March 29, 2017

Anthera Announces Positive Results from the Extension Period of the SOLUTION Study of Sollpura

- Sollpura demonstrated comparable maintenance in key measurements of height, weight, and BMI
- Sollpura was well tolerated throughout the 20-Week Extension Period

HAYWARD, Calif., March 29, 2017 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals, Inc. (NASDAQ:ANTH) today announced the findings from the Extension Period of the Phase 3 SOLUTION, non-inferiority clinical study in cystic fibrosis patients with exocrine pancreatic insufficiency (EPI). The Extension Period was designed as an observational analysis of the long-term effects of Sollpura and Pancreaze as it pertains to weight, height, BMI, and safety.

"We are pleased to see the continued tolerability and maintenance of weight and height in all of the Sollpura treated cystic fibrosis patients with EPI during the Extension Period and in particular, increases in weight and height in patients less than 17 years of age," stated William Shanahan, Anthera's Chief Medical Officer. "The 20-Week data provides support that Sollpura may offer patients an alternative to existing, porcine-based pancreatic enzyme replacement therapies."

During the Extension Period (Week 7 through Week 20), all patients treated with Sollpura maintained their weight at 56.4 kg-56.9 kg and all patients treated with Pancreaze maintained their weight at 54.6 kg-54.8 kg. Both groups showed small increases in height, with Sollpura increasing from 163.2 cm to 163.7 cm, and Pancreaze increasing from 160.6 cm to 160.8 cm. A modest decrease in body mass index (BMI) was observed in both treatment groups with Sollpura treated patients decreasing from 20.99 kg/m^2 to 20.76 kg/m^2 and Pancreaze treated patients decreasing from 20.75 kg/m^2 to 20.66 kg/m^2. In pediatric patients less than 17 years of age, the key age group for growth and development, similar trends in weight and height were observed in both treatment groups, as shown in the table below.

	Patients < 17 years of age			
	Sollpura mean (standard deviation)		Pancreaze mean (standard deviation)	
	Week 7	Week 20	Week 7	Week 20
	n=15	n=15	n=20	n=19
Weight (kg)	49.2 (13.8)	49.7 (13.1)	41.8 (15.1)	41.5 (15.0)
Height (cm)	158.3 (13.8)	159.8 (13.3)	144.6 (16.6)	145.0 (16.8)
BMI (kg/m^2)	19.2 (2.8)	19.1 (2.5)	19.2 (3.6)	19.0 (3.6)

Sollpura and Pancreaze were generally well tolerated with 40% and 54% of patients experiencing a treatment emergent adverse event, respectively. Most of the difference was comprised of a lower rate of infective pulmonary exacerbations of CF in the Sollpura versus Pancreaze arm (9.2% vs. 20.6%) and respiratory disorders (9.3% vs. 15.9%). Proportions of patients experiencing mild, moderate, or serious events in the Sollpura versus Pancreaze arm were 27.7% vs 41.3%, 9.2% vs 11.1% and 3.1% vs 1.6%, respectively. The rate of serious adverse events was balanced at 4.6% for Sollpura and 6.3% for Pancreaze with no discontinuations in either arm.

The Extension Period data concludes the Phase 3 SOLUTION trial. Anthera plans to initiate a Phase 3 trial, RESULT, (Reliable Emergent Solution Using Liprotamase Treatment) in 1H 2017, with topline data anticipated at the end of 2017 or early 2018.

About SOLUTION

The Phase 3 SOLUTION study was designed to evaluate the non-inferiority of Sollpura compared to approved, porcine-derived, enteric-coated pancreatic enzyme replacement therapy when administered at approximately equivalent doses to patients with exocrine pancreatic insufficiency due to cystic fibrosis. The study enrolled patients with exocrine pancreatic insufficiency due to cystic fibrosis who were well controlled on stable PERT therapy, as demonstrated by a coefficient of fat absorption (CFA) of at least 80% at screening. The primary efficacy variable evaluated the change from baseline in CFA following 7 weeks of therapy with either Sollpura or Pancreaze, 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. 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 of 150% of baseline but not to exceed 10,000 units/kg/day of lipase. After the Week 7 CFA measurement, patients enrolled into the SOLUTION study were followed through Week 20 for additional assessments of safety and efficacy.

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 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 PERT therapy at screening, as demonstrated by a coefficient of fat absorption (CFA) of at least 80%. The primary efficacy variable will evaluate the change from baseline in CFA following treatment through 4 weeks of therapy with either Sollpura or Pancreaze. Patients randomized to Sollpura will begin at 125% of the baseline porcine lipase dose and may undergo individualized dose adjustments based upon gastrointestinal signs and symptoms up to the lesser of two times the baseline lipase dose or 15,000 lipase units/kg/day in adults or 10,000 lipase units/kg/day in patients ages 7 to less than 17. Anthera believes that this optimized dosing paradigm will correct for differences in solubility between the lipases in Sollpura and porcine PERTs in the more acidic duodenal pH of patients with cystic fibrosis. Patients randomized to Pancreaze will begin their dose at the equivalent of their pre-study lipase units/kg/day. 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 viral contamination), precise dose standardization, resistance against proteolysis without enteric coating, and stability in acid pH for 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 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 due to cystic fibrosis, 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 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.

Investor Relations, Anthera Pharmaceuticals

ir@anthera.com

Primary Logo

Source: Anthera Pharmaceuticals, Inc.