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Anthera Announces First Patient Screened in RESULT Pivotal Phase 3 Clinical Study of Sollpura

- Four-week non-inferiority, Coefficient of Fat Absorption (CFA) primary endpoint comparing Sollpura to Pancreaze in patients with exocrine pancreatic insufficiency due to cystic fibrosis
- Study design leverages input from the US FDA and CF Community
- Target enrollment of 150 patients 7 years of age and older
- Top line data expected end of 2017 or early 2018

HAYWARD, Calif., May 15, 2017 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals. (Nasdaq:ANTH) today announced that it has commenced screening in the RESULT Phase 3 clinical study of Sollpura for exocrine pancreatic insufficiency due to cystic fibrosis. Based on feedback from the US FDA, this non-inferiority study will compare the efficacy of Sollpura, a biologically manufactured pancreatic enzyme replacement therapy (PERT), to Pancreaze, a porcine-extracted PERT, as assessed by CFA after 4 weeks of treatment. Topline data are expected at the end of 2017 or early 2018, depending on the speed of patient enrollment.

"As a key investigator in the SOLUTION study and now participating in the RESULT study, I am excited to be part of this important study for Cystic Fibrosis patients with exocrine pancreatic insufficiency. Sollpura has the potential to address an unmet need for PERTs with a reduction in pill burden, as well as the benefit of a product that is not extracted from pigs," shared Dr. Steven R. Boas, M.D., FAAP, FACSM President and CEO, The Cystic Fibrosis Institute, Glenview, IL.

The RESULT clinical study builds upon data from the previous Sollpura trial (SOLUTION) and allows for more frequent and higher dose adjustments based upon clinical signs and symptoms. As with current practice with porcine enzymes, the RESULT study allows patients to increase their daily dose to an individualized dose that achieves maximum therapeutic benefit, while maintaining a potential reduction in daily pill burden as compared to porcine PERTs.

"We are very pleased to achieve this important milestone for Sollpura," shared William Shanahan, Chief Medical Officer, "and we appreciate the input from the US FDA and members of the CF Community in the design of RESULT. There is enthusiasm within patient and provider communities for a non-porcine derived product and we look forward to this important study."

About RESULT

The Phase 3 RESULT study is designed to evaluate the non-inferiority of Sollpura at individualized doses compared to approved, porcine-derived, enteric-coated PERT when administered to patients with exocrine pancreatic insufficiency due to cystic fibrosis. The study will enroll patients (N≈150) with exocrine pancreatic insufficiency due to cystic fibrosis who are well controlled on stable porcine PERT at screening, as demonstrated by a minimum CFA. The primary efficacy variable will evaluate the change from baseline in CFA following 4 weeks of treatment with either Sollpura or Pancreaze. Patients randomized to Sollpura will then be followed for an additional 20-Week extension period (total of 24 weeks on study) for additional assessments of weight, height, BMI, and safety.

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 porcine viral contamination), formulation of enzymes in a precise and fixed ratio, stability in acid pH without enteric coating, and 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 require gastric tubes in order to maintain appropriate nutritional health.

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 and IgA nephropathy. Additional information on Anthera 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 Annual Report on Form 10-K for the year ended December 31, 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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