December 13, 2016

Anthera Pharmaceuticals Announces Continuation of SIMPLICITY Study of Sollpura™ Following Positive DMC Review

HAYWARD, Calif., Dec. 13, 2016 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals, Inc. (NASDAQ:ANTH) today announced that the Data Monitoring Committee (DMC) completed its pre-planned safety review of the SIMPLICITY clinical study of Sollpura supplied as a powder for oral solution in an initial cohort of cystic fibrosis patients seven years of age and older with exocrine pancreatic insufficiency. The DMC was in unanimous agreement "that there are no safety concerns and that the study can move forward to enrolling Part B," which will enroll patients from 28 days to 6 years of age.

The SIMPLICITY study evaluates the safety and efficacy of Sollpura powder for oral solution which supplies the digestive enzymes in sachets that are dissolved into water or apple juice and drunk with meals. This study is being conducted in 2 parts in patients with exocrine pancreatic insufficiency due to cystic fibrosis. An initial evaluation of safety in patients aged 7 years and older has been completed before commencing enrollment of younger patients aged 28 days to 6 years into Part B.

Anthera can now begin screening and enrollment activities for Part B of the SIMPLICITY study following the positive outcome of the DMC review. In Part B, Sollpura powder for oral solution will be administered to pediatric patients ranging in age from 28 days to 6 years. Efficacy will be measured based on the observed coefficient of fat absorption following seven weeks of open-label treatment with Sollpura.

Anthera plans to report topline data including efficacy and safety data in the second quarter of 2017. Topline data from the Phase 3 SOLUTION clinical study evaluating the efficacy and safety of the capsule formulation of Sollpura remains on track for this quarter.

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 lupus, lupus with glomerulonephritis, IgA nephropathy, and exocrine pancreatic insufficiency due to cystic fibrosis. 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.

CONTACT: Nikhil Agarwal of Anthera Pharmaceuticals, Inc.

nagarwal@anthera.com or 510.856.5600 x5621

Primary Logo

Source: Anthera Pharmaceuticals, Inc.

News Provided by Acquire Media