BIRMINGHAM, AL, September 30, 2013 /**24-7PressRelease**/ -- *To see if you qualify for this RA Clinical Trial in Alabama, visit Achieve Clinical Research on the web (http://www.achieveclinical.com/) or contact us directly at (205) 380-6434. There is no cost to participate, no insurance is required, and you may receive compensation for time and travel.

STUDY DESIGN

This is a 48-week, double-blind, multiple dose, parallel group trial to compare the safety, efficacy, immunogenicity and tolerability of an experimental drug to Rituxan and MabThera in patients with moderately to severely active RA. Patients will be enrolled across 250 clinical sites, in 26 countries.

Part I (48-week duration) will include 150 patients, which is considered sufficient for pharmacokinetics (PK) testing. Part II consists of a 48-week comparative safety/efficacy analyses with an additional 150 patients.

BACKGROUND & RATIONALE

Rheumatoid arthritis (RA) is a chronic systemic inflammatory disease characterized by synovial inflammation in the joints and consequently, progressive joint destruction. Depending on the severity of the disease, systemic manifestations may occur including lung disease, rheumatoid nodules and cardiovascular system effects. Without effective RA treatment, this disease may lead to severe functional disabilities, and therefore a considerable reduction in quality of life for the patient. The prevalence of RA varies with factors such as gender, race and smoking status and is approximately 0.5-1%.

B lymphocytes (B cells) are thought to play a crucial role in the pathogenesis of RA. They are also the primary source of rheumatoid factors (RFs) and anti-cyclic citrullinated peptide (anti-CCP) antibodies which contribute to the formation of immune complexes and complement activation in inflamed joints. Thus, B cell targeted therapy could play an important role in RA through a reduction in the B cell count as well as a reduction in B cell-mediated downstream effects on other cell types involved in the inflammatory response.

PRIMARY OBJECTIVES

The primary objectives of this trial are:

To show PK similarity of this new drug to MabThera and Rituxan and of Rituxan to MabThera (three-way PK similarity).

To establish statistical equivalence of efficacy of this new drug and Rituxan/MabThera, in patients with moderately to severely active RA, based on the change in Disease Activity Score 28, the score is measured at 24 weeks compared to Baseline and the American College of Rheumatology 20% response rate at Week 24.

INCLUSION CRITERIA

Must give written informed consent and be willing to follow the protocol.

Male or female participants, between 18 and 80 years of age, who have a diagnosis of moderately to severely active RA for at least 6 months as defined by at least six swollen joints (66 joint count) and at least eight tender joints (68 joint count) at Screening and Baseline (Day 1), and either an erythrocyte sedimentation rate (ESR) of _ 28 mm/hour OR a CRP level _ 1.0 mg/dL (normal: _ 0.4 mg/dL) at Screening. Patients must have had an inadequate response or intolerance to conventional DMARD therapy including at least one TNF inhibitor.

Positive for RF and/or anti-CCP antibodies.

Current treatment for RA on an outpatient basis:

-- Must be currently receiving and tolerating oral or parenteral MTX therapy at a dose of 15-25 mg per week (dose may be as low as 10 mg per week if the patient is unable to tolerate a higher dose) for at least 12 weeks immediately prior to Day 1. The dose should be stable for at least 4 weeks prior to Day 1 until Week 24. After Week 24 the administration route can be changed at the investigatorâEUR s discretion.

-- Patients must be willing to receive oral folic acid (at least 5 mg/week or as per local practice) or equivalent during the entire study (mandatory co-medication for MTX treatment).

-- Biologic agents and DMARDs (other than MTX) must be withdrawn at least 2 weeks prior to Day 1, except azathioprine and etanercept which must be withdrawn at least 4 weeks prior to Day 1; abatacept, adalimumab, anakinra, certolizumab, infliximab, and golimumab at least 8 weeks prior to Day 1; tocilizumab at least 10 weeks prior to Day 1.

-- Leflunomide must be withdrawn at least 8 weeks prior to Day 1 or a minimum of 2 weeks prior to Day 1 if after 11 days of standard cholestyramine washout.

-- If receiving current treatment with oral corticosteroids (other than intra-articular or parenteral), the dose must not exceed 10 mg/day prednisolone or equivalent. During the 4 weeks prior to Baseline (Day 1) the dose must remain stable.

-- Intra-articular and parenteral corticosteroids are not permitted within 6 weeks prior to Baseline Day 1 or throughout the trial, with the exception of IV administration of 100 mg methylprednisolone 30 to 60 minutes prior to each infusion as this is part of the trial procedures.

-- Any concomitant non-steroidal anti-inflammatory drugs (NSAIDs) must be stable for at least 2 weeks prior to Day 1.

-- Patients may be taking oral hydroxychloroquine provided that the dose is not greater than 400 mg/day or chloroquine provided that the dose is not greater than 250 mg/day. These doses must have been stable for a minimum of 12 weeks prior to Day 1. The hydroxychloroquine or chloroquine treatment will need to be continued at a stable dose with the same formulation until the end of the trial.

For participants of reproductive potential (males and females), use of a reliable means of contraception (e.g., hormonal contraceptive, patch, intrauterine device, physical barrier) has to be used throughout trial participation. Females of child-bearing potential must also agree to use an acceptable method of contraception for 12 months following completion or discontinuation

from the trial.

*Achieve Clinical Research conducts Phase II-IV Clinical Trials in Alabama. For more information about participating in an RA Clinical Study, please visit our website or contact us directly at (205) 380-6434.