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Anthera Announces FDA Orphan Drug Designation for Blisibimod for the Treatment of IgA Nephropathy

HAYWARD, Calif., Aug. 09, 2017 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals (Nasdaq:ANTH) today announced that blisibimod has received orphan drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of Immunoglobulin A nephropathy (IgAN). Blisibimod targets B-cell activating factor, or BAFF, which has been shown to be elevated in a variety of B-cell mediated autoimmune diseases, including IgAN, systemic lupus erythematosus, and others.

"We are pleased by the FDA's decision to designate blisibimod with orphan drug designation," said Craig Thompson, Chief Executive Officer of Anthera. "There remains a very high need for patients with IgA nephropathy, as no approved therapies currently exist despite the high proportion of patients who progress to end-stage renal disease. We remain optimistic that blisibimod may be a well-tolerated, disease-modifying therapeutic that targets the underlying pathology for IgAN."

Anthera is currently analyzing the data from the randomized, double-blind, placebo controlled, Phase 2 BRIGHT-SC study of blisibimod in patients with IgA nephropathy (IgAN). After Week 24, patients were given the opportunity to continue blinded treatment for up to 104 weeks, discontinue treatment but continue to be followed, or discontinue from the study. Most patients, 42 of 57, completed at least 60 weeks of evaluation and 21 completed assessments through at least 104 weeks. Anthera anticipates reporting top-line data later this month.

IgAN, also known as Berger's disease is the most common cause of primary glomerulonephritis (acute inflammation of the kidney) worldwide, occurring more frequently in Asia than in Europe or North America. IgAN is characterized by deposition of immune complexes in the kidney, resulting in inflammation, the leakage of blood and protein into the urine, and loss of kidney function. The disease typically progresses slowly but as many as 40-50% of adults will eventually develop end-stage-renal disease and require dialysis or kidney transplant. There are currently no approved therapies for IgA nephropathy.

The [Orphan Drug Designation program](#) provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. annually. Orphan designation qualifies the sponsor of the drug for various development incentives, including tax credits for qualified clinical testing.

About Anthera Pharmaceuticals

Anthera Pharmaceuticals is a clinical-stage biopharmaceutical company focused on developing products to treat serious and life-threatening diseases, including exocrine pancreatic insufficiency and IgA nephropathy. 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. 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 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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