November 10, 2016

Anthera Announces that the Blisibimod CHABLIS-SC1 Phase 3 Study Did Not Achieve the Primary Endpoint in Patients with Active Systemic Lupus Erythematosus

- ***Assessing next steps for blisibimod for the treatment of Systemic Lupus Erythematosus***
- ***Continuing to explore blisibimod as treatment for IgA nephropathy - Phase 2 data in December***
- ***Sollpura™ SOLUTION phase 3 study in exocrine pancreatic insufficiency on track for topline data in December***

HAYWARD, Calif., Nov. 10, 2016 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals, Inc. (NASDAQ:ANTH) today announced that the CHABLIS-SC1 clinical trial with blisibimod for the treatment of systemic lupus erythematosus (SLE) failed to meet its primary endpoint based upon the SLE Responder Index-6 (SRI-6) at 52 weeks. Although 47% of patients in the blisibimod arm versus 42% of patients in the placebo arm achieved this endpoint, the difference was not statistically significant. The SRI is a composite index comprised of SELENA-SLEDAI, BILAG and Physician Global Assessment criteria. A SRI-6 response requires a decrease of at least 6 points in SELENA-SLEDAI. The magnitude of blisibimod treatment effects for other SLE Response (SRI-4, and SRI-8) also did not achieve statistical significance.

Serum biological markers including B-cells, immunoglobulins, and complement demonstrated statistically significant treatment effects consistent with expectations and previous blisibimod clinical studies in lupus and IgA nephropathy. Adverse events between the blisibimod and placebo treatment arms were well balanced and blisibimod was generally well tolerated.

"We are disappointed that the results did not demonstrate a meaningful improvement in patients' disease activity as assessed by SRI endpoints," said William Shanahan, M.D., Anthera's Chief Medical Officer. "We would like to thank the patients, caregivers, investigators and key opinion leaders who made the CHABLIS-SC1 clinical study possible. It has yielded significant amounts of data which we look forward to sharing with the scientific community in the future which we believe will help to further inform the development of treatments for severe lupus."

The Company will continue to analyze the data in the coming weeks from the CHABLIS-SC1 trial in consultation with key lupus disease thought leaders to expeditiously determine the future of the blisibimod lupus program including the on-going CHABLIS 7.5 clinical study. As the pharmacological effects on immunological markers, such as B-cells and immunoglobulins, were as expected, the company is continuing the development of blisibimod for the treatment of IgA Nephropathy (IgAN) pending 48 week results from the ongoing phase 2 BRIGHT study. IgAN has a very different pathogenesis than systemic lupus, and the pharmacological activity of blisibimod might prove effective in its treatment. The Company expects to report 48-week data from the BRIGHT-SC IgAN study and topline data from the Sollpura™ SOLUTION phase 3 study later this year.

Anthera will host a conference call to further discuss the data from the CHABLIS-SC1 clinical study.

Conference Call Access:

Date: **November 10, 2016**

Time: **8:30 am Eastern Time**

Conference ID: **18122260**

Toll-Free Dial-In Number: **(855) 226-3021**

International Dial-In Number: **(315) 625-6892**

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 Information:

Nikhil Agarwal of Anthera Pharmaceuticals, Inc.,

nagarwal@anthera.com or 510.856.5600 x5621


Primary Logo

Source: Anthera Pharmaceuticals, Inc.