ARYx Therapeutics Inc. Commences Phase 2/3 Clinical Trial on Oral Anticoagulant Agent ATI-5923 - EmbraceAC Comparative Study Against Leading Anticoagulant Warfarin

FREMONT, Calif., Jun 17, 2008 (BUSINESS WIRE) -- ARYx Therapeutics Inc. (NASDAQ:ARYX), a biopharmaceutical company, today announced it has commenced enrollment in a Phase 2/3 clinical trial comparing its oral anticoagulation therapy, ATI-5923, against the leading anticoagulant agent, warfarin. The purpose of the trial, named EmbraceAC, is to evaluate whether ATI-5923 is superior to warfarin in its ability to maintain patients within a target therapeutic range of the level of anticoagulation. Based upon recent interactions with the United States Food and Drug Administration (FDA), ARYx Therapeutics believes this trial could be positioned as one of the required registration studies for ATI-5923. Results will be announced at the end of the second quarter of 2009.

The trial is expected to enroll approximately 600 patients at over fifty clinical study sites in the United States. It is a randomized, double-blind, parallel group, active control study comparing ATI-5923 with warfarin in patients who require chronic, oral anticoagulation. The patients will be treated for a minimum of six months. Participants will require anticoagulation therapy to avoid serious blood clotting resulting from any of the following conditions: atrial fibrillation; existence of a prosthetic heart valve; a history of venous thromboembolic disease (DVT/PE); a history of myocardial infarction or cardiomyopathy; or another indication for which they are currently receiving chronic warfarin therapy.

The level of anticoagulation achieved will be measured by the standard method applied to warfarin therapy called the International Normalization Ratio (INR). The target therapeutic range for warfarin therapy will also be applied to patients administered ATI-5923. The primary endpoint of the trial is to demonstrate that patients are maintained within the target INR range a higher percentage of the time when treated with ATI-5923 than with warfarin.

In a study conducted by Jones et al. (Heart 2005;91;472-477), it was determined that the risk of mortality, ischemic stroke, and thromboembolic events increases with reduced time in therapeutic INR range after adjustment for age, sex, and baseline morbidity. A 10% decrease in time in therapeutic INR range was associated with a 29% increase in mortality risk (odds ratio 1.29, p less than 0.001).

For more information, go to http://www.clinicaltrials.gov/ct2/show/NCT00691470.

About ATI-5923

ATI-5923 is modeled on the drug warfarin as an oral anticoagulation therapy for patients who are in danger of forming life-threatening blood clots as a result of atrial fibrillation, prosthetic heart valve replacement or venous thromboembolism. This represents at least 3.5 million patients in the United States alone. Patients with implanted mechanical heart valves are also amongst those requiring anticoagulation therapy. ATI-5923, like warfarin, is a selective inhibitor of VKOR, or vitamin K epoxide reductase enzyme, and has the same mechanism of anticoagulation action as warfarin. Unlike warfarin, which is dependent upon cytochrome P450 enzymes for metabolism, ATI-5923 was designed to avoid drug-drug interactions through its alternative metabolic pathway. We believe the avoidance of cytochrome P450 metabolism will cause the dosing and response to ATI-5923 to be more predictable than with warfarin, avoiding the dangers of over-or-under therapeutic anticoagulation long associated with that therapy.

About ARYx Therapeutics, Inc.

ARYx Therapeutics is a biopharmaceutical company focused on developing a portfolio of internally discovered products designed to eliminate known safety issues associated with well-established, commercially successful drugs. ARYx uses its RetroMetabolic Drug Design(TM) technology to design structurally unique molecules that retain the efficacy of these original drugs but are metabolized through a potentially safer pathway to avoid specific adverse side effects associated with these compounds. ARYx currently has three products in Phase 2 clinical trials: a prokinetic agent for the treatment of various gastrointestinal disorders, ATI-7505; an oral anticoagulant agent for patients at risk for the formation of dangerous blood clots, ATI-5923; and, an oral anti-arrhythmic agent for the treatment of atrial fibrillation, ATI-2042. A fourth product for the treatment of schizophrenia and other psychiatric disorders, ATI-9242, is in Phase 1 clinical trials. Please visit our web site at www.aryx.com for additional information.

Forward-looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to the timing and availability of our clinical results, the initiation of new clinical trials, the completion of preclinical work, the ability of preclinical packages to lead to further clinical trials, the ability of a product candidate to be more predictable than currently available therapies regarding dosing and response to treatment, and the ability of a product candidate to avoid the dangers existing in currently available therapies. Words such as "is expected," "will," "we believe," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the company's current expectations. Forward-looking statements involve risks and uncertainties. The company's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the risk that collaborative arrangements will likely place the development of our product candidates outside of our control, the risk that we may have to alter our development and commercialization plans if collaborative relationships are not established for ATI-5923 and ATI-2042, the risk that our product candidates may not demonstrate safety and efficacy or lead to regulatory approval, the risk that we may be unable to raise additional capital when needed which would force us to delay, reduce or eliminate product development programs, the risk that any failure or delay in commencing or completing clinical trials for our product candidates could severely harm our business, and the risk that third party manufacturers could delay or prevent the clinical development of our product candidates. These and other risk factors are discussed under "Risk Factors" and elsewhere in the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008. The company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.

SOURCE: ARYx Therapeutics, Inc.

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