

# Anthera Pharmaceuticals Reports Top Line Data from the RESULT Phase 3 Clinical Study of Sollpura

March 12, 2018

- Sollpura did not achieve the primary endpoint of the coefficient of fat absorption ("CFA")
- Sollpura did achieve the secondary endpoint of coefficient of nitrogen absorption ("CNA")
- Further development of Sollpura to be discontinued
- Anthera to evaluate all strategic alternatives
- Anthera to host teleconference today at 8:30 am ET

HAYWARD, Calif., March 12, 2018 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals, Inc. (Nasdaq:ANTH) announced today that Sollpura did not meet the non-inferiority margin of the CFA primary endpoint in the RESULT Phase 3 clinical study of exocrine pancreatic insufficiency ("EPI") due to cystic fibrosis.

The design of the RESULT study was based on the outcome of the previous Phase 3 SOLUTION study and included a higher starting dose and more aggressive dose optimizations based on clinical signs and symptoms of malabsorption. In the RESULT study, all patients randomized to Sollpura received a starting dose that was approximately 25% higher than their pre-study porcine pancreatic enzyme replacement therapy ("PERT") dose and 59% of subjects received further dose adjustments, yielding a mean Sollpura dose (8,673 [range 2,925 – 14,941 lipase units/kg/day]) that was both substantially higher than the comparator Pancreaze mean dose (6527 [range 2358 - 10253 units/kg/day]) and higher than the Sollpura dose in the previous SOLUTION study (mean dose of 7,286 [range 4478 - 10000 units/kg/day]). Although a proportion of patients randomized to Sollpura maintained or improved their CFA from baseline, a higher proportion of patients experienced a worsening. The mean treatment difference in CFA change from baseline was 14.3%, with upper and lower 95% confidence intervals of -18.22 and -10.39. In contrast, the treatment difference in CNA change from baseline (-1.53%) was well within the 15% non-inferiority margin. In comparison to the earlier SOLUTION study, the presence or absence of concomitant gastric acid suppressants had no meaningful effect on CFA (mean changes from baseline in CFA of -15.06% and -16.58%, respectively).

"We are greatly disappointed by the findings of the RESULT study," shared Craig Thompson, President & CEO. "We would like to extend our deepest gratitude to the patients and their families, study investigators, and the cystic fibrosis community for the support they have provided in the clinical development of Sollpura."

Anthera Pharmaceuticals, Inc. plans to evaluate the full data outputs and will suspend further clinical development of Sollpura, including the 20-Week Extension Period of RESULT, the SIMPLICITY study in patients ages 28 days to <7 years which was designed to assess Sollpura powder for oral solution, and the EASY study which was designed to follow the long-term safety of patients on Sollpura. In addition, Anthera Pharmaceuticals, Inc. plans to evaluate all strategic alternatives in order to maximize shareholder value.

## Conference Call Details

Anthera Pharmaceuticals, Inc. management will discuss the top line RESULT data via a conference call today at 8:30 am ET. To access the call, please dial (855) 226-3021 (US/Canada Toll-Free) or (315) 625-6892 (International Toll-Free). A replay of this call will be available approximately two hours after the call is ended at (855) 859-2056 or (404) 537-3406 using the conference ID 1868069 and will be available for one week.

## About RESULT

The RESULT study was a randomized, open-label, assessor-blind, non-inferiority, active-comparator study evaluating the non-inferiority of Sollpura with respect CFA compared to a commercially available PERT in a population of porcine-derived PERT responders. The RESULT study design was modified from the previous Phase 3 SOLUTION study design by 1) starting Sollpura dosing at 125% of the pre-study PERT dose, 2) allowing for a more "real life" dose adjustment, as needed, based on signs and symptoms throughout the primary treatment phase of the study, and 3) providing a shorter treatment duration of 4 weeks, with 3 weeks of dose optimization and 1 week of stable dosing. The RESULT study design was discussed with the United States Food and Drug Administration ("FDA") prior to initiation. Furthermore, the study had been approved by the Cystic Fibrosis Foundation Therapeutics Development Network ("CFFTDN") Protocol Review Committee, and the European Cystic Fibrosis Society Clinical Trial Network Executive Committee.

The RESULT study enrolled 140 patients in North America, Eastern and Western Europe and Israel. In December 2017 and January 2018, pre-specified interim futility analyses of the RESULT study were conducted by a Data Monitoring Committee ("DMC") comprised of experts appointed by the CFFTDN when approximately 25% and 50% of patients had completed the 4-week treatment period; in each instance, the committee recommended the study to continue to completion as planned.

## About Anthera Pharmaceuticals, Inc.

Anthera Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on developing products to treat serious and life-threatening diseases, including exocrine pancreatic insufficiency and B-cell associated renal diseases. Additional information on Anthera Pharmaceuticals, Inc. can be found at [www.anthera.com](http://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. Such 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, including but not limited to those 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, 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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