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Anthera Pharmaceuticals Surpasses 50% Milestone for Screening of Patients in RESULT Phase 3 Clinical Study of Sollpura in Cystic Fibrosis

HAYWARD, Calif., Sept. 07, 2017 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals, Inc. (Nasdaq:ANTH) today announced that the screening for the RESULT Phase 3 clinical study has surpassed the halfway mark. RESULT is studying the use of a more frequent and flexible dosing of Sollpura for the treatment of exocrine pancreatic insufficiency (EPI) due to cystic fibrosis. Topline data are expected at the end of 2017 to early 2018.

"The rapid pace of screening in the RESULT study is a testament to the need for a new therapeutic option for cystic fibrosis patients and caregivers. As we move forward with screening and enrollment, we remain excited about this alternative treatment for EPI patients who are unable to maintain appropriate nutritional health, and especially for those who seek soluble or non-porcine therapeutic options." Said Michael W. Konstan, M.D., Vice Dean for Translational Research, Gertrude Lee Chandler Tucker Professor of Pediatrics, Case Western Reserve University School of Medicine

"We are very pleased that more than 50% of the anticipated patients needed to complete enrollment have entered screening for the RESULT trial. The acceleration of recruitment in recent weeks has been encouraging and validating for the need for an alternative to today's current enzyme therapies," said William Shanahan, MD, Chief Medical Officer of Anthera.

The RESULT study 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 dose increases on an individualized basis to achieve maximum therapeutic benefit from Sollpura. Sollpura is potentially the first non-porcine Pancreatic Enzyme Replacement Therapy ("PERT"), which could provide a potential reduction in the size and number of daily pills patients must administer due to a significantly more compact formulation than porcine PERTs.

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 pancreatic enzyme replacement therapy (PERT) when administered to patients with EPI due to CF. The study will enroll patients (N≈150) who are well-controlled on stable porcine PERT at screening, as demonstrated by the coefficient of fat absorption (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 longer term 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, formulated in a precise and fixed ratio to provide stability in acidic pH environments, like that found in the stomach, without enteric coating. Being non-porcine, Sollpura mitigates porcine-associated risks including supply limitations and the potential for contamination with pig-associated viral transmission and increased risk of gout, renal impairment and hyperuricemia. In addition, given its stability in the absence of enteric coating, a soluble, drinkable formulation of Sollpura is in development, which may provide an easy-to-administer option especially for pediatric patients and patients who receive their nutrition through feeding tubes.

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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2017. 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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