed to provide insight into the potential prevention of secondary Major Adverse Cardiovascular Events (MACE) by varespladib. In this study, MACE was defined as a composite endpoint consisting of all-cause mortality, non-fatal stroke, non-fatal myocardial infarction, unstable angina, and a subset of revascularization following the initial event. During the course of the study, patients received therapeutic standard of care in addition to high dose Lipitor® (atorvastatin).

In previous clinical trials, varespladib, a potent and highly selective inhibitor of secretory phospholipase A<sub>2</sub> (sPLA<sub>2</sub>), has demonstrated marked improvements in independent markers of cardiovascular risk including, a near complete suppression of sPLA<sub>2</sub> activity and mass, clinically meaningful and statistically significant reduction in LDL cholesterol, and a reduction in C-reactive protein.

#### **About Acute Coronary Syndrome**

Acute coronary syndrome is a heart condition characterized by chest pain occurring at rest or upon minimal exertion. This condition is also referred to as unstable angina. If the chest pain is associated with heart muscle damage and heart tracing abnormalities, it is typically classified as a heart attack or myocardial infarction.

#### **About Anthera Pharmaceuticals**

Anthera Pharmaceuticals is a privately-held company committed to developing and commercializing clinical pharmaceutical products that address unmet medical needs of patients with life-threatening, chronic and acute inflammatory diseases and autoimmune disorders. The Company has acquired from Eli Lilly and Company and Shionogi & Co., Ltd. worldwide rights (excluding Japan) to a series of clinical and pre-clinical compounds that inhibit the enzymatic activity of members of the phospholipase (PLA<sub>2</sub>) family - a group of enzymes responsible for the release of arachidonic acid and subsequent production of leukotrienes, prostacyclins and other mediators of inflammation. These highly potent compounds inhibit novel, upstream steps in the inflammation cascade and have the potential to address a variety of diseases. For more information, please visit [www.anthera.com](http://www.anthera.com)

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