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Anthera Announces Completion of Dosing in the Phase 2 BRIGHT-SC Study of Blisibimod in Patients with IgA Nephropathy

HAYWARD, Calif., April 10, 2017 (GLOBE NEWSWIRE) -- Anthera Pharmaceuticals. (Nasdaq:ANTH) today announced the completion of dosing in 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 in Q3.

Interim analyses of blisibimod, conducted by an independent statistician once all ongoing patients had completed Week 24 and 48, demonstrated a consistent slowing of proteinuria progression and significant pharmacological effects on B cells and serum immunoglobulins. Patients, investigators, and the sponsor have remained blinded as to treatment assignment.

"We are encouraged by the trends on proteinuria seen in the interim analyses and look forward to the unblinded results from the BRIGHT-SC study," said William Shanahan, MD, Anthera's Chief Medical Officer. "There is a significant unmet need for patients with IgA nephropathy, for which there is no approved therapy, and we remain optimistic that blisibimod may provide a well-tolerated treatment option that targets disease pathology for these patients."

About BRIGHT-SC

The study enrolled 57 patients, 42 of whom completed at least 60 weeks of evaluation and 21 of whom completed at least 104 weeks. Patients with persistent proteinuria (1-6 g/24hrs) despite background optimized therapy with angiotensin converting enzyme inhibitors (ACEi) or angiotensin receptor blockers (ARB), and estimated glomerular filtration rate > 30mL/min/1.73m² were randomized to receive either blisibimod (300mg/wk for 8 weeks and 200mg/wk thereafter) or matching placebo for up to 104 weeks and were followed thereafter in the absence of study drug to assess longer term outcome. All patients were treated with an optimal dose of ACEi or ARB for a minimum of 90 days prior to randomization and this therapy was continued throughout the trial as background medication for all patients. Patients were not allowed to receive corticosteroids for the treatment of IgA nephropathy within 3 months of screening.

The BRIGHT-SC study was originally designed as a two-part Phase 2/3 study with a target enrollment of 200 patients. Part A was a 24-Week study of the effects of blisibimod on proteinuria, and Part B was an extension phase in which long term effects on the prevention of end stage renal disease would be assessed. After Week 24, patients had the option of continuing blinded treatment for up to two years, discontinuing treatment but continuing in the study under observation only, or discontinuing from the trial. The primary endpoint of the study was the number of patients who achieved a partial or complete response in urinary protein excretion at Week 24. A partial response was defined as achieving proteinuria ≤1g/24hrs, and a complete response as follows: for patients with baseline proteinuria ≥1g/24hrs but ≤2g/24hrs, achievement of proteinuria ≤1.0g/24hr AND a 50% reduction from baseline at 2 consecutive visits; for patients with baseline proteinuria > 2g/24hrs, achievement of proteinuria ≤1.0g/24hr OR a 50% reduction from baseline at 2 consecutive visits. Due to slow recruitment, enrollment was curtailed at 57 patients and the study was converted to a Phase 2 study. An observed case analysis was conducted when all patients had the opportunity to complete Week 24 and another at Week 48, and topline results were previously announced for both analyses. Mean effects by treatment group on proteinuria and certain measures of expected pharmacology (circulating B cells and B cell subpopulations, serum immunoglobulins) were analyzed and reported to Anthera by an independent statistician, with the treatment blind maintained for the patient, investigator, and sponsor personnel.

About IgA Nephropathy

IgA nephropathy (IgAN, also known as Berger's disease) is the most common cause of primary glomerulonephritis worldwide, occurring more frequently in Asia than in Europe or North America. Patients express under-glycosylated immunoglobulin A1 (IgA1) which is immunogenic and targeted by other immunoglobulins. The resulting IgA-containing immune complexes are deposited in the kidney, causing inflammation with consequent blood and protein leakage into the urine. 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. The current management of IgAN is non-specific treatment aimed at blood pressure control and reduction of proteinuria with angiotensin converting enzyme inhibitors (ACEI) and/or angiotensin II

receptor blockers (ARBs); corticosteroids and immunosuppressive therapy are used in some patients but benefits are uncertain.

About Blisibimod

Blisibimod is a selective peptibody antagonist of the B-cell activating factor (BAFF) cytokine. BAFF is a tumor necrosis family member and is critical to the development, maintenance and survival of B-cells. It is primarily expressed by macrophages, monocytes and dendritic cells and interacts with three different receptors on B-cells including BAFF receptor, or BAFF-R, B-cell maturation, or BCMA, and transmembrane activator and cyclophilin ligand interactor, or TACI. The BAFF-R receptor is expressed primarily on peripheral B-cells. Blisibimod consists of a novel BAFF binding domain fused to the N-terminus of the Fc region of human antibody. Blisibimod binds to BAFF and inhibits the interaction of BAFF with its receptors.

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 Annual Report on Form 10-K for the year ended December 31, 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.

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