December 27, 2016

Anthera Announces the Phase 3 SOLUTION Study with Sollpura™ in Cystic Fibrosis Patients with Exocrine Pancreatic Insufficiency Demonstrates Encouraging Results - Additional Study Needed

- Sollpura narrowly missed the primary endpoint for change in the Coefficient of Fat Absorption (CFA) non-inferiority margin
- Sollpura demonstrated non-inferiority in the per protocol CFA analysis
- Sollpura demonstrated non-inferiority in Coefficient of Nitrogen Absorption (CNA) analyses
- Anthera will initiate a new study to demonstrate the efficacy of Sollpura by addressing the scientific findings from the SOLUTION study; anticipates BLA Filing 1Q'18

HAYWARD, Calif., Dec. 27, 2016 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals, Inc. (NASDAQ:ANTH) today announced the top line results of the SOLUTION clinical study in cystic fibrosis patients with exocrine pancreatic insufficiency (EPI). The study narrowly missed the CFA non-inferiority margin of the primary modified Intent to Treat (mITT) analysis; however, by additional pre-specified analyses of CFA (mITT-Baseline Observation Carried Forward and Per Protocol), Sollpura met the non-inferiority criterion. The study also confirmed that the ratio of the three enzymes in Sollpura demonstrated an appropriate response in the coefficient of nitrogen absorption (CNA). CNA is a measure of protein digestion and absorption and is a key requirement of Anthera's planned US FDA regulatory submission. Anthera expects to release data from the extension phase of the study in Q1 2017.

In analyzing the results of the SOLUTION study, patients' ability to increase their doses during the study were hindered by time restrictions and amounts allowed per protocol, while other patients were prevented from increasing their dose due to the daily limit (10,000 lipase units/kg/day) for porcine pancreatic enzyme replacement therapies (PERTs). Sollpura was generally well tolerated compared to Pancreaze, although symptoms related to malabsorption were generally modestly more frequent in the Sollpura arm.

In addition to the challenges to dose escalation inherent in the design of the SOLUTION study, analytical techniques for measuring the activity of lipase enzymes based on duodenal pH of Cystic Fibrosis patients, indicate that Sollpura may have been under dosed versus the Pancreaze labeled dose.

Given the robust activity of Sollpura in this study, in the context of dose titration limitation and apparent reduced dosage activity, Anthera will initiate activities for an additional clinical study of Sollpura in patients with EPI due to Cystic Fibrosis, which Anthera expects will enable optimized dosing and dose titration. This study will provide investigators and patients the flexibility to adjust their Sollpura dose based upon malabsorption symptoms at any time during the study. Anthera believes that these modifications in the study design will allow patients to achieve the optimal level of fat absorption as measured by CFA. The new study will begin in 1Q'17, and Anthera anticipates only a modest delay in the filing of the BLA around Q1 2018, as the new study will complete concurrently with the completion of required CMC activities.

"In the SOLUTION study, Sollpura nearly met the non-inferiority margin with respect to fat absorption, and met the statistical criterion for nitrogen absorption. The study data suggest that the deficiency in fat absorption may be addressed by small changes in study design, including more liberal dose adjustment. A need for alternative treatments remains for EPI patients who are unable to maintain appropriate nutritional health, especially those who seek soluble or non-porcine therapeutic options" said Michael Konstan, MD, Vice Dean for Translational Research at Case Western Reserve University School of Medicine.

"Although we are disappointed to narrowly miss the primary endpoint, we remain encouraged by the overall SOLUTION study results and look forward to releasing final data from and its 12 week extension phase in the future, the SIMPLICITY study and continuation of the open-label EASY study. We would like to thank the patients, investigators and study staff for their hard work and dedication to our study. We are most grateful for their commitment to our shared hope of developing new treatments for exocrine pancreatic insufficiency, and believe that the shortcomings of Sollpura in SOLUTION can be addressed in the new study that we plan to initiate in 1Q'17," said William Shanahan, M.D., Anthera's Chief Medical Officer.

Anthera will host a conference call to further discuss the data from the SOLUTION clinical study.

Conference Call Access:

Date: December 28, 2016

Time: 08:00 AM ET

Conference ID: 45395933

Toll-Free Dial-In Number: (855) 226-3021

International Dial-In Number: (315) 625-6892

About SOLUTION

The Phase 3 SOLUTION study was designed to evaluate the non-inferiority of Sollpura compared to approved, porcine-derived, enterically-coated pancreatic enzyme replacement therapy when administered to patients with exocrine pancreatic insufficiency due to cystic fibrosis. The study enrolled subjects with exocrine pancreatic insufficiency due to cystic fibrosis who were well controlled on stable PERT therapy prior to screening, as demonstrated by a coefficient of fat absorption (CFA) of at least 80%. The primary efficacy variable evaluated the change from baseline in CFA following 7 weeks of therapy with either Sollpura or an alternative porcine PERT to that being taken during screening. Individualized doses of Sollpura and the PERT comparator were chosen to match the lipase units of pre-study PERT. Additional adjustment of the study drug doses was allowed during the first 2 weeks of study based on clinical signs of malabsorption up to a maximum allowed dose of 10,000 units/kg/day of lipase. Subjects enrolled into the SOLUTION study will continue to be followed through Week 20 for additional assessments of safety and efficacy. For more information on the SOLUTION clinical study, please visit http://www.anthera.com/clinical-studies/solution_study/.

About Sollpura® (liprotamase)

Sollpura is a novel, non-porcine PERT containing a proprietary, biotechnology-derived formulation of cross-linked crystalline lipase, crystalline protease, and amorphous amylase with broad substrate specificity, that has been designed for purity (no potential for viral contamination), precise dose standardization, resistance against proteolysis without polymeric coating, and stability in acid pH for reliable potency of activity in the proximal small intestine.

Sollpura represents potentially the first soluble, stable and non-pig derived enzyme product to offer a solution to people with EPI, including young children and adults, who are either unable to swallow multiple pills or are forced to use gastric tubes in order to maintain appropriate nutritional health. Unlike other enzyme products for the treatment of EPI derived from pig pancreas, the purified enzymes in Sollpura exhibit enhanced solubility and stability that make it an ideal product to be conveniently co-administered with a variety of liquids and food products.

About Anthera Pharmaceuticals, Inc.

Anthera Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing products to treat serious and life-threatening diseases, including exocrine pancreatic insufficiency due to cystic fibrosis and IgA nephropathy. Additional information on the Company can be found at www.anthera.com.

Safe Harbor Statement

Any statements contained in this press release that refer to future events or other non-historical matters, including statements that are preceded by, followed by, or that include such words as "estimate," "intend," "anticipate," "believe," "plan," "goal," "expect," "project," or similar statements, are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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 Anthera's public filings with the SEC, including Anthera's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016. 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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